

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Cohort Selection

DO NOT USE THE OPTIONS STAGE 1 NONSENTINEL and STAGE 2 from this CRF. As per protocol amendment 5, STAGE 3 option is equivalent to PHASE 2/3.

1.	Select appropriate response - Protocol version	24 JUL 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/11/2020
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Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: DEMOGRAPHY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10191010]
2.	Birth Date:	(b) (6) /1940
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Aug/11/2020
2.	Erroneous Visit	

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Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

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[Form Comments](#)

[eCRF Audit Trail History](#)

Inclusion Criteria Not Met

1.a	Description of Inclusion Criterion Not Met	Not Applicable _____
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Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	Not Applicable _____
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

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[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Aug/11/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

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[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Cataracts - bilateral]
	Start Date:	UNK/UNK/2016
	Ongoing:	NO End Date: UNK/UNK/2016
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Myopia - bilateral]
	Start Date:	UNK/UNK/1984
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Presbyopia]
	Start Date:	UNK/UNK/1984
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Tonsillitis]
	Start Date:	UNK/UNK/1961
	Ongoing:	NO End Date: UNK/UNK/1961

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1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[nasal polyps]
	Start Date:	May/UNK/2018
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Dry mouth]
	Start Date:	UNK/UNK/2012
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Pneumonia]
	Start Date:	Mar/UNK/2009
	Ongoing:	NO End Date: Mar/UNK/2009
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Chronic Obstructive Pulmonary Disease]
	Start Date:	UNK/UNK/1984
	Ongoing:	YES
1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Sleep apnea]
	Start Date:	UNK/UNK/1989
	Ongoing:	YES

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1 j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[CPAP]
	Start Date:	UNK/UNK/1989
	Ongoing:	YES
1 k	Line/MH Number:	[11]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[bronchitis]
	Start Date:	Nov/12/2010
	Ongoing:	NO End Date: Nov/24/2010
1 l	Line/MH Number:	[12]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypertension]
	Start Date:	UNK/UNK/2004
	Ongoing:	YES
1 m	Line/MH Number:	[13]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypercholesterolemia]
	Start Date:	UNK/UNK/1994
	Ongoing:	YES
1 n	Line/MH Number:	[14]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Heart murmur]
	Start Date:	UNK/UNK/2004
	Ongoing:	YES

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Subject Initials: ---

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1.o	Line/MH Number:	[15]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Peripheral Vascular Disease]
	Start Date:	May/UNK/2018
	Ongoing:	YES
1.p	Line/MH Number:	[16]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[External hemorrhoids]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.q	Line/MH Number:	[17]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Anal fistula]
	Start Date:	UNK/UNK/1981
	Ongoing:	NO End Date: UNK/UNK/1981
1.r	Line/MH Number:	[18]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Obesity]
	Start Date:	UNK/UNK/1985
	Ongoing:	YES
1.s	Line/MH Number:	[19]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Urinary incontinence]
	Start Date:	UNK/UNK/2002
	Ongoing:	YES

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1.t	Line/MH Number:	[20]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Chronic kidney disease stage III]
	Start Date:	Apr/25/2018
	Ongoing:	YES
1.u	Line/MH Number:	[21]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Endometriosis]
	Start Date:	UNK/UNK/1960
	Ongoing:	NO End Date: UNK/UNK/1980
1.v	Line/MH Number:	[22]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Uterine lesion - benign]
	Start Date:	UNK/UNK/2005
	Ongoing:	NO End Date: UNK/UNK/2006
1.w	Line/MH Number:	[23]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Insomnia]
	Start Date:	UNK/UNK/2014
	Ongoing:	YES
1.x	Line/MH Number:	[24]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Tension headaches]
	Start Date:	UNK/UNK/1993
	Ongoing:	YES

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Subject Initials: ---

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1.y	Line/MH Number:	[25]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Carpal tunnel syndrome, bilateral]
	Start Date:	UNK/UNK/1996
	Ongoing:	NO End Date: UNK/UNK/1996
1.z	Line/MH Number:	[26]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Familial tremors]
	Start Date:	UNK/UNK/1974
	Ongoing:	YES
1.aa	Line/MH Number:	[27]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Diabetic neuropathy bilateral hands]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES
1.ab	Line/MH Number:	[28]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Diabetic neuropathy, bilateral lower extremities]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES
1.ac	Line/MH Number:	[29]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Osteoarthritis, bilateral hands and knees]
	Start Date:	UNK/UNK/1997
	Ongoing:	YES

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Subject Initials: ---

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1.ad	Line/MH Number:	[30]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Gout]
	Start Date:	UNK/UNK/1998
	Ongoing:	YES
1.ae	Line/MH Number:	[31]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Osteopenia]
	Start Date:	UNK/UNK/2012
	Ongoing:	YES
1.af	Line/MH Number:	[32]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Osteoporosis]
	Start Date:	UNK/UNK/2016
	Ongoing:	YES
1.ag	Line/MH Number:	[33]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Fibromyalgia]
	Start Date:	Apr/UNK/2014
	Ongoing:	YES
1.ah	Line/MH Number:	[34]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Fracture L. 5th toe]
	Start Date:	UNK/UNK/2003
	Ongoing:	NO End Date: UNK/UNK/2003

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Site No: 1019

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1.ai	Line/MH Number:	[35]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Fracture, right foot]
	Start Date:	UNK/UNK/2010
	Ongoing:	NO End Date: UNK/UNK/2010
1.aj	Line/MH Number:	[36]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Bilateral leg cramps]
	Start Date:	Apr/UNK/2018
	Ongoing:	YES
1.ak	Line/MH Number:	[37]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Recurrent joint pain, neck, shoulders, ankles, elbows, hips, knees, wrists]
	Start Date:	UNK/UNK/1980
	Ongoing:	YES
1.al	Line/MH Number:	[38]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Recurrent back pain - lumbar]
	Start Date:	UNK/UNK/2004
	Ongoing:	YES
1.am	Line/MH Number:	[39]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Fracture, right shoulder]
	Start Date:	Jul/UNK/2010
	Ongoing:	NO End Date: Jul/UNK/2010

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Site No: 1019

Subject No: 10191010

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Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

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1.an	Line/MH Number:	[40]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Shoulder implant, right - insertion]
	Start Date:	UNK/UNK/2013
	Ongoing:	NO End Date: UNK/UNK/2013
1.ao	Line/MH Number:	[41]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Shoulder implant removal, right]
	Start Date:	Apr/UNK/2014
	Ongoing:	NO End Date: Apr/UNK/2014
1.ap	Line/MH Number:	[42]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Shoulder implant infection, right]
	Start Date:	UNK/UNK/2014
	Ongoing:	NO End Date: UNK/UNK/2014
1.aq	Line/MH Number:	[43]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Tendonitis, left wrist]
	Start Date:	Jan/UNK/2006
	Ongoing:	NO End Date: Jan/UNK/2006

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1.ar	Line/MH Number:	[44]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[cyst, right ankle, benign]
	Start Date:	UNK/UNK/2009
	Ongoing:	NO End Date: Jul/UNK/2010
1.as	Line/MH Number:	[45]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Tennis elbow]
	Start Date:	UNK/UNK/1998
	Ongoing:	NO End Date: UNK/UNK/1999
1.at	Line/MH Number:	[46]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Stress fracture, right ankle]
	Start Date:	Aug/UNK/2010
	Ongoing:	NO End Date: Oct/5/2010
1.au	Line/MH Number:	[47]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Depression]
	Start Date:	UNK/UNK/2001
	Ongoing:	YES

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1.av	Line/MH Number:	[48]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Anxiety]
	Start Date:	UNK/UNK/2001
	Ongoing:	YES
1.aw	Line/MH Number:	[49]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Diabetes mellitus type 2]
	Start Date:	UNK/UNK/2002
	Ongoing:	YES
1.ax	Line/MH Number:	[50]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypothyroidism]
	Start Date:	UNK/UNK/2004
	Ongoing:	YES
1.ay	Line/MH Number:	[51]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Iron deficiency anemia]
	Start Date:	Sep/UNK/2010
	Ongoing:	NO End Date: Jul/31/2020
1.az	Line/MH Number:	[52]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Psoriasis]
	Start Date:	UNK/UNK/2002
	Ongoing:	YES

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1.ba	Line/MH Number:	[53]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Rosacea]
	Start Date:	Nov/26/2001
	Ongoing:	YES
1.bb	Line/MH Number:	[54]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Left rotator cuff tear]
	Start Date:	Jan/UNK/2018
	Ongoing:	NO End Date: Mar/1/2018
1.bc	Line/MH Number:	[55]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Left fourth trigger finger]
	Start Date:	UNK/UNK/1999
	Ongoing:	NO End Date: UNK/UNK/1999
1.bd	Line/MH Number:	[56]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Allergic rhinitis]
	Start Date:	UNK/UNK/1972
	Ongoing:	YES
1.be	Line/MH Number:	[57]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Drug allergy - penicillin]
	Start Date:	UNK/UNK/1950
	Ongoing:	YES

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1.bf	Line/MH Number:	[58]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Drug allergy - macrodantin]
	Start Date:	UNK/UNK/1950
	Ongoing:	YES
1.bg	Line/MH Number:	[59]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Tonsillectomy]
	Start Date:	UNK/UNK/1961
	Ongoing:	NO End Date: UNK/UNK/1961
1.bh	Line/MH Number:	[60]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Anal fistulectomy]
	Start Date:	UNK/UNK/1981
	Ongoing:	NO End Date: UNK/UNK/1981
1.bi	Line/MH Number:	[61]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Arthroscopy left knee]
	Start Date:	UNK/UNK/1980
	Ongoing:	NO End Date: UNK/UNK/1980

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1.bj	Line/MH Number:	[62]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Cholecystectomy]
	Start Date:	UNK/UNK/1994
	Ongoing:	NO End Date: UNK/UNK/1994
1.bk	Line/MH Number:	[63]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Carpal tunnel release surgery, bilateral]
	Start Date:	UNK/UNK/1996
	Ongoing:	NO End Date: UNK/UNK/1996
1.bl	Line/MH Number:	[64]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Trigger release surgery, left fourth finger]
	Start Date:	UNK/UNK/1999
	Ongoing:	NO End Date: UNK/UNK/1999
1.bm	Line/MH Number:	[65]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Excision, uterine lesion]
	Start Date:	UNK/UNK/2006
	Ongoing:	NO End Date: UNK/UNK/2006

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1.bn	Line/MH Number:	[66]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Left wrist tendonitis repair]
	Start Date:	Jan/UNK/2006
	Ongoing:	NO End Date: Jan/UNK/2006
1.bo	Line/MH Number:	[67]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Left knee arthroplasty]
	Start Date:	UNK/UNK/2007
	Ongoing:	NO End Date: UNK/UNK/2007
1.bp	Line/MH Number:	[68]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Cyst excision, right ankle]
	Start Date:	Jul/UNK/2010
	Ongoing:	NO End Date: Jul/UNK/2010
1.bq	Line/MH Number:	[69]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Left rotator cuff repair surgery]
	Start Date:	Mar/1/2018
	Ongoing:	NO End Date: Mar/1/2018

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1.br	Line/MH Number:	[70]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Chest Pain]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.bs	Line/MH Number:	[71]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[atrial fibrillation]
	Start Date:	Nov/1/2017
	Ongoing:	YES
1.bt	Line/MH Number:	[72]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[implantable loop recorder]
	Start Date:	Nov/1/2017
	Ongoing:	YES
1.bu	Line/MH Number:	[73]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[mitral valve regurgitation]
	Start Date:	UNK/UNK/2005
	Ongoing:	YES
1.bv	Line/MH Number:	[74]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[edema- bilateral lower extremities]
	Start Date:	Apr/25/2018
	Ongoing:	YES

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1.bw	Line/MH Number:	[75]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[cholelithiasis]
	Start Date:	UNK/UNK/1994
	Ongoing:	NO End Date: UNK/UNK/1994
1.bx	Line/MH Number:	[76]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[heartburn]
	Start Date:	UNK/UNK/1990
	Ongoing:	YES
1.by	Line/MH Number:	[77]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[duodenal ulcer]
	Start Date:	UNK/UNK/1990
	Ongoing:	NO End Date: UNK/UNK/2000
1.bz	Line/MH Number:	[78]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[esophageal ulcer]
	Start Date:	UNK/UNK/1990
	Ongoing:	NO End Date: UNK/UNK/2000

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1.ca	Line/MH Number:	[79]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[chronic constipation]
	Start Date:	Apr/UNK/2010
	Ongoing:	YES

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Aug/11/2020
2.	Weight:	[189.7]
3.	Unit:	LB
4.	Height:	[62.5]
5.	Unit:	in
6.	Body Mass Index:	[34.1]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[97.8]
	Unit:	F
	Temperature Location:	EAR

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Aug/11/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	
	Not Done:	NOT DONE

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Aug/11/2020
2.	Randomization Number:	[225292]
3.	Randomization Group:	[]

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/11/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BM86C1]
5.b	Sample ID	[BM86C2]
5.c	Sample ID	[BM86C3]
5.d	Sample ID	[BPRM37]
5.e	Sample ID	[BPRM38]

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/11/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BM85ZL]
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090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/11/2020 10:15
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Reactogenicity Diary

1.	Select appropriate response - Reactogenicity diary collection	YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT
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090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Sep/1/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	YES Ongoing? NO Stop Date: Aug/12/2020
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERED JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	YES Ongoing? NO Stop Date: Aug/12/2020

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/1/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[98.1]
	Unit:	F
	Temperature Location:	EAR

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/1/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	
	Not Done:	NOT DONE

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/1/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BM8649]
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090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/1/2020 08:18
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/6/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERED JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/6/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP98K5]
5.b	Sample ID	[BRTLKK]
5.c	Sample ID	[BRTLKL]
5.d	Sample ID	[BRTLKM]

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Electronic Sample Tracking

1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Electronic Sample Tracking

1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
----	-----------	-----

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Electronic Sample Tracking

1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
----	-----------	-----

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET
on Aug/17/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Aug/17/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_A
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090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
on Aug/17/2020

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[Form Comments](#)
[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Not Applicable _____ //	Comments
2.	Date of First Symptom Started:	Not Applicable _____ //	Comments
3.	Symptoms Ongoing?	Not Applicable _____	Comments

Symptoms

4.a	Symptoms:	FEVER	
	Was symptom present?	Not Applicable _____	Comments
4.b	Symptoms:	NEW OR INCREASED COUGH	
	Was symptom present?	Not Applicable _____	Comments
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH	
	Was symptom present?	Not Applicable _____	Comments
4.d	Symptoms:	CHILLS	
	Was symptom present?	Not Applicable _____	Comments
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN	
	Was symptom present?	Not Applicable _____	Comments
4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL	
	Was symptom present?	Not Applicable _____	Comments

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
on Aug/17/2020

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

4.g	Symptoms:	NEW OR INCREASED SORE THROAT	
	Was symptom present?	Not Applicable _____	Comments
4.h	Symptoms:	DIARRHEA	
	Was symptom present?	Not Applicable _____	Comments
4.i	Symptoms:	VOMITING	
	Was symptom present?	Not Applicable _____	Comments
Symptoms - Other			
5.	Symptoms - Other Text:	Not Applicable _____ []	

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN
on Aug/17/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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[eCRF Audit Trail History](#)

Microbiology Specimen

1.	Actual Date of Collection:	Not Applicable _____ //	Comments
2.	Specimen Type:	Not Applicable _____	Comments
3.	Specimen Collection Location:	Not Applicable _____	Comments
4.	Assay Code and Description:	Not Applicable _____	Comments
5.	Device Type:	Not Applicable _____	Comments
6.	Trade Name:	Not Applicable _____	Comments
7.	Test Result:	Not Applicable _____	Comments
8.	Comments/Findings/Details:	Not Applicable _____ []	Comments
9.	Trade Name Other, Specify:	Not Applicable _____ []	Comments

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF on Aug/17/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[Form Comments](#)
[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	Not Applicable _____	Comments
2.	Sample Type	Not Applicable _____	Comments
3.	Sample Collected?	Not Applicable _____	Comments
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	Not Applicable []	Comments

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	Not Applicable _____ []
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090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
on Aug/17/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[Form Comments](#)
[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	Not Applicable _____	Comments
2.	Sample Type	Not Applicable _____	Comments
3.	Sample Collected?	Not Applicable _____	Comments
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	Not Applicable _____ []	Comments

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	Not Applicable _____ []
----	-----------	--------------------------------

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION
on Aug/17/2020**Form Version:** 15-Sep-2020 21:53**Form Status:** Data Complete, Frozen, Verified**Site No:** 1019**Site Name:** (1019) Diagnostics Research Group**Subject No:** 10191010**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44[eCRF Audit Trail History](#)**Health Care Utilization**

1.a	Physician or Healthcare Professional:	SPECIALIST
	Occurrence of Visits or Contacts:	NO
1.b	Physician or Healthcare Professional:	EMERGENCY ROOM
	Occurrence of Visits or Contacts:	YES Number of Visits or Contacts: [1]
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN
	Occurrence of Visits or Contacts:	NO
1.d	Physician or Healthcare Professional:	URGENT CARE
	Occurrence of Visits or Contacts:	NO
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION
	Occurrence of Visits or Contacts:	NO
1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	NO

Health Care Utilization Other

2.	Other Type of Practitioner Specify:	[]
----	-------------------------------------	-----

Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	YES Has the subject been in intensive care due to potential COVID-19 illness? NO
----	--	--

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: HOSPITALIZATION DETAILS

Form Version: 22-Apr-2020 21:02

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

#	Hospitalization Category	Hospitalization Term	Admission Date	Ongoing	Form Instance
1.	HOSPITALIZATION STATUS	HOSPITAL	Aug/27/2020	NO Discharge Date: Aug/29/2020	Repeating Pages

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HOSPITALIZATION DETAILS
on Aug/17/2020

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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[Form Audit Trail](#)

Hospitalization Details

1.	Hospitalization Category:	HOSPITALIZATION STATUS	Comments
2.	Hospitalization Term:	HOSPITAL	Comments
3.	Admission Date:	Aug/27/2020	Comments
4.	Ongoing?	NO Discharge Date: Aug/29/2020	Comments

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT
on Aug/17/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Respiratory Treatment

1.	What is the treatment Identifier?	Not Applicable _____ []	Comments
2.	Concomitant Non-drug Treatment Pre-specified:	Not Applicable _____	Comments
3.	Treatment:	Not Applicable _____	Comments
4.	Treatment:	Not Applicable _____ []	Comments
5.	Start Date:	Not Applicable _____ //	Comments
6.	Ongoing?	Not Applicable _____	Comments

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS
on Aug/17/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[Form Comments](#)
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Illness Details

1.	Category of Clinical Event:	Not Applicable _____	Comments
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	Not Applicable _____	Comments
3.	Toxicity Grade:	Not Applicable _____	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

#	Category of Clinical Event	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE
on Aug/17/2020

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Illness Details

1.	Category of Clinical Event:	Not Applicable _____	Comments
2.	Subcategory of Clinical Event:	Not Applicable _____	Comments
3.	Was a diagnosis obtained?	Not Applicable _____	Comments
4.	Toxicity Grade:	Not Applicable _____	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 30-Jul-2020 21:27

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

#	Category for Lab Test	Vendor Name	Collection Date	Specimen Type	Lab Result	Form Instance																								
1.	CLINICAL CHEMISTRY	Methodist and Children's Hospital, 7700 Floyd Curl Dr., San Antonio, Texas 78229	Aug/27/2020	BLOOD	<table border="1"> <thead> <tr> <th>Sponsor-Defined Identifier</th> <th>Test:</th> <th>Result:</th> </tr> </thead> <tbody> <tr> <td>329</td> <td>Not Applicable</td> <td></td> </tr> <tr> <td>30</td> <td>Not Applicable</td> <td>23</td> </tr> <tr> <td>28</td> <td>Not Applicable</td> <td>22</td> </tr> <tr> <td>35</td> <td>Not Applicable</td> <td>98</td> </tr> <tr> <td>21</td> <td>Not Applicable</td> <td>0.6</td> </tr> <tr> <td>47</td> <td>Not Applicable</td> <td>10</td> </tr> <tr> <td>48</td> <td>Not Applicable</td> <td>1.01</td> </tr> </tbody> </table>	Sponsor-Defined Identifier	Test:	Result:	329	Not Applicable		30	Not Applicable	23	28	Not Applicable	22	35	Not Applicable	98	21	Not Applicable	0.6	47	Not Applicable	10	48	Not Applicable	1.01	Repeating Pages
Sponsor-Defined Identifier	Test:	Result:																												
329	Not Applicable																													
30	Not Applicable	23																												
28	Not Applicable	22																												
35	Not Applicable	98																												
21	Not Applicable	0.6																												
47	Not Applicable	10																												
48	Not Applicable	1.01																												

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY on Aug/17/2020

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Lab Chemistry Details

1.	Lab Panel:	CLINICAL CHEMISTRY	Comments
2.	Laboratory Name and Address	[Methodist and Children's Hospital,7700 Floyd Curl Dr.,San Antonio, Texas 78229]	Comments
3.	Collection Date:	Aug/27/2020	Comments
4.	Specimen Type:	BLOOD	Comments

Lab Result

5.a	Sponsor ID:	[329]	Comments
	Test:	C Reactive Protein_PX329	
	Result:	[]	Comments
	Not Done:	NOT DONE	Comments
	LNMT	Low [] High [] Unit	Comments
5.b	Sponsor ID:	[30]	Comments
	Test:	Alanine Aminotransferase_PX30	
	Result:	[23]	Comments
	Not Done:		Comments
	LNMT	Low [13] High [61] Unit U/L	Comments

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Aug/17/2020

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

5.c	Sponsor ID:	[28]	Comments
	Test:	Aspartate Aminotransferase_PX28	
	Result:	[22]	Comments
	Not Done:		Comments
	LNMT	Low [15] High [37] Unit U/L	Comments
5.d	Sponsor ID:	[35]	Comments
	Test:	Alkaline Phosphatase_PX35	
	Result:	[98]	Comments
	Not Done:		Comments
	LNMT	Low [45] High [117] Unit U/L	Comments
5.e	Sponsor ID:	[21]	Comments
	Test:	Bilirubin_PX21	
	Result:	[0.6]	Comments
	Not Done:		Comments
	LNMT	Low [0.2] High [1.0] Unit mg/dL	Comments

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Aug/17/2020

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

5.f	Sponsor ID:	[47]	Comments
	Test:	Blood Urea Nitrogen_PX47	
	Result:	[10]	Comments
	Not Done:		Comments
	LNMT	Low [7] High [18] Unit mg/dL	Comments
5.g	Sponsor ID:	[48]	Comments
	Test:	Creatinine_PX48	
	Result:	[1.01]	Comments
	Not Done:		Comments
	LNMT	Low [0.6] High [1.3] Unit mg/dL	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 30-Jul-2020 21:28

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date	Specimen Type	Lab Result	Form Instance																																	
1.	HEMATOLOGY	Methodist and Children's Hospitals, 7700 Floyd Curl Dr., San Antonio, Texas 78229	Aug/27/2020	BLOOD	<table border="1"> <thead> <tr> <th>Sponsor-Defined Identifier</th> <th>Test:</th> <th>Result:</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Not Applicable</td> <td>12.6</td> </tr> <tr> <td>2</td> <td>Not Applicable</td> <td>37.5</td> </tr> <tr> <td>3</td> <td>Not Applicable</td> <td></td> </tr> <tr> <td>5</td> <td>Not Applicable</td> <td>322</td> </tr> <tr> <td>7</td> <td>Not Applicable</td> <td></td> </tr> <tr> <td>608</td> <td>Not Applicable</td> <td>5.3</td> </tr> <tr> <td>609</td> <td>Not Applicable</td> <td>0.8</td> </tr> <tr> <td>612</td> <td>Not Applicable</td> <td>0.8</td> </tr> <tr> <td>610</td> <td>Not Applicable</td> <td>0.1</td> </tr> <tr> <td>611</td> <td>Not Applicable</td> <td>2.6</td> </tr> </tbody> </table>	Sponsor-Defined Identifier	Test:	Result:	1	Not Applicable	12.6	2	Not Applicable	37.5	3	Not Applicable		5	Not Applicable	322	7	Not Applicable		608	Not Applicable	5.3	609	Not Applicable	0.8	612	Not Applicable	0.8	610	Not Applicable	0.1	611	Not Applicable	2.6	Repeating Pages
Sponsor-Defined Identifier	Test:	Result:																																					
1	Not Applicable	12.6																																					
2	Not Applicable	37.5																																					
3	Not Applicable																																						
5	Not Applicable	322																																					
7	Not Applicable																																						
608	Not Applicable	5.3																																					
609	Not Applicable	0.8																																					
612	Not Applicable	0.8																																					
610	Not Applicable	0.1																																					
611	Not Applicable	2.6																																					

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING Hematology on Aug/17/2020

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Laboratory Data Hematology

1.	Lab Panel:	HEMATOLOGY	Comments
2.	Laboratory Name and Address	[Methodist and Children's Hospitals,7700 Floyd Curl Dr.,San Antonio, Texas 78229]	Comments
3.	Collection Date:	Aug/27/2020	Comments
4.	Specimen Type:	BLOOD	Comments

Lab Result

5.a	Sponsor ID:	[1]	Comments
	Test:	Hemoglobin_PX1	
	Result:	[12.6]	Comments
	Not Done:		Comments
	LNMT	Low [12.0] High [16.0] Unit g/dL	Comments
5.b	Sponsor ID:	[2]	Comments
	Test:	Hematocrit_PX2	
	Result:	[37.5]	Comments
	Not Done:		Comments
	LNMT	Low [36.0] High [46.0] Unit %	Comments

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
on Aug/17/2020

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

5.c	Sponsor ID:	[3]	Comments
	Test:	Erythrocytes_PX3	
	Result:	[]	Comments
	Not Done:	NOT DONE	Comments
	LNMT	Low [] High [] Unit	Comments
5.d	Sponsor ID:	[5]	Comments
	Test:	Platelets_PX5	
	Result:	[322]	Comments
	Not Done:		Comments
	LNMT	Low [150] High [400] Unit /uL	Comments
5.e	Sponsor ID:	[7]	Comments
	Test:	Leukocytes_PX7	
	Result:	[]	Comments
	Not Done:	NOT DONE	Comments
	LNMT	Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
on Aug/17/2020

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

5.f	Sponsor ID:	[608]	Comments
	Test:	Neutrophils_PX608	
	Result:	[5.3]	Comments
	Not Done:		Comments
	LNMT	Low [1.5] High [7.8] Unit /uL	Comments
5.g	Sponsor ID:	[609]	Comments
	Test:	Eosinophils_PX609	
	Result:	[0.8]	Comments
	Not Done:		Comments
	LNMT	Low [0.0] High [6.0] Unit /uL	Comments
5.h	Sponsor ID:	[612]	Comments
	Test:	Monocytes_PX612	
	Result:	[0.8]	Comments
	Not Done:		Comments
	LNMT	Low [0.2] High [1.0] Unit /uL	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
on Aug/17/2020

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

5.i	Sponsor ID:	[610]	Comments
	Test:	Basophils_PX610	
	Result:	[0.1]	Comments
	Not Done:		Comments
	LNMT	Low [0.0] High [0.1] Unit /uL	Comments
5.j	Sponsor ID:	[611]	Comments
	Test:	Lymphocytes_PX611	
	Result:	[2.6]	Comments
	Not Done:		Comments
	LNMT	Low [0.8] High [3.4] Unit /uL	Comments

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Header Text: c4591001
Visit: POT_COVID_ILL 1 **Form:** VITAL SIGNS - COVID
Form Version: 30-Jul-2020 21:27
Site No: 1019 **Site Name:** (1019) Diagnostics Research Group
Subject No: 10191010 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 04:44

#	Date:	Vital Signs Details			Form Instance						
1. DELETED	Aug/27/2020	<table border="1"> <tr> <th data-bbox="631 432 911 478">Record Identifier:</th> <th data-bbox="911 432 1057 478">Systolic:</th> <th data-bbox="1057 432 1211 478">Diastolic:</th> </tr> <tr> <td data-bbox="631 478 911 533">Not Applicable</td> <td data-bbox="911 478 1057 533">187</td> <td data-bbox="1057 478 1211 533">74</td> </tr> </table>	Record Identifier:	Systolic:	Diastolic:	Not Applicable	187	74			Repeating Pages
Record Identifier:	Systolic:	Diastolic:									
Not Applicable	187	74									

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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 10-Oct-2020 15:59

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: VITAL SIGNS - COVID

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

#	Date:	Vital Signs Details			Form Instance
2. DELETED	Aug/27/2020	Record Identifier:	Systolic:	Diastolic:	Repeating Pages
		1	162	73	
3. DELETED	Aug/27/2020	Record Identifier:	Systolic:	Diastolic:	Repeating Pages
		1	178	76	
4. DELETED		Record Identifier:	Systolic:	Diastolic:	Repeating Pages
		1			
5. DELETED	Aug/27/2020	Record Identifier:	Systolic:	Diastolic:	Repeating Pages
		1	175	78	
6. DELETED	Aug/27/2020	Record Identifier:	Systolic:	Diastolic:	Repeating Pages
		1	177	109	
7.	Aug/27/2020	Record Identifier:	Systolic:	Diastolic:	Repeating Pages
		1	136	48	
8. DELETED	Aug/27/2020	Record Identifier:	Systolic:	Diastolic:	Repeating Pages
		1	202	81	
9. DELETED	Aug/27/2020	Record Identifier:	Systolic:	Diastolic:	Repeating Pages
		1	192	78	
10. DELETED	Aug/27/2020	Record Identifier:	Systolic:	Diastolic:	Repeating Pages
		1	169	72	
11. DELETED	Aug/28/2020	Record Identifier:	Systolic:	Diastolic:	Repeating Pages
		1	146	67	
12. DELETED	Aug/28/2020	Record Identifier:	Systolic:	Diastolic:	Repeating Pages
		1	151	96	
13. DELETED	Aug/28/2020	Record Identifier:	Systolic:	Diastolic:	Repeating Pages
		1	123	50	

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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 10-Oct-2020 15:59

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: VITAL SIGNS - COVID

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

#	Date:	Vital Signs Details			Form Instance
14. DELETED	Aug/28/2020	Record Identifier:	Systolic:	Diastolic:	Repeating Pages
		1	149	71	
15.	Aug/28/2020	Record Identifier:	Systolic:	Diastolic:	Repeating Pages
		1	122	63	
16.	Aug/29/2020	Record Identifier:	Systolic:	Diastolic:	Repeating Pages
		1	138	69	

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID
on Aug/17/2020

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Deleted

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Vital Signs

1.	Date:	Aug/27/2020	Comments
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Vital Signs Details

2.a	Record Identifier:	1	
	Systolic:	[187]	Comments
	Diastolic:	[74]	Comments
	Respiratory Rate in respirations/minute:	[20]	Comments
	Heart Rate in beats/minute:	[69]	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID
on Aug/17/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Deleted

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

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Vital Signs

1.	Date:	Aug/27/2020
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Vital Signs Details

2.a	Record Identifier:	4
	Systolic:	[462]
	Diastolic:	[73]
	Respiratory Rate in respirations/minute:	[18]
	Heart Rate in beats/minute:	[83]

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID
on Aug/17/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Deleted

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

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Vital Signs

1.	Date:	Aug/27/2020
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Vital Signs Details

2.a	Record Identifier:	±
	Systolic:	[178]
	Diastolic:	[76]
	Respiratory Rate in respirations/minute:	[18]
	Heart Rate in beats/minute:	[77]

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID
on Aug/17/2020

Form Version: 10-Oct-2020 15:59

Form Status: Incomplete, Data Complete, Deleted

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Vital Signs

1.	Date:	//
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Vital Signs Details

2.a	Record Identifier:	±
	Systolic:	[]
	Diastolic:	[]
	Respiratory Rate in respirations/minute:	[]
	Heart Rate in beats/minute:	[]

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID
on Aug/17/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Deleted

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

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Vital Signs

1.	Date:	Aug/27/2020
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Vital Signs Details

2.a	Record Identifier:	4
	Systolic:	[475]
	Diastolic:	[78]
	Respiratory Rate in respirations/minute:	[18]
	Heart Rate in beats/minute:	[75]

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID
on Aug/17/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Deleted

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

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Vital Signs

1.	Date:	Aug/27/2020
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Vital Signs Details

2.a	Record Identifier:	4
	Systolic:	[177]
	Diastolic:	[109]
	Respiratory Rate in respirations/minute:	[20]
	Heart Rate in beats/minute:	[75]

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID
on Aug/17/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

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Vital Signs

1.	Date:	Aug/27/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Systolic:	[136]
	Diastolic:	[48]
	Respiratory Rate in respirations/minute:	[20]
	Heart Rate in beats/minute:	[66]

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID
on Aug/17/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Deleted

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

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Vital Signs

1.	Date:	Aug/27/2020
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Vital Signs Details

2.a	Record Identifier:	4
	Systolic:	[202]
	Diastolic:	[84]
	Respiratory Rate in respirations/minute:	[22]
	Heart Rate in beats/minute:	[69]

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID
on Aug/17/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Deleted

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

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Vital Signs

1.	Date:	Aug/27/2020
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Vital Signs Details

2.a	Record Identifier:	4
	Systolic:	[492]
	Diastolic:	[78]
	Respiratory Rate in respirations/minute:	[18]
	Heart Rate in beats/minute:	[72]

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID
on Aug/17/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Deleted

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Vital Signs

1.	Date:	Aug/27/2020
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Vital Signs Details

2.a	Record Identifier:	4
	Systolic:	[469]
	Diastolic:	[72]
	Respiratory Rate in respirations/minute:	[18]
	Heart Rate in beats/minute:	[72]

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID
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Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Deleted

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Vital Signs

1.	Date:	Aug/28/2020
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Vital Signs Details

2.a	Record Identifier:	4
	Systolic:	[446]
	Diastolic:	[67]
	Respiratory Rate in respirations/minute:	[18]
	Heart Rate in beats/minute:	[126]

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID
on Aug/17/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Deleted

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

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Vital Signs

1.	Date:	Aug/28/2020
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Vital Signs Details

2.a	Record Identifier:	4
	Systolic:	[154]
	Diastolic:	[96]
	Respiratory Rate in respirations/minute:	[18]
	Heart Rate in beats/minute:	[72]

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID
on Aug/17/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Deleted

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

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Vital Signs

1.	Date:	Aug/28/2020
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Vital Signs Details

2.a	Record Identifier:	4
	Systolic:	[123]
	Diastolic:	[50]
	Respiratory Rate in respirations/minute:	[16]
	Heart Rate in beats/minute:	[78]

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID
on Aug/17/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Deleted

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

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Vital Signs

1.	Date:	Aug/28/2020
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Vital Signs Details

2.a	Record Identifier:	4
	Systolic:	[449]
	Diastolic:	[74]
	Respiratory Rate in respirations/minute:	[46]
	Heart Rate in beats/minute:	[70]

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID
on Aug/17/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Vital Signs

1.	Date:	Aug/28/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Systolic:	[122]
	Diastolic:	[63]
	Respiratory Rate in respirations/minute:	[16]
	Heart Rate in beats/minute:	[73]

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID
on Aug/17/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

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Vital Signs

1.	Date:	Aug/29/2020
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Vital Signs Details

2.a	Record Identifier:	1	
	Systolic:	[138]	Comments
	Diastolic:	[69]	Comments
	Respiratory Rate in respirations/minute:	[18]	Comments
	Heart Rate in beats/minute:	[56]	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 30-Jul-2020 21:28

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

#	Date:	Vital Signs Details		Form Instance
1. DELETED	Aug/27/2020	Record Identifier:	Oxygen Saturation	Repeating Pages
		Unknown	100.0	

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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 10-Oct-2020 16:04

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: VITAL SIGNS - PULSE OX ROOM AIR

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

#	Date:	Vital Signs Details		Form Instance
2. DELETED	Aug/27/2020	Record Identifier:	Oxygen Saturation	Repeating Pages
		1	98.0	
3. DELETED	Aug/27/2020	Record Identifier:	Oxygen Saturation	Repeating Pages
		1	100.0	
4. DELETED	Aug/27/2020	Record Identifier:	Oxygen Saturation	Repeating Pages
		1	99.0	
5. DELETED	Aug/27/2020	Record Identifier:	Oxygen Saturation	Repeating Pages
		1	99.0	
6. DELETED	Aug/27/2020	Record Identifier:	Oxygen Saturation	Repeating Pages
		1	99.0	
7.	Aug/27/2020	Record Identifier:	Oxygen Saturation	Repeating Pages
		1	95.0	
8. DELETED	Aug/27/2020	Record Identifier:	Oxygen Saturation	Repeating Pages
		1	100.0	
9. DELETED	Aug/28/2020	Record Identifier:	Oxygen Saturation	Repeating Pages
		1	97.0	
10. DELETED	Aug/28/2020	Record Identifier:	Oxygen Saturation	Repeating Pages
		1	99.0	
11. DELETED	Aug/28/2020	Record Identifier:	Oxygen Saturation	Repeating Pages
		1	99.0	
12. DELETED	Aug/28/2020	Record Identifier:	Oxygen Saturation	Repeating Pages
		1	99.0	
13.	Aug/28/2020	Record Identifier:	Oxygen Saturation	Repeating Pages
		1	96.0	

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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 10-Oct-2020 16:04

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: VITAL SIGNS - PULSE OX ROOM AIR

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

#	Date:	Vital Signs Details		Form Instance
14.	Aug/29/2020	Record Identifier:	Oxygen Saturation	Repeating Pages
		1	93.0	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR
on Aug/17/2020

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Deleted

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

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Vital Signs

1.	Date:	Aug/27/2020	Comments
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Vital Signs Details

2.a	Record Identifier:	1	
	SPO2 Pulse Oximetry %	[100.0]	Comments

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR
on Aug/17/2020

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Deleted, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

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Vital Signs

1.	Date:	Aug/27/2020
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Vital Signs Details

2.a	Record Identifier:	4
	SPO2 Pulse Oximetry %	[98.0]

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR
on Aug/17/2020

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Deleted, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Vital Signs

1.	Date:	Aug/27/2020
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Vital Signs Details

2.a	Record Identifier:	1
	SPO2 Pulse Oximetry %	[400.0]

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR
on Aug/17/2020

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Deleted, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Vital Signs

1.	Date:	Aug/27/2020
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Vital Signs Details

2.a	Record Identifier:	±
	SPO2 Pulse Oximetry %	[99.0]

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR
on Aug/17/2020

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Deleted, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Vital Signs

1.	Date:	Aug/27/2020
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Vital Signs Details

2.a	Record Identifier:	±
	SPO2 Pulse Oximetry %	[99.0]

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR
on Aug/17/2020

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Deleted, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

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Generated Time (GMT): 29-Mar-2021 04:44

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Vital Signs

1.	Date:	Aug/27/2020
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Vital Signs Details

2.a	Record Identifier:	±
	SPO2 Pulse Oximetry %	[99.0]

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR
on Aug/17/2020

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

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Vital Signs

1.	Date:	Aug/27/2020
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Vital Signs Details

2.a	Record Identifier:	1
	SPO2 Pulse Oximetry %	[95.0]

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR
on Aug/17/2020

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Deleted, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

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Vital Signs

1.	Date:	Aug/27/2020
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Vital Signs Details

2.a	Record Identifier:	1
	SPO2 Pulse Oximetry %	[400.0]

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR
on Aug/17/2020

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Deleted, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

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Vital Signs

1.	Date:	Aug/28/2020
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Vital Signs Details

2.a	Record Identifier:	4
	SPO2 Pulse Oximetry %	[97.0]

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR
on Aug/17/2020

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Deleted, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

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Vital Signs

1.	Date:	Aug/28/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	4
	SPO2 Pulse Oximetry %	[99.0]

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR
on Aug/17/2020

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Deleted, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

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Vital Signs

1.	Date:	Aug/28/2020
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Vital Signs Details

2.a	Record Identifier:	4
	SPO2 Pulse Oximetry %	[99.0]

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR
on Aug/17/2020

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Deleted, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

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Vital Signs

1.	Date:	Aug/28/2020
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Vital Signs Details

2.a	Record Identifier:	4
	SPO2 Pulse Oximetry %	[99.0]

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR
on Aug/17/2020

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Vital Signs

1.	Date:	Aug/28/2020
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Vital Signs Details

2.a	Record Identifier:	1
	SPO2 Pulse Oximetry %	[96.0]

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR
on Aug/17/2020

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Vital Signs

1.	Date:	Aug/29/2020
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Vital Signs Details

2.a	Record Identifier:	1
	SPO2 Pulse Oximetry %	[93.0]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS
on Aug/17/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Oxygenation Parameters

1.	Date Time of Assessment:	Not Applicable _____ //	Comments
2.	Arterial Blood Gases PaO2 (mmHg):	Not Applicable _____ []	Comments
3.	FiO2 (Fraction of Inhaled Oxygen):	Not Applicable _____ []	Comments

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS
on Aug/17/2020

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Concomitant Medications

1.	What is the medication identifier?	Not Applicable _____ []	Comments
2.	Category:	Not Applicable _____	Comments
3.	Concomitant Medications Pre-specified:	Not Applicable _____	Comments
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	Not Applicable _____ []	Comments
5.	Start Date:	Not Applicable _____ //	Comments
6.	Ongoing?	Not Applicable _____	Comments

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING
on Aug/17/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Imaging

1.	Date of Assessment:	Not Applicable _____ //	Comments
2.	Location of Assessment:	Not Applicable _____	Comments
3.	Type of Imaging Exam:	Not Applicable _____	Comments
4.	Assessment:	Not Applicable _____	Comments

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	
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090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Electronic Sample Tracking

1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
----	-----------	-----

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Unplanned Assessments

1.	Assessments	
----	-------------	--

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Oct/6/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Data Complete, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Disposition - Follow-Up

1.	Date of Completion/Discontinuation /Death :	Dec/2/2020
2.	Phase of Disposition:	FOLLOW-UP
3.	Status:	LOST TO FOLLOW-UP
4.	Specify Status:	[lost to follow up]

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

3.	COVID-19 Repeat Swab:	
----	-----------------------	--

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Electronic Sample Tracking

1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
----	-----------	-----

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Diarrhea	Aug/17/2020 00:00	NO End Date Time: Aug/27/2020 00:00	Repeating Pages
2.	ADVERSE EVENT	2	Diarrhea	Aug/27/2020 UNK:UNK	NO End Date Time: Aug/29/2020 UNK:UNK	Repeating Pages
3.	ADVERSE EVENT	3	Mental State Status Change	Oct/2/2020 UNK:UNK	NO End Date Time: Oct/2/2020 UNK:UNK	Repeating Pages

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Not Complete

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Diarrhea]
4.	Start Date Time:	Aug/17/2020 00:00
5.	Is the adverse event still ongoing?	NO End Date Time: Aug/27/2020 00:00
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Pre-Existing conditions]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Not Complete

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Answered Queries

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Adverse Event Report

1.	Category:	ADVERSE EVENT	
2.	AE ID:	[2]	Comments
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Diarrhea]	Comments
4.	Start Date Time:	Aug/27/2020 UNK:UNK	
5.	Is the adverse event still ongoing?	NO End Date Time: Aug/29/2020 UNK:UNK	
6.	Toxicity Grade:	4	
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? YES Other medically important serious event YES	
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO	

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Answered Queries

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Unknown]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020339743]

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Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Mental State Status Change]
4.	Start Date Time:	Oct/2/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/2/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [unknown]

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

Medication Error

1.	Category:	
2.	Medication Error (Type of Medication Error):	[]
3.	Start Date:	//
4.	Is the medication error still ongoing?	
5.	Latest Action Taken with Study Treatment:	
6.	Was a Concomitant Medication given?	
7.	Was a Non-Drug Treatment given?	
8.	Did the Medication Error cause the subject to be discontinued from the study?	
9.	Was this medication error associated with any adverse events?	
10.	Serious Adverse Event Number: For Pfizer Use Only	[]

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Concomitant Medications

1.	What is the medication identifier?	[]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[]
5.	Date:	//

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.						Repeating Pages

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Concomitant Medications

1.	What is the medication identifier?	[]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[]
5.	Dose:	[]
6.	Dose Unit:	
7.	Dose Frequency:	
8.	Route:	
9.	Start Date:	//
10.	Ongoing?	

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

Radiation Treatment

1.	Category:	
2.	What is the treatment Identifier?	[]
3.	Concomitant Non-drug Treatment Pre-specified:	
4.	Treatment:	[]
5.	Start Date:	//
6.	Ongoing?	

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

#	Transfusion Type	Date of Transfusion	Form Instance
1.			Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1.	Transfusion Type:	
2.	Date of Transfusion:	//

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VITAL SIGNS - TEMP

Form Version: 20-Feb-2021 02:16

Form Status: Not Started

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Vital Signs

1.	Date:	//
----	-------	----

Vital Signs Details

2.	Record Identifier:	
	Temperature:	[]
	Unit:	
	Temperature Location:	

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: LAB URINALYSIS - PREGNANCY TEST

Form Version: 20-Feb-2021 02:14

Form Status: Not Started

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Lab Urinalysis

1.	Lab Panel:	
2.	Lab Sub-Panel:	
3.	Collection Date:	//
4.	Laboratory Name and Address (Derived)	[]
5.	Specimen Type:	

Lab Result

6.	Sponsor ID:	[]
	Test:	
	Result:	
	Not Done:	

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Vaccination

1.	Was there a temporary delay of vaccination?	
2.	Treatment Name	[]
3.	Formulation:	
4.	Dose Date Time:	//
5.	Anatomical Location:	
6.	Body Side:	
7.	Route:	
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Contact Outcome

1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[]

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 6

Form Version: 10-Oct-2020 16:01

Form Status: Not Started

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Contact Outcome

1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[]

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Not Started

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Informed Consent - Asymptomatic Surveillance

1.	Consent Was:	
----	--------------	--

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Electronic Sample Tracking

1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
----	-----------	-----

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Electronic Sample Tracking

1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
----	-----------	-----

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Not Started

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	
----	---	--

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Treatment Unblinded

1.	Date Treatment Unblinded :	//
2.	Primary Reason for Unblinding:	

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Withdrawal Of Consent

1.	Withdrawal of Consent Date :	//
----	------------------------------	----

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Death Details

1.	Date of Collection / Notification of Death:	//
----	---	----

Cause of Death

2.	Cause of Death Status:	
	Cause of Death:	[]

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	DISCONTINUED
2.	Subject Status Date	Dec/2/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Casebook Signature Form

1.	Casebook Signature	Click Here to Enable
----	--------------------	--------------------------------------

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[Audit Trail](#)

This form requires signing by a member of each of the following signature groups:

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
------	-------------------	------	------	--------

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
Form	Aug-18-2020 07:58:22 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	N/A
Form	Aug-13-2020 12:04:16 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - Comments

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
Form	Sep-22-2020 07:17:01 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -
Comments

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
1	Sep-22-2020 07:17:01 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -
Comments

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
2	Sep-22-2020 07:17:01 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -
Comments

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
3	Sep-22-2020 07:17:01 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -
Comments

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
4.a	Sep-22-2020 07:17:01 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -
Comments

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
4.b	Sep-22-2020 07:17:01 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -
Comments

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
4.c	Sep-22-2020 07:17:01 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -
Comments

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
4.d	Sep-22-2020 07:17:01 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -
Comments

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
4.e	Sep-22-2020 07:17:01 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -
Comments

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
4 f	Sep-22-2020 07:17:01 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -
Comments

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
4.g	Sep-22-2020 07:17:01 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -
Comments

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
4 h	Sep-22-2020 07:17:01 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -
Comments

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
4.i	Sep-22-2020 07:17:01 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
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Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

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Item	Date	User	Comment
Form	Sep-21-2020 15:39:57 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
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Form Status: Data Complete, Frozen, Verified

Site No: 1019

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Item	Date	User	Comment
1	Sep-21-2020 15:39:57 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
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Item	Date	User	Comment
2	Sep-21-2020 15:39:57 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
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Item	Date	User	Comment
3	Sep-21-2020 15:39:57 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Applicable

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
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Item	Date	User	Comment
4	Sep-21-2020 15:39:57 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

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Item	Date	User	Comment
5	Sep-21-2020 15:39:57 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

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Item	Date	User	Comment
6	Sep-21-2020 15:39:57 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
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Form Status: Data Complete, Frozen, Verified

Site No: 1019

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8	Sep-21-2020 15:39:57 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Applicable

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9	Sep-21-2020 15:39:57 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Applicable

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Header Text: c4591001

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Form Status: Data Complete, Frozen, Verified

Site No: 1019

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Form	Sep-21-2020 15:40:08 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF -
Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1019

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Item	Date	User	Comment
1	Sep-21-2020 15:40:08 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

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Item	Date	User	Comment
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Header Text: c4591001

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Item	Date	User	Comment
1	Sep-21-2020 15:40:19 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

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Item	Date	User	Comment
4	Sep-21-2020 15:40:19 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HOSPITALIZATION DETAILS - Comments
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Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

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Item	Date	User	Comment
Form	Oct-07-2020 10:18:25 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [Redacted]	
Form	Sep-21-2020 15:41:08 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HOSPITALIZATION DETAILS - Comments
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Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

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Item	Date	User	Comment
1	Oct-07-2020 10:18:25 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
1	Sep-21-2020 15:41:08 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HOSPITALIZATION DETAILS - Comments
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Item	Date	User	Comment
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4	Sep-21-2020 15:41:08 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

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Site No: 1019

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Form	Sep-21-2020 15:41:17 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

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Site No: 1019

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Item	Date	User	Comment
1	Sep-21-2020 15:41:17 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Applicable

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Item	Date	User	Comment
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Item	Date	User	Comment
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - Comments
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Form Status: Data Complete, Frozen, Verified

Site No: 1019

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Item	Date	User	Comment
Form	Oct-24-2020 09:44:50 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
Form	Oct-22-2020 10:21:05 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
Form	Sep-21-2020 15:41:38 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Item	Date	User	Comment
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1	Oct-22-2020 10:21:05 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
1	Sep-21-2020 15:41:38 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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3	Oct-22-2020 10:21:05 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
3	Sep-21-2020 15:41:38 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments
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Form	Sep-21-2020 15:41:29 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments
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2	Sep-21-2020 15:41:29 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

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Form	Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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5.g	Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1019

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5.g	Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Form	Sep-21-2020 15:42:25 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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2.a	Sep-21-2020 15:42:25 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Form Status: Data Complete, Deleted

Site No: 1019

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Item	Date	User	Comment
2.a	Nov-11-2020 11:37:19 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	heart rate and respiratory rate not done

Header Text: c4591001

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Item	Date	User	Comment
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Form	Sep-21-2020 15:42:34 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Unknown

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Comments
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Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments
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Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1019

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Subject No: 10191010

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Item	Date	User	Comment
Form	Nov-11-2020 09:05:30 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	participant did not receive oxygen while hospitalized <hr/> Not Applicable
Form	Sep-21-2020 15:42:42 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Unknown

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments
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1	Sep-21-2020 15:42:42 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Unknown

Header Text: c4591001

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2	Nov-11-2020 09:05:30 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	participant did not receive oxygen while hospitalized Not Applicable
2	Sep-21-2020 15:42:42 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Unknown

Header Text: c4591001

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3	Nov-11-2020 09:05:30 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	participant did not receive oxygen while hospitalized Not Applicable
3	Sep-21-2020 15:42:42 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Unknown

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

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Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1019

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Item	Date	User	Comment
Form	Sep-21-2020 15:42:51 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
1	Sep-21-2020 15:42:51 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
2	Sep-21-2020 15:42:51 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Aug/17/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS -
Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
3	Sep-21-2020 15:42:51 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
4	Sep-21-2020 15:42:51 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
5	Sep-21-2020 15:42:51 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
6	Sep-21-2020 15:42:51 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments
on Aug/17/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
Form	Sep-21-2020 15:43:01 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments
on Aug/17/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
1	Sep-21-2020 15:43:01 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments
on Aug/17/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
2	Sep-21-2020 15:43:01 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments
on Aug/17/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
3	Sep-21-2020 15:43:01 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments
on Aug/17/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
4	Sep-21-2020 15:43:01 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Comments

Form Status: Data Complete, Locked, Frozen, Not Complete

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
Form	Oct-01-2020 09:54:18 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Please delete

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Comments

Form Status: Data Complete, Locked, Frozen, Not Complete

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
2	Sep-30-2020 07:20:35 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Comments

Form Status: Data Complete, Locked, Frozen, Not Complete

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
3	Oct-05-2020 14:20:25 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
3	Sep-30-2020 09:33:09 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	please delete <hr/> Not Applicable

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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This form requires signing by a member of each of the following signature groups:

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
(b) (6)	N/A	Mar-08-2021 07:41:29 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated

Affidavit:

N/A

(b) (6)	Approved	Feb-05-2021 18:45:15 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, (b) (6), verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

(b) (6)	N/A	Feb-02-2021 08:11:30 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Dec-03-2020 13:53:34 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, (b) (6), verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

(b) (6)	N/A	Dec-02-2020 13:51:22 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Nov-16-2020 13:57:24 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, (b) (6), verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

(b) (6)	N/A	Nov-13-2020 22:44:10 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Nov-13-2020 15:55:52 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, (b) (6), verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

(b) (6)	N/A	Nov-11-2020 08:13:58 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Oct-26-2020 12:58:20 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Affidavit:

By my dated signature below, I, (b) (6), verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

(b) (6)	N/A	Oct-24-2020 09:44:38 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Oct-22-2020 10:44:19 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, (b) (6), verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

(b) (6)	N/A	Oct-22-2020 10:21:05 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Oct-12-2020 12:12:38 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, (b) (6), verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

(b) (6)	N/A	Sep-17-2020 10:12:31 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Sep-15-2020 15:40:42 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, (b) (6), verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: COHORT_SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-11-2020 14:23:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: 24 JUL 2020	Initial Entry

2. Select appropriate response - What cohort does the subject belong to?

Date	Location	User	Value	Reason
Aug-11-2020 14:23:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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I. Consent Was:

Date	Location	User	Value	Reason
Aug-11-2020 14:23:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Aug/11/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Subject ID

Date	Location	User	Value	Reason
Sep-03-2020 06:02:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	event added in Inform
Sep-02-2020 07:33:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Entered
Sep-02-2020 07:16:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020339743 diarrhea(onset date:27Aug2020)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Aug-11-2020 14:23:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10191010	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-14-2020 05:23:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	DOB added in SDB. Issue resolved
Sep-11-2020 04:43:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Candidate	SAE RECON: TO check next SAE listing if DOB will be added
Sep-10-2020 08:38:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Follow Up form submitted on 10SEP20
Sep-03-2020 06:10:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020339743 ,the date of birth was missing in SAE form but

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

				was recorded as (b) (6) 1940 in AE CRF. Please confirm if date of birth was reported. If safety update is required, please submit a follow-up form.
Aug-11-2020 14:23:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) /1940	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-14-2020 05:24:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Gender added. issue resolved
Sep-11-2020 04:45:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Candidate	SAE RECON: TO check next SAE listing if gender will be added
Sep-10-2020 08:38:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Follow Up form submitted on 10SEP20
Sep-03-2020 06:11:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020339743 ,the GENDER was missing in SAE form but was recorded as FEMALE in AE CRF. Please confirm if date of birth was reported. If safety update is required, please submit a follow-up form.
Aug-11-2020 14:30:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-11-2020 14:30:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Aug-11-2020 14:30:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: WHITE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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I. Date of Visit

Date	Location	User	Value	Reason
Aug-11-2020 14:30:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/11/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

I.a

Date	Location	User	Value	Reason
Aug-11-2020 16:07:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Criterion Description:	Transcription Error
Aug-11-2020 16:07:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Crit erio n De scri ptio n: Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 a nd 85 years, inclusive, at ra ndomization (dependent up on study phase)	Initial Entry

I.a Description of Inclusion Criterion Not Met

Date	Location	User	Value	Reason
Aug-19-2020 06:05:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closed by DM: (b) (6)
Aug-18-2020 07:58:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	completed
Aug-17-2020 13:32:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM query: Thank you for your response, however there is no Form level comment. A form level comment is located across from the title. Please review and update appropriate.
Aug-13-2020 12:04:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Aug-13-2020 06:05:06	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	As per Protocol

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)		Amendment 5 (24Jul2020). INC EXC form is not applicable. Please add Form level comment as "Not Applicable"
Aug-11-2020 16:07:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Aug-11-2020 16:07:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study phase)	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-11-2020 14:31:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/11/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-11-2020 14:31:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-11-2020 14:31:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1019**Subject No:** 10191010**Generated By:** (b) (4)**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1019) Diagnostics Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)**I.a**

Date	Location	User	Value	Reason
Aug-11-2020 14:40:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: Medical History Cataracts - bilateral Term: Start Date: UNK/UNK/2016 Ongoing: NO End Date: UNK/UNK/ 2016	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 14:40:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

I.a Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 14:40:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Cataracts - bilateral	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 14:40:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: UNK/UNK/2016	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Aug-11-2020 14:40:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2016	Initial Entry
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I.b

Date	Location	User	Value	Reason
Aug-11-2020 14:41:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 2 : Medical History Term: Myopia - bilateral Start Date: UNK/UNK/1984 Ongoing: YES	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 14:41:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

1.b Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 14:41:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Myopia - bilateral	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 14:41:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1984	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 14:41:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.c

Date	Location	User	Value	Reason
Aug-11-2020 14:42:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3 Medical History Te Presbyopia rm: Start Date: UNK/UNK/1 984 Ongoing: YES	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

I.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 14:42:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

I.c Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 14:42:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Presbyopia	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 14:42:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1984	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 14:42:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Aug-11-2020 14:42:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4 Medical History Term: Tonsillitis Start Date: UNK/UNK/1961 Ongoing: NO End Date: UNK/UNK/1961	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

I.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 14:42:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

I.d Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 14:42:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Tonsillitis	Initial Entry

I.d Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 14:42:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1961	Initial Entry

I.d Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 14:42:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/1961	Initial Entry

I.e

Date	Location	User	Value	Reason
Aug-11-2020 14:43:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 5 Medical History Te nasal polyps rm: Start Date: May/UNK/20 18 Ongoing: YES	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

I.e Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 14:43:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

I.e Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 14:43:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: nasal polyps	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 14:43:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: May/UNK/2018	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 14:43:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.f

Date	Location	User	Value	Reason
Aug-11-2020 14:43:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 6 Medical History Term: Dry mouth Start Date: UNK/UNK/2012 Ongoing: YES	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1.f Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 14:43:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

1.f Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 14:43:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dry mouth	Initial Entry

1.f Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 14:43:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2012	Initial Entry

1.f Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 14:43:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.g

Date	Location	User	Value	Reason
Aug-11-2020 14:44:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 7 Medical History Term: Pneumonia Start Date: Mar/UNK/2009 Ongoing: NO End Date: Mar/UNK/2009	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

I.g Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 14:44:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

I.g Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 14:44:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Pneumonia	Initial Entry

I.g Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 14:44:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/UNK/2009	Initial Entry

I.g Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 14:44:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Mar/UNK/2009	Initial Entry

I.h

Date	Location	User	Value	Reason
Aug-11-2020 14:45:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N umber: 8 Medical His tory Term: Chronic Obstructive Pulmonary Disease Start Date: UNK/UNK/1984 Ongoing: YES	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1.h Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 14:45:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

1.h Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 14:45:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Chronic Obstructive Pulmonary Di sease	Initial Entry

1.h Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 14:45:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1984	Initial Entry

1.h Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 14:45:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.i

Date	Location	User	Value	Reason
Aug-11-2020 14:45:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 9 Medical History Te Sleep apnea rm: Start Date: UNK/UNK/1 989 Ongoing: YES	Initial Entry

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Header Text: c4591001

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Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1.i Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 14:45:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 9	Initial Entry

1.i Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 14:45:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sleep apnea	Initial Entry

1.i Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 14:45:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1989	Initial Entry

1.i Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 14:45:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.j

Date	Location	User	Value	Reason
Aug-11-2020 14:46:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 10 Medical History Te CPAP rm: Start Date: UNK/UNK/1 989 Ongoing: YES	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

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Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1.j Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 14:46:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10	Initial Entry

1.j Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 14:46:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: CPAP	Initial Entry

1.j Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 14:46:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: UNK/UNK/1989	Initial Entry

1.j Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 14:46:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: YES	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

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Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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<i>I.k</i>				
Date	Location	User	Value	Reason
Aug-11-2020 14:46:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 11 Medical History Te bronchitis rm: Start Date: Nov/12/2010 Ongoing: NO End Date: Nov/24/20 10	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1.k Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 14:46:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11	Initial Entry

1.k Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 14:46:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: bronchitis	Initial Entry

1.k Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 14:46:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/12/2010	Initial Entry

1.k Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 14:46:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Nov/24/2010	Initial Entry

1.l

Date	Location	User	Value	Reason
Aug-11-2020 14:47:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 12 Medical History T Hypertension erm: Start Date: UNK/UNK/2 004 Ongoing: YES	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1.1 Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 14:47:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12	Initial Entry

1.1 Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 14:47:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hypertension	Initial Entry

1.1 Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 14:47:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2004	Initial Entry

1.1 Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 14:47:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.m

Date	Location	User	Value	Reason
Aug-11-2020 14:47:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 13 Medical History Term: Hypercholesterolemia Start Date: UNK/UNK/1994 Ongoing: YES	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1019

Subject No: 10191010

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Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1.m Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 14:47:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 13	Initial Entry

1.m Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 14:47:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hypercholesterolemia	Initial Entry

1.m Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 14:47:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1994	Initial Entry

1.m Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 14:47:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.n

Date	Location	User	Value	Reason
Aug-11-2020 14:48:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 14 Medical History T Heart murmur erm: Start Date: UNK/UNK/2 004 Ongoing: YES	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

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Subject No: 10191010

Generated By: (b) (4)

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Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1.n Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 14:48:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 14	Initial Entry

1.n Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 14:48:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Heart murmur	Initial Entry

1.n Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 14:48:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2004	Initial Entry

1.n Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 14:48:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.o

Date	Location	User	Value	Reason
Aug-11-2020 14:48:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 15 ber: Medical Histor Peripheral Vascul y Term: ar Disease Start Date: May/UNK/2018 Ongoing: YES	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

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Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1.o Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 14:48:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 15	Initial Entry

1.o Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-17-2020 20:48:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Aug-14-2020 07:56:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	answer is unknown
Aug-13-2020 18:41:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Please specify whether the peripheral vascular disease is arterial or venous and update the reported term accordingly.
Aug-11-2020 14:48:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Peripheral Vascular Disease	Initial Entry

1.o Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 14:48:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: May/UNK/2018	Initial Entry

1.o Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 14:48:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.p

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Header Text: c4591001

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Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

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Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

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Date	Location	User	Value	Reason
Aug-11-2020 14:49:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 16 Medical History Term: External hemorrhoids Start Date: UNK/UNK/2010 Ongoing: YES	Initial Entry

1.p Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 14:49:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 16	Initial Entry

1.p Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 14:49:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: External hemorrhoids	Initial Entry

1.p Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 14:49:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2010	Initial Entry

1.p Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 14:49:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.q

Date	Location	User	Value	Reason
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Header Text: c4591001

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Subject No: 10191010

Generated By: (b) (4)

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Aug-11-2020 14:49:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Numbe 17 r: Medical History Anal fistula Term: Start Date: UNK/UNK/198 1 Ongoing: NO End Date: UNK/UNK/ 1981	Initial Entry
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1.q Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 14:49:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 17	Initial Entry

1.q Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 14:49:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Anal fistula	Initial Entry

1.q Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 14:49:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1981	Initial Entry

1.q Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 14:49:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/1981	Initial Entry

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Header Text: c4591001

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Subject No: 10191010

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<i>I.r</i>				
Date	Location	User	Value	Reason
Aug-11-2020 14:50:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 18 Medical History Term: Obesity Start Date: UNK/UNK/1985 Ongoing: YES	Initial Entry

<i>I.r Line/MH Number:</i>				
Date	Location	User	Value	Reason
Aug-11-2020 14:50:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 18	Initial Entry

<i>I.r Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:</i>				
Date	Location	User	Value	Reason
Aug-11-2020 14:50:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Obesity	Initial Entry

<i>I.r Start Date:</i>				
Date	Location	User	Value	Reason
Aug-11-2020 14:50:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1985	Initial Entry

<i>I.r Ongoing:</i>				
Date	Location	User	Value	Reason
Aug-11-2020 14:50:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

<i>I.s</i>				
Date	Location	User	Value	Reason

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Subject No: 10191010

Generated By: (b) (4)

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Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Aug-11-2020 14:50:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Numbe 19 r: Medical History Urinary inconti Term: nence Start Date: UNK/UNK/200 2 Ongoing: YES	Initial Entry
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1.s Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 14:50:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 19	Initial Entry

1.s Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 14:50:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Urinary incontinence	Initial Entry

1.s Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 14:50:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2002	Initial Entry

1.s Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 14:50:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.t

Date	Location	User	Value	Reason
Aug-11-2020 14:51:13 (UTC-06:00) Central	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 20	Initial Entry

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Time (US & Canada)			mber:	
			Medical History Term:	Chronic kidney disease stage III
			Start Date:	Apr/25/2018
			Ongoing:	YES

Header Text: c4591001

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Subject No: 10191010

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1.t Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 14:51:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 20	Initial Entry

1.t Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 14:51:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Chronic kidney disease stage III	Initial Entry

1.t Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 14:51:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Apr/25/2018	Initial Entry

1.t Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 14:51:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.u

Date	Location	User	Value	Reason
Aug-11-2020 14:52:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 21 Medical History Term: Endometriosis Start Date: UNK/UNK/1960	Initial Entry

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Subject No: 10191010

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Subject Initials: ---

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			Ongoing:	NO End Date: UNK/UNK/ 1980
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I.u Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 14:52:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 21	Initial Entry

I.u Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 14:52:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Endometriosis	Initial Entry

I.u Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 14:52:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: UNK/UNK/1960	Initial Entry

I.u Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 14:52:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: NO End Date: UNK/UNK/1980	Initial Entry

I.v

Date	Location	User	Value	Reason
Aug-11-2020 14:53:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Numb 22 er:	Initial Entry

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			Medical History Term: Uterine lesion - benign Start Date: UNK/UNK/2005 Ongoing: NO End Date: UNK/UNK/2006	
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I.v Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 14:53:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 22	Initial Entry

I.v Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 14:53:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Uterine lesion - benign	Initial Entry

I.v Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 14:53:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2005	Initial Entry

I.v Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 14:53:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2006	Initial Entry

I.w

Date	Location	User	Value	Reason
Aug-11-2020 14:53:44	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

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(UTC-06:00) Central Time (US & Canada)		(autocalc)	Line/MH Number: 23 Medical History Term: Insomnia Start Date: UNK/UNK/2014 Ongoing: YES
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I.w Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 14:53:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 23	Initial Entry

I.w Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 14:53:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Insomnia	Initial Entry

I.w Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 14:53:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2014	Initial Entry

I.w Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 14:53:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.x

Date	Location	User	Value	Reason
Aug-11-2020 14:54:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 24 : Medical History Term: Tension headaches	Initial Entry

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Header Text: c4591001

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Subject No: 10191010

Generated By: (b) (4)

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			Start Date:	UNK/UNK/1993
			Ongoing:	YES

I.x Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 14:54:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 24	Initial Entry

I.x Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 14:54:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Tension headaches	Initial Entry

I.x Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 14:54:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1993	Initial Entry

I.x Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 14:54:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.y

Date	Location	User	Value	Reason
Aug-11-2020 14:55:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 25 mber: Medical Hist Carpal tunnel syndr ory Term: ome, bilateral Start Date: UNK/UNK/1996	Initial Entry

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			Ongoing: NO	
			End Date:	
			UNK/UNK/1996	

I.y Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 14:55:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 25	Initial Entry

I.y Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 14:55:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Carpal tunnel syndrome, bilateral	Initial Entry

I.y Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 14:55:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1996	Initial Entry

I.y Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 14:55:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/1996	Initial Entry

I.z

Date	Location	User	Value	Reason
Aug-11-2020 14:56:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 26 Medical History Term: Familial tremors	Initial Entry

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Header Text: c4591001

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Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

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			Start Date:	UNK/UNK/1974	
			Ongoing:	YES	

1.z Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 14:56:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 26	Initial Entry

1.z Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 14:56:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Familial tremors	Initial Entry

1.z Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 14:56:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1974	Initial Entry

1.z Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 14:56:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.aa

Date	Location	User	Value	Reason
Aug-11-2020 14:57:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Number: 27 Medical History Term: Diabetic neuropathy bilateral hands Start Date: UNK/UNK/2000 Ongoing: YES	Transcription Error

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Subject No: 10191010

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Aug-11-2020 14:56:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 27 Medical History Term: Diabetic neuropathy Start Date: UNK/UNK/2000 Ongoing: YES	Initial Entry
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1.aa Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 14:56:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 27	Initial Entry

1.aa Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 14:57:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Diabetic neuropathy bilateral hands	Transcription Error
Aug-11-2020 14:56:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Diabetic neuropathy	Initial Entry

1.aa Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 14:56:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2000	Initial Entry

1.aa Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 14:56:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.ab

Date	Location	User	Value	Reason
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Aug-11-2020 14:57:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N umber: Medical History Term Diabetic neuropathy, bilateral lower extremities Start Date: UNK/UNK/2000 Ongoing: YES	Initial Entry
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1.ab Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 14:57:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 28	Initial Entry

1.ab Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 14:57:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Diabetic neuropathy, bilateral lower extremities	Initial Entry

1.ab Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 14:57:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2000	Initial Entry

1.ab Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 14:57:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.ac

Date	Location	User	Value	Reason
Aug-11-2020 14:59:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N umber: 29	Initial Entry

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Subject No: 10191010

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			Medical History Term: Osteoarthritis, bilateral hands and knees Start Date: UNK/UNK/1997 Ongoing: YES	
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I.ac Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 14:59:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 29	Initial Entry

I.ac Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 14:59:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Osteoarthritis, bilateral hands and knees	Initial Entry

I.ac Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 14:59:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1997	Initial Entry

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1.ac Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 14:59:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.ad

Date	Location	User	Value	Reason
Aug-11-2020 14:59:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 30 Medical History Te Gout rm: Start Date: UNK/UNK/1 998 Ongoing: YES	Initial Entry

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Subject Initials: ---

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I.ad Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 14:59:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30	Initial Entry

I.ad Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-17-2020 12:16:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Aug-17-2020 08:00:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	does not receive systemic corticosteroids
Aug-16-2020 06:23:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	GPDCLIN: please confirm patient do not receive systemic corticosteroids (i.e. Exclusion # 13 not met). thank you
Aug-13-2020 14:32:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Aug-12-2020 10:51:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	GPDCLIN:Please can you confirm that subject does not meet exclusion criterion #13 as a result of gout. Thanks
Aug-11-2020 14:59:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Gout	Initial Entry

I.ad Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 14:59:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1998	Initial Entry

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I.ad Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 14:59:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.ae

Date	Location	User	Value	Reason
Aug-11-2020 15:00:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 31 Medical History Te Osteopenia rm: Start Date: UNK/UNK/2 012 Ongoing: YES	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

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Subject No: 10191010

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Subject Initials: ---

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1.ae Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 15:00:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 31	Initial Entry

1.ae Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 15:00:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Osteopenia	Initial Entry

1.ae Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 15:00:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2012	Initial Entry

1.ae Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 15:00:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.af

Date	Location	User	Value	Reason
Aug-11-2020 15:00:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 32 Medical History Te Osteoporosis rm: Start Date: UNK/UNK/2 016 Ongoing: YES	Initial Entry

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Subject No: 10191010

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1.af Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 15:00:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 32	Initial Entry

1.af Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 15:00:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Osteoporosis	Initial Entry

1.af Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 15:00:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: UNK/UNK/2016	Initial Entry

1.af Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 15:00:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: YES	Initial Entry

1.ag

Date	Location	User	Value	Reason
Aug-11-2020 15:01:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 33 Medical History Te Fibromyalgia rm: Start Date: Apr/UNK/20 14 Ongoing: YES	Initial Entry

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Header Text: c4591001

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Subject No: 10191010

Generated By: (b) (4)

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Subject Initials: ---

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I.ag Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 15:01:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 33	Initial Entry

I.ag Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 15:01:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Fibromyalgia	Initial Entry

I.ag Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 15:01:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Apr/UNK/2014	Initial Entry

I.ag Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 15:01:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.ah

Date	Location	User	Value	Reason
Aug-11-2020 15:22:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Numbr: 34 Medical History Term: Fracture L. 5th toe Start Date: UNK/UNK/2003 Ongoing: NO End Date: UNK/UNK/2003	Transcription Error

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Header Text: c4591001

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Subject No: 10191010

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Aug-11-2020 15:22:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 34 Medical History Term: Fracture L. 5th tow Start Date: UNK/UNK/20 03 Ongoing: NO End Date: UNK/UNK/ 2003	Initial Entry
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Header Text: c4591001

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Subject No: 10191010

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I.ah Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 15:22:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 34	Initial Entry

I.ah Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 15:22:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Fracture L. 5th toe	Transcription Error
Aug-11-2020 15:22:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Fracture L. 5th tow	Initial Entry

I.ah Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 15:22:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2003	Initial Entry

I.ah Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 15:22:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2003	Initial Entry

I.ai

Date	Location	User	Value	Reason
Aug-11-2020 15:30:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 35 Medical History Term: Fracture, right foot Start Date: UNK/UNK/2010	Initial Entry

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			Ongoing:	NO End Date: UNK/UNK/ 2010
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1.ai Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 15:30:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 35	Initial Entry

1.ai Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 15:30:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Fracture, right foot	Initial Entry

1.ai Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 15:30:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: UNK/UNK/2010	Initial Entry

1.ai Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 15:30:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: NO End Date: UNK/UNK/2010	Initial Entry

1.aj

Date	Location	User	Value	Reason
Aug-11-2020 15:31:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 36	Initial Entry

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Subject No: 10191010

Generated By: (b) (4)

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Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

			Medical History Term: Bilateral leg cramps Start Date: Apr/UNK/2018 Ongoing: YES	
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I.aj Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 15:31:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 36	Initial Entry

I.aj Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 15:31:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Bilateral leg cramps	Initial Entry

I.aj Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 15:31:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Apr/UNK/2018	Initial Entry

I.aj Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 15:31:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.ak

Date	Location	User	Value	Reason
Aug-11-2020 15:32:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/M 37 H Number: Medical History Term: Recurrent joint pain, neck, shoulders, ankles, elbows, hips, knees, wrists	Initial Entry

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			Start Date: UNK/UNK/1980	
			Ongoing: YES	

1.ak Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 15:32:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 37	Initial Entry

1.ak Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 15:32:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Recurrent joint pain, neck, shoulders, ankles, elbows, hips, knees, wrists	Initial Entry

1.ak Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 15:32:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1980	Initial Entry

1.ak Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 15:32:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.al

Date	Location	User	Value	Reason
Aug-11-2020 15:33:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 38 Medical History Term: Recurrent back pain - lumbar Start Date: UNK/UNK/2004	Initial Entry

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Header Text: c4591001

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Subject No: 10191010

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			Ongoing:	YES	
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Header Text: c4591001

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Subject No: 10191010

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1.al Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 15:33:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 38	Initial Entry

1.al Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 15:33:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Recurrent back pain - lumbar	Initial Entry

1.al Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 15:33:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2004	Initial Entry

1.al Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 15:33:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.am

Date	Location	User	Value	Reason
Aug-11-2020 15:33:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 39 Medical History Term: Fracture, right shoulder Start Date: Jul/UNK/2010 Ongoing: NO End Date: Jul/UNK/2010	Initial Entry

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Header Text: c4591001

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Subject No: 10191010

Generated By: (b) (4)

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I.am Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 15:33:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 39	Initial Entry

I.am Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 15:33:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Fracture, right shoulder	Initial Entry

I.am Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 15:33:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jul/UNK/2010	Initial Entry

I.am Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 15:33:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Jul/UNK/2010	Initial Entry

I.an

Date	Location	User	Value	Reason
Aug-14-2020 07:43:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH N 40 umber: Medical His Shoulder implant, r tory Term: ight - insertion Start Date: UNK/UNK/2013	New Information

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Header Text: c4591001

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Subject No: 10191010

Generated By: (b) (4)

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Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

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			Ongoing: NO End Date: UNK/UNK/2013	
Aug-11-2020 15:34:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (auto calc)	Data Entry: Line/MH Number: 40 Medical History Term: Shoulder implant, right Start Date: UNK/UNK/2013 Ongoing: NO End Date: UNK/UNK/2013	Initial Entry

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Header Text: c4591001

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Subject No: 10191010

Generated By: (b) (4)

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Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

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1.an Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 15:34:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 40	Initial Entry

1.an Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-14-2020 08:45:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Aug-14-2020 07:43:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Aug-14-2020 07:43:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Shoulder implant, right - insertion	New Information
Aug-12-2020 04:13:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Clarify SHOULDER IMPLANT, RIGHT as follows...Device only term. Are you reporting INSERTION? REMOVAL? INFECTION OF? Other? If so, update the verbatim term as such. Otherwise clarify and edit the term. Thank you.
Aug-11-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

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Subject No: 10191010

Generated By: (b) (4)

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15:34:38 (UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	Shoulder implant, right	
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I.an Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 15:34:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2013	Initial Entry

I.an Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 15:34:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2013	Initial Entry

I.ao

Date	Location	User	Value	Reason
Aug-11-2020 15:35:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 41 Medical History Term: Shoulder implant removal, right Start Date: Apr/UNK/2014 Ongoing: NO End Date: Apr/UNK/2014	Initial Entry

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Subject Initials: ---

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I.ao Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 15:35:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 41	Initial Entry

I.ao Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 15:35:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Shoulder implant removal, right	Initial Entry

I.ao Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 15:35:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Apr/UNK/2014	Initial Entry

I.ao Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 15:35:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Apr/UNK/2014	Initial Entry

I.ap

Date	Location	User	Value	Reason
Aug-11-2020 15:36:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 42 Medical History Term: Shoulder implant infection, right Start Date: UNK/UNK/2014 Ongoing: NO End Date: UNK/UNK/2014	Initial Entry

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Subject No: 10191010

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1.ap Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 15:36:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 42	Initial Entry

1.ap Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 15:36:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Shoulder implant infection, right	Initial Entry

1.ap Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 15:36:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2014	Initial Entry

1.ap Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 15:36:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2014	Initial Entry

1.aq

Date	Location	User	Value	Reason
Aug-11-2020 15:37:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 43 r: Medical History: Tendonitis, left wrist Term: Start Date: Jan/UNK/2006	Initial Entry

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			Ongoing:	NO End Date: Jan/UNK/2006
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1.aq Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 15:37:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 43	Initial Entry

1.aq Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 15:37:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Tendonitis, left wrist	Initial Entry

1.aq Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 15:37:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/UNK/2006	Initial Entry

1.aq Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 15:37:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Jan/UNK/2006	Initial Entry

1.ar

Date	Location	User	Value	Reason
Aug-11-2020 15:37:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 44	Initial Entry

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Subject No: 10191010

Generated By: (b) (4)

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			Medical History Term: cyst, right ankle, benign Start Date: UNK/UNK/2009 Ongoing: NO End Date: Jul/UNK/2010	
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I.ar Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 15:37:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 44	Initial Entry

I.ar Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 15:37:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: cyst, right ankle, benign	Initial Entry

I.ar Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 15:37:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2009	Initial Entry

I.ar Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 15:37:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Jul/UNK/2010	Initial Entry

I.as

Date	Location	User	Value	Reason
Aug-11-2020 15:38:25 (UTC-06:00) Central	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Numbe 45	Initial Entry

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Generated Time (GMT): 29-Mar-2021 04:44

Time (US & Canada)			r: Medical History Term: Tennis elbow Start Date: UNK/UNK/1998 Ongoing: NO End Date: UNK/UNK/1999
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I.as Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 15:38:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 45	Initial Entry

I.as Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 15:38:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Tennis elbow	Initial Entry

I.as Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 15:38:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1998	Initial Entry

I.as Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 15:38:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/1999	Initial Entry

I.at

Date	Location	User	Value	Reason
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Aug-11-2020 15:39:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 46 ber: Medical Histor Stress fracture, rig y Term: ht ankle Start Date: Aug/UNK/2010 Ongoing: NO End Date: Oct/5/2010	Initial Entry
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I.at Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 15:39:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 46	Initial Entry

I.at Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 15:39:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Stress fracture, right ankle	Initial Entry

I.at Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 15:39:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/UNK/2010	Initial Entry

I.at Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 15:39:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Oct/5/2010	Initial Entry

I.au

Date	Location	User	Value	Reason
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Subject No: 10191010

Generated By: (b) (4)

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Aug-11-2020 15:39:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 47 Medical History Te Depression rm: Start Date: UNK/UNK/2 001 Ongoing: YES	Initial Entry
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Header Text: c4591001

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Subject No: 10191010

Generated By: (b) (4)

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I.au Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 15:39:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 47	Initial Entry

I.au Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 15:39:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Depression	Initial Entry

I.au Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 15:39:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2001	Initial Entry

I.au Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 15:39:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.av

Date	Location	User	Value	Reason
Aug-11-2020 15:40:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 48 Medical History Te Anxiety rm: Start Date: UNK/UNK/2 001 Ongoing: YES	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

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1.av Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 15:40:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 48	Initial Entry

1.av Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 15:40:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Anxiety	Initial Entry

1.av Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 15:40:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: UNK/UNK/2001	Initial Entry

1.av Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 15:40:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: YES	Initial Entry

1.av

Date	Location	User	Value	Reason
Aug-11-2020 15:40:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Numb 49 er: Medical History Diabetes mellitu Term: s type 2 Start Date: UNK/UNK/2002 Ongoing: YES	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

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Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

I.aw Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 15:40:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 49	Initial Entry

I.aw Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 15:40:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Diabetes mellitus type 2	Initial Entry

I.aw Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 15:40:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2002	Initial Entry

I.aw Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 15:40:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.ax

Date	Location	User	Value	Reason
Aug-11-2020 15:41:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 50 Medical History Term: Hypothyroidism Start Date: UNK/UNK/2004 Ongoing: YES	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

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Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

I.ax Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 15:41:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 50	Initial Entry

I.ax Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 15:41:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hypothyroidism	Initial Entry

I.ax Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 15:41:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2004	Initial Entry

I.ax Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 15:41:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.ay

Date	Location	User	Value	Reason
Aug-11-2020 15:42:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Numb 51 er: Medical History Iron deficiency a Term: nemia Start Date: Sep/UNK/2010 Ongoing: NO End Date: Jul/31/2020	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1.ay Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 15:42:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 51	Initial Entry

1.ay Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 15:42:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Iron deficiency anemia	Initial Entry

1.ay Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 15:42:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/UNK/2010	Initial Entry

1.ay Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 15:42:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Jul/31/2020	Initial Entry

1.az

Date	Location	User	Value	Reason
Aug-11-2020 15:42:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 52 Medical History Te Psoriasis rm: Start Date: UNK/UNK/2 002 Ongoing: YES	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

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Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191010

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Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1.az Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 15:42:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 52	Initial Entry

1.az Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-17-2020 12:15:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Aug-17-2020 08:00:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	does not receive systemic therapy and has been stable
Aug-16-2020 06:21:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	GPDCLIN: Please confirm disease is stable (inclusion criterion #3 is met) and that exclusion criterion #13 (systemic therapy) is not MET. thank you
Aug-13-2020 14:32:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Aug-12-2020 10:52:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	GPDCLIN: Please can you confirm that subject does not meet exclusion criterion #13 as a result of psoriasis. Thanks
Aug-11-2020 15:42:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Psoriasis	Initial Entry

1.az Start Date:

Date	Location	User	Value	Reason
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Aug-11-2020 15:42:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2002	Initial Entry
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1.az Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 15:42:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.ba

Date	Location	User	Value	Reason
Aug-11-2020 15:43:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 53 Medical History Term: Rosacea Start Date: Nov/26/2001 Ongoing: YES	Initial Entry

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Header Text: c4591001

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Site No: 1019

Subject No: 10191010

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Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1.ba Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 15:43:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 53	Initial Entry

1.ba Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 15:43:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Rosacea	Initial Entry

1.ba Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 15:43:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/26/2001	Initial Entry

1.ba Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 15:43:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.bb

Date	Location	User	Value	Reason
Aug-11-2020 15:44:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Numbe 54 r: Medical History Left rotator cuff Term: tear Start Date: Jan/UNK/2018 Ongoing: NO End Date: Mar/1/2018	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

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Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1.bb Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 15:44:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 54	Initial Entry

1.bb Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 15:44:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Left rotator cuff tear	Initial Entry

1.bb Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 15:44:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/UNK/2018	Initial Entry

1.bb Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 15:44:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Mar/1/2018	Initial Entry

1.bc

Date	Location	User	Value	Reason
Aug-11-2020 15:44:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 55 ber: Medical Histor Left fourth trigge y Term: r finger Start Date: UNK/UNK/1999	Initial Entry

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			Ongoing: NO End Date: UNK/UNK/1999	
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1.bc Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 15:44:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 55	Initial Entry

1.bc Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 15:44:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Left fourth trigger finger	Initial Entry

1.bc Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 15:44:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1999	Initial Entry

1.bc Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 15:44:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/1999	Initial Entry

1.bd

Date	Location	User	Value	Reason
Aug-11-2020 15:45:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 56 Medical History Te rm: Allergic rhinitis	Initial Entry

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Header Text: c4591001

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Subject No: 10191010

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			Start Date:	UNK/UNK/1 972	
			Ongoing:	YES	

Header Text: c4591001

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Site No: 1019

Subject No: 10191010

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1.bd Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 15:45:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 56	Initial Entry

1.bd Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 15:45:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Allergic rhinitis	Initial Entry

1.bd Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 15:45:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1972	Initial Entry

1.bd Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 15:45:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.be

Date	Location	User	Value	Reason
Aug-11-2020 15:49:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 57 Medical History: Drug allergy - penicillin Term: nicillin Start Date: UNK/UNK/1950 Ongoing: YES	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

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Subject No: 10191010

Generated By: (b) (4)

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Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1.be Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 15:49:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 57	Initial Entry

1.be Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 15:49:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Drug allergy - penicillin	Initial Entry

1.be Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 15:49:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: UNK/UNK/1950	Initial Entry

1.be Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 15:49:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: YES	Initial Entry

1.bf

Date	Location	User	Value	Reason
Aug-11-2020 15:49:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 58 ber: Medical Histor Drug allergy - ma y Term: crodantin Start Date: UNK/UNK/1950 Ongoing: YES	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

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Subject No: 10191010

Generated By: (b) (4)

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Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1.bf Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 15:49:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 58	Initial Entry

1.bf Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 15:49:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Drug allergy - macrodantin	Initial Entry

1.bf Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 15:49:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1950	Initial Entry

1.bf Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 15:49:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.bg

Date	Location	User	Value	Reason
Aug-11-2020 15:50:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 59 r: Medical History Term: Tonsillectomy Start Date: UNK/UNK/1961 Ongoing: NO End Date: UNK/UNK/1961	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

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Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

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1.bg Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 15:50:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 59	Initial Entry

1.bg Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 15:50:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Tonsillectomy	Initial Entry

1.bg Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 15:50:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1961	Initial Entry

1.bg Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 15:50:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/1961	Initial Entry

1.bh

Date	Location	User	Value	Reason
Aug-13-2020 12:08:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Number: 60 Medical History Anal fistulectomy Term: my Start Date: UNK/UNK/1981	Transcription Error

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

			Ongoing: NO End Date: UNK/UNK/ 1981	
Aug-11-2020 15:50:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 60 Medical History Term: Anal fistulaectomy Start Date: UNK/UNK/1981 Ongoing: NO End Date: UNK/UNK/ 1981	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1.bh Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 15:50:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 60	Initial Entry

1.bh Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-14-2020 12:09:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Aug-13-2020 12:08:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Aug-13-2020 12:08:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Anal fistulectomy	Transcription Error
Aug-12-2020 01:06:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Clarify ANAL FISTULAECTOMY as follows...Should the spelling be ANAL FISTULECTOMY? If so, edit. Otherwise clarify. Thank you.
Aug-11-2020 15:50:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Anal fistulaectomy	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1.bh Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 15:50:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1981	Initial Entry

1.bh Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 15:50:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/1981	Initial Entry

1.bi

Date	Location	User	Value	Reason
Aug-11-2020 15:52:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Numb 61 er: Medical History Arthroscopy left Term: knee Start Date: UNK/UNK/198 0 Ongoing: NO End Date: UNK/UNK/1 980	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1.bi Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 15:52:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 61	Initial Entry

1.bi Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 15:52:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Arthroscopy left knee	Initial Entry

1.bi Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 15:52:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1980	Initial Entry

1.bi Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 15:52:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/1980	Initial Entry

1.bj

Date	Location	User	Value	Reason
Aug-11-2020 15:52:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 62 r: Medical History Term: Cholecystectomy Start Date: UNK/UNK/1994	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

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Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

			Ongoing:	NO End Date: UNK/UNK/ 1994
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1.bj Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 15:52:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 62	Initial Entry

1.bj Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 15:52:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Cholecystectomy	Initial Entry

1.bj Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 15:52:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: UNK/UNK/1994	Initial Entry

1.bj Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 15:52:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO End Date: UNK/UNK/1994	Initial Entry

1.bk

Date	Location	User	Value	Reason
Aug-11-2020 15:53:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N umber: 63	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

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Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

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Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

			Medical History Term: Carpal tunnel release surgery, bilateral Start Date: UNK/UNK/1996 Ongoing: NO End Date: UNK/UNK/1996	
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1.bk Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 15:53:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 63	Initial Entry

1.bk Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 15:53:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Carpal tunnel release surgery, bilateral	Initial Entry

1.bk Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 15:53:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1996	Initial Entry

1.bk Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 15:53:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/1996	Initial Entry

1.bl

Date	Location	User	Value	Reason
Aug-11-2020 15:54:39 (UTC-06:00) Central	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 64	Initial Entry

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Header Text: c4591001

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Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Time (US & Canada)			umber: Medical His tory Term: Start Date: Ongoing: End Date: UNK/UNK/1999	
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1.bl Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 15:54:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 64	Initial Entry

1.bl Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 15:54:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Trigger release surgery, left fourth finger	Initial Entry

1.bl Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 15:54:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1999	Initial Entry

1.bl Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 15:54:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/1999	Initial Entry

1.bm

Date	Location	User	Value	Reason
Aug-11-2020 15:55:59	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-06:00) Central
Time (US & Canada)

(autocalc)

Line/MH Number: 65

Medical History Term: Excision, uterine lesion

Start Date: UNK/UNK/2006

Ongoing: NO
End Date:

UNK/UNK/2006

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1.bm Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 15:55:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 65	Initial Entry

1.bm Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 15:55:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Excision, uterine lesion	Initial Entry

1.bm Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 15:55:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2006	Initial Entry

1.bm Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 15:55:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2006	Initial Entry

1.bn

Date	Location	User	Value	Reason
Aug-11-2020 15:56:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 66 Medical History Term: Left wrist tendonitis repair Start Date: Jan/UNK/2006	Initial Entry

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Header Text: c4591001

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Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

			Ongoing: NO End Date: Jan/UNK/2006
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1.bn Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 15:56:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 66	Initial Entry

1.bn Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 15:56:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Left wrist tendonitis repair	Initial Entry

1.bn Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 15:56:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Jan/UNK/2006	Initial Entry

1.bn Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 15:56:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: NO End Date: Jan/UNK/2006	Initial Entry

1.bo

Date	Location	User	Value	Reason
Aug-11-2020 15:57:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 67 Medical History Term: Left knee arthroplasty	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

			Start Date: UNK/UNK/2007 Ongoing: NO End Date: UNK/UNK/2007	
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1.bo Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 15:57:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 67	Initial Entry

1.bo Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 15:57:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Left knee arthroplasty	Initial Entry

1.bo Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 15:57:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2007	Initial Entry

1.bo Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 15:57:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2007	Initial Entry

1.bp

Date	Location	User	Value	Reason
Aug-11-2020 15:58:13 (UTC-06:00) Central	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 68	Initial Entry

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Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

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Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Time (US & Canada)			ber: Medical Histor y Term: Cyst excision, rig ht ankle Start Date: Jul/UNK/2010 Ongoing: NO End Date: Jul/UNK/2010
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1.bp Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 15:58:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 68	Initial Entry

1.bp Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 15:58:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Cyst excision, right ankle	Initial Entry

1.bp Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 15:58:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jul/UNK/2010	Initial Entry

1.bp Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 15:58:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Jul/UNK/2010	Initial Entry

1.bq

Date	Location	User	Value	Reason
Aug-11-2020 16:00:08	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Generated By: (b) (4)

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Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-06:00) Central Time (US & Canada)		(autocalc)	Line/MH Number: 69 Medical History Term: Left rotator cuff repair surgery Start Date: Mar/1/2018 Ongoing: NO End Date: Mar/1/2018
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1.bq Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 16:00:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 69	Initial Entry

1.bq Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 16:00:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Left rotator cuff repair surgery	Initial Entry

1.bq Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 16:00:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/1/2018	Initial Entry

1.bq Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 16:00:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Mar/1/2018	Initial Entry

1.br

Date	Location	User	Value	Reason
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090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Aug-11-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 70 Medical History Te Chest Pain rm: Start Date: UNK/UNK/2 018 Ongoing: YES	Initial Entry
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1.br Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 70	Initial Entry

1.br Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Chest Pain	Initial Entry

1.br Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2018	Initial Entry

1.br Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.bs

Date	Location	User	Value	Reason
Aug-11-2020 16:00:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 71 Medical History Te atrial fibrillati rm: on	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

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Subject No: 10191010

Generated By: (b) (4)

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Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

			Start Date:	Nov/1/2017	
			Ongoing:	YES	

I.bs Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 16:00:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 71	Initial Entry

I.bs Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 16:00:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: atrial fibrillation	Initial Entry

I.bs Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 16:00:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/1/2017	Initial Entry

I.bs Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 16:00:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.bt

Date	Location	User	Value	Reason
Aug-11-2020 16:01:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 72 ber: Medical Histor implantable loop y Term: recorder Start Date: Nov/1/2017 Ongoing: YES	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1.bt Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 16:01:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 72	Initial Entry

1.bt Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 16:01:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: implantable loop recorder	Initial Entry

1.bt Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 16:01:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/1/2017	Initial Entry

1.bt Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 16:01:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.bu

Date	Location	User	Value	Reason
Aug-11-2020 16:02:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Numbr: 73 Medical History Term: mitral valve regurgitation Start Date: UNK/UNK/2005 Ongoing: YES	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1.bu Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 16:02:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 73	Initial Entry

1.bu Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 16:02:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: mitral valve regurgitation	Initial Entry

1.bu Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 16:02:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2005	Initial Entry

1.bu Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 16:02:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.bv

Date	Location	User	Value	Reason
Aug-11-2020 16:02:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 74 mber: Medical History Term: edema- bilateral lower extremities Start Date: Apr/25/2018 Ongoing: YES	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1.bv Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 16:02:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 74	Initial Entry

1.bv Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 16:02:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: edema- bilateral lower extremities	Initial Entry

1.bv Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 16:02:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Apr/25/2018	Initial Entry

1.bv Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 16:02:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.bw

Date	Location	User	Value	Reason
Aug-11-2020 16:03:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 75 r: Medical History Term: cholelithiasis Start Date: UNK/UNK/1994 Ongoing: NO End Date: UNK/UNK/1994	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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I.bw Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 16:03:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 75	Initial Entry

I.bw Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 16:03:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: cholelithiasis	Initial Entry

I.bw Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 16:03:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1994	Initial Entry

I.bw Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 16:03:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/1994	Initial Entry

I.bx

Date	Location	User	Value	Reason
Aug-11-2020 16:03:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 76 Medical History Te heartburn rm: Start Date: UNK/UNK/1 990 Ongoing: YES	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1.bx Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 16:03:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 76	Initial Entry

1.bx Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 16:03:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: heartburn	Initial Entry

1.bx Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 16:03:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1990	Initial Entry

1.bx Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 16:03:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.by

Date	Location	User	Value	Reason
Aug-11-2020 16:04:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 77 r: Medical History Term: duodenal ulcer Start Date: UNK/UNK/1990 Ongoing: NO End Date: UNK/UNK/ 2000	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1.by Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 16:04:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 77	Initial Entry

1.by Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 16:04:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: duodenal ulcer	Initial Entry

1.by Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 16:04:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1990	Initial Entry

1.by Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 16:04:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2000	Initial Entry

1.bz

Date	Location	User	Value	Reason
Aug-11-2020 16:04:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Numbe 78 r: Medical History esophageal ulce Term: r Start Date: UNK/UNK/199 0	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

			Ongoing:	NO End Date: UNK/UNK/ 2000
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1.bz Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 16:04:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 78	Initial Entry

1.bz Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 16:04:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: esophageal ulcer	Initial Entry

1.bz Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 16:04:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1990	Initial Entry

1.bz Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 16:04:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2000	Initial Entry

1.ca

Date	Location	User	Value	Reason
Aug-11-2020 16:05:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 79	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

			Medical History Term: chronic constipation Start Date: Apr/UNK/2010 Ongoing: YES	
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I.ca Line/MH Number:

Date	Location	User	Value	Reason
Aug-11-2020 16:05:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 79	Initial Entry

I.ca Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-11-2020 16:05:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: chronic constipation	Initial Entry

I.ca Start Date:

Date	Location	User	Value	Reason
Aug-11-2020 16:05:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Apr/UNK/2010	Initial Entry

I.ca Ongoing:

Date	Location	User	Value	Reason
Aug-11-2020 16:05:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date:

Date	Location	User	Value	Reason
Aug-11-2020 16:01:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/11/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-11-2020 16:01:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 189.7	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-11-2020 16:01:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-11-2020 16:01:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 62.5	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-11-2020 16:01:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-11-2020 16:01:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 34.1	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

7.a

Date	Location	User	Value	Reason
Aug-11-2020 16:08:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 97.8 Temperature Unit: F Temperature Location:: EAR	Transcription Error
Aug-11-2020 16:01:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 96.3 Temperature Unit: F Temperature Location:: EAR	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-11-2020 16:01:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-11-2020 16:08:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-11-2020 16:08:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 97.8	Transcription Error
Aug-11-2020 16:01:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Temperature 96.3 F is outside of Normal Range 97 - 99.5 F.
Aug-11-2020 16:01:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 96.3	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
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090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Aug-11-2020 16:01:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: F	Initial Entry
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7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-11-2020 16:01:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: EAR	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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1. Lab Panel:

Date	Location	User	Value	Reason
Aug-12-2020 07:16:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Aug-12-2020 07:16:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Aug-12-2020 07:16:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/11/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Aug-12-2020 07:16:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Aug-12-2020 07:16:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Aug-11-2020 16:01:36 (UTC-06:00) Central Time	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

(US & Canada)			Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin in Beta_PX113 Result:: Not Done:: NOT DONE
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Aug-11-2020 16:01:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-11-2020 16:01:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Aug-11-2020 16:01:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Randomization Date :

Date	Location	User	Value	Reason
Aug-11-2020 16:03:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/11/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-11-2020 16:03:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 225292	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1019**Site Name:** (1019) Diagnostics Research Group**Subject No:** 10191010**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Aug-11-2020 15:56:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-11-2020 15:56:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-11-2020 15:57:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-11-2020 15:56:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-11-2020 15:56:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/11/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-11-2020 15:57:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BM86C1	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

5.a Sample ID

Date	Location	User	Value	Reason
Aug-11-2020 15:57:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BM86C1	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-11-2020 15:57:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BM86C2	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-11-2020 15:57:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BM86C2	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-11-2020 15:57:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BM86C3	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-11-2020 15:57:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BM86C3	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-11-2020 15:57:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BPRM37	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

5.d Sample ID

Date	Location	User	Value	Reason
Aug-11-2020 15:57:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPRM37	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-11-2020 15:58:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPRM38	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-11-2020 15:58:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPRM38	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1019**Site Name:** (1019) Diagnostics Research Group**Subject No:** 10191010**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Aug-11-2020 15:56:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-11-2020 15:56:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-11-2020 15:56:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-11-2020 15:56:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-11-2020 15:56:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/11/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-11-2020 15:56:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BM85ZL	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

5.a Sample ID

Date	Location	User	Value	Reason
Aug-11-2020 15:56:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BM85ZL	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-11-2020 16:04:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-11-2020 16:04:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-11-2020 16:04:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Aug-11-2020 16:04:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/11/2020 10:15	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-11-2020 16:04:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Aug-11-2020 16:04:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

7. Route:

Date	Location	User	Value	Reason
Aug-11-2020 16:04:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-11-2020 16:04:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Aug-11-2020 16:04:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: YES	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Sep-10-2020 01:16:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Query closed per site response.
Sep-08-2020 08:37:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	VAX 2 diary was activated. Subject has not provided any
Sep-04-2020 06:46:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	eDiary: REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT is 'Yes' however VAX 2 eDiary records are not available for the subject. Please verify and update. Else, confirm in query response appropriately.
Aug-11-2020 16:06:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES - REACTOGENICITY E -DIARY COLLECTED FOR T HIS SUBJECT	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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I. Date of Visit

Date	Location	User	Value	Reason
Sep-16-2020 04:21:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	DOV changed on COVID illness visit
Sep-15-2020 12:17:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Pt notified site at visit 2 visit
Sep-15-2020 04:10:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW4695565;The Date of Visit at Visit V2_VAX2_L is the same as the other Date of Visit at Visit COVID_A. Please review for duplication and update as appropriate.
Sep-01-2020 12:44:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/1/20 20	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-01-2020 12:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-01-2020 12:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FE VE R Were fever or systemic symptoms present on the last day the Subject Diary was completed?: N O	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 12:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-01-2020 12:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Sep-15-2020 08:18:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FATIGUE	New Information

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

			<p>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</p> <p>YES Ongoing ?</p> <p>NO</p> <p>Stop Date:</p> <p>Au g/1 2/2 020</p>	
Sep-14-2020 14:08:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Symptom:: FA TI GU E</p> <p>Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO</p>	Transcription Error
Sep-03-2020 08:43:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Symptom:: FATIGUE</p> <p>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</p> <p>YES Ongoing ?</p> <p>NO</p> <p>Stop Date:</p> <p>Au g/1 1/2 020</p>	Transcription Error
Sep-01-2020 12:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Symptom:: FA TI GU E</p>	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	NO
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Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

2.b Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 12:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-15-2020 12:00:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Sep-15-2020 08:18:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	New Information
Sep-15-2020 08:18:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Ongoing? NO Stop Date: Aug/12/2020	New Information
Sep-15-2020 04:44:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	e-Diary: Per diary records, FATIGUE present on Last day however inform entered with 'No' for the same. Please verify and update. If diary entered in error, please enter stop date as last date of diary or consider raising DCF to correct diary data.
Sep-15-2020 03:05:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Closed by DM: (b) (6)

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1019**Site Name:** (1019) Diagnostics Research Group**Subject No:** 10191010**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44

Sep-14-2020 14:08:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Sep-14-2020 14:08:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Transcription Error
Sep-12-2020 01:03:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 2: Opened	As per ed diary, Fatigue started on 12Aug2020, but stop date is reported as 11AUG2020. Please clarify.
Sep-09-2020 03:29:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closed by DM: (b) (6)
Sep-03-2020 08:43:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Sep-03-2020 08:43:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Ongoing? NO Stop Date: Aug/11/2020	Transcription Error
Sep-02-2020 13:42:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	e-Diary: Per eDiary records, FATIGUE is reported on Last day however the last day in inform is entered as 'No' for the same. Please verify and update. Else, clarify. Thanks
Sep-01-2020 12:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.c

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Sep-01-2020 12:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: HE AD AC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.c Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 12:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HEADACHE	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-01-2020 12:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Sep-01-2020 12:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: CH IL LS Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

2.d Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 12:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> CHILLS	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-01-2020 12:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Sep-01-2020 12:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: VO MIT ING Were fever or systemic sy NO mptoms present on the las t day the Subject Diary w as completed?:	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 12:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-01-2020 12:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
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090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Sep-01-2020 12:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DIA RR HE A Were fever or systemic sy mptoms present on the las t day the Subject Diary wa s completed?: NO	Initial Entry
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2.f Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 12:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-01-2020 12:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Sep-01-2020 12:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE N ED MUS CLE PAI N Were fever or system NO ic symptoms present on the last day the S ubject Diary was co mpleted?:	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

2.g Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 12:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENER MUSCLE PAIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-01-2020 12:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Sep-01-2020 12:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSENER JOINT PAIN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 12:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENER JOINT PAIN	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-01-2020 12:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

3. Injection Site Location:

Date	Location	User	Value	Reason
Sep-01-2020 12:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Sep-01-2020 12:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-01-2020 12:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reactio ns present on the last day t he Subject Diary was com pleted?: NO	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-01-2020 12:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry

5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-01-2020 12:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
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090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Sep-01-2020 12:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: SWE LLI NG Were injection site reactio ns present on the last day the Subject Diary was co mpleted?: NO	Initial Entry
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5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-01-2020 12:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-01-2020 12:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-15-2020 08:18:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site React PAIN AT I ion:: NJECTION SITE Were injection site YES reactions present o Ongoing? n the last day the S ubject Diary was c NO ompleted?: Stop D ate: Aug/ 12/20 20	New Information
Sep-14-2020 14:08:01 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Time (US & Canada)		(b) (4), (b) (6)	Injection Site Reaction PAIN A :: T INJE CTION SITE Were injection site rea NO ctions present on the la st day the Subject Diar y was completed?:	
Sep-03-2020 08:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site React PAIN AT I ion:: NJECTION SITE Were injection site YES reactions present o Ongoing? n the last day the S ubject Diary was c NO ompleted?: Stop D ate: Aug/ 11/20 20	Transcription Error
Sep-01-2020 12:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction PAIN A :: T INJE CTION SITE Were injection site rea NO ctions present on the la st day the Subject Diar y was completed?:	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-01-2020 12:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-15-2020 12:00:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Sep-15-2020 08:18:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	New Information
Sep-15-2020 08:18:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Ongoing? NO Stop Date: Aug/12/2020	New Information
Sep-15-2020 04:45:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	e-Diary: Per diary records, PAIN AT INJECTION SITE present on Last day however inform entered with 'No' for the same.Please verify and update. If diary entered in error, please enter stop date as last date of diary or consider raising DCF to correct diary
Sep-15-2020 03:04:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Closed by DM: (b) (6)

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1019**Site Name:** (1019) Diagnostics Research Group**Subject No:** 10191010**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44

Sep-14-2020 14:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Sep-14-2020 14:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Transcription Error
Sep-12-2020 01:03:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 2: Opened	As per ed diary, Pain at injection site started on 12Aug2020, but stop date is reported as 11AUG2020. Please clarify.
Sep-09-2020 03:31:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closed by DM: (b) (6)
Sep-03-2020 08:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Sep-03-2020 08:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Ongoing? NO Stop Date: Aug/11/2020	Transcription Error
Sep-02-2020 13:18:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	e-Diary: Per eDiary records, PAIN AT INJECTION SITE is reported on Last day however the last day in inform is entered as 'No' for the same. Please verify and update. Else, clarify. Thanks
Sep-01-2020 12:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date:

Date	Location	User	Value	Reason
Sep-01-2020 12:46:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/1/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-01-2020 12:46:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 98.1 Temperature Unit: F Temperature Location:: EAR	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-01-2020 12:46:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-01-2020 12:46:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 98.1	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-01-2020 12:46:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
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090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Sep-01-2020 12:46:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EAR	Initial Entry
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Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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1. Lab Panel:

Date	Location	User	Value	Reason
Sep-01-2020 12:46:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-01-2020 12:46:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-01-2020 12:46:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/1/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-01-2020 12:46:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-01-2020 12:46:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-01-2020 12:46:50 (UTC-06:00) Central Time	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

(US & Canada)			Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin in Beta_PX113 Result:: Not Done:: NOT DONE
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-01-2020 12:46:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-01-2020 12:46:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Sep-01-2020 12:46:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1019**Site Name:** (1019) Diagnostics Research Group**Subject No:** 10191010**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-01-2020 09:24:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-01-2020 09:24:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-01-2020 09:24:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-01-2020 09:24:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-01-2020 09:24:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/1/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-01-2020 09:24:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BM8649	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

5.a Sample ID

Date	Location	User	Value	Reason
Sep-01-2020 09:24:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BM8649	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-01-2020 12:48:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-01-2020 12:48:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-01-2020 12:48:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-01-2020 12:48:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/1/2020 08:18	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-01-2020 12:48:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-01-2020 12:48:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

7. Route:

Date	Location	User	Value	Reason
Sep-01-2020 12:48:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-01-2020 12:48:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Sep-01-2020 12:48:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Visit

Date	Location	User	Value	Reason
Oct-06-2020 13:14:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/6/2020	Initial Entry

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1019**Site Name:** (1019) Diagnostics Research Group**Subject No:** 10191010**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Oct-06-2020 13:14:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-06-2020 13:14:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FE VE R Were fever or systemic sym N ptoms present on the last d O ay the Subject Diary was co mpleted?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Oct-06-2020 13:14:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-06-2020 13:14:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Oct-06-2020 13:14:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FA TIG UE	Initial Entry

Header Text: c4591001
Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History
Form Version: 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1019 **Site Name:** (1019) Diagnostics Research Group
Subject No: 10191010 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 04:44

			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	
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2.b Symptom:

Date	Location	User	Value	Reason
Oct-06-2020 13:14:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-06-2020 13:14:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Oct-06-2020 13:14:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: HE AD AC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

2.c Symptom:

Date	Location	User	Value	Reason
Oct-06-2020 13:14:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HEADACHE	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-06-2020 13:14:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Oct-06-2020 13:14:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: CH IL LS Were fever or systemic sym NO ptoms present on the last d ay the Subject Diary was co mpleted?:	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Oct-06-2020 13:14:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-06-2020 13:14:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
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090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Oct-06-2020 13:14:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VO MIT ING Were fever or systemic sy mptoms present on the las t day the Subject Diary w as completed?: NO	Initial Entry
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2.e Symptom:

Date	Location	User	Value	Reason
Oct-06-2020 13:14:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-06-2020 13:14:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Oct-06-2020 13:14:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DIA RR HE A Were fever or systemic sy mptoms present on the las t day the Subject Diary wa s completed?: NO	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

2.f Symptom:

Date	Location	User	Value	Reason
Oct-06-2020 13:14:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-06-2020 13:14:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Oct-06-2020 13:14:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE NED MUS CLE PAI N Were fever or system NO ic symptoms present on the last day the S ubject Diary was co mpleted?:	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Oct-06-2020 13:14:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSE NED MUSCL E PAIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-06-2020 13:14:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

2.h

Date	Location	User	Value	Reason
Oct-06-2020 13:14:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE NED JOINT PAIN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Oct-06-2020 13:14:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSE NED JOINT PAIN	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-06-2020 13:14:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Oct-06-2020 13:14:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Oct-06-2020 13:14:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

5.a

Date	Location	User	Value	Reason
Oct-06-2020 13:14:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reactio ns present on the last day t he Subject Diary was com pleted?: NO	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-06-2020 13:14:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry

5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-06-2020 13:14:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-06-2020 13:14:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: SWE LLI NG Were injection site reactio ns present on the last day the Subject Diary was co mpleted?: NO	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-06-2020 13:14:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-06-2020 13:14:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-06-2020 13:14:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Injection Site Reaction PAIN A :: T INJE CTION SITE Were injection site rea NO ctions present on the la st day the Subject Diar y was completed?:	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-06-2020 13:14:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> PAIN AT INJECTION SITE	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-06-2020 13:14:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1019**Site Name:** (1019) Diagnostics Research Group**Subject No:** 10191010**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-06-2020 13:50:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-06-2020 13:50:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-06-2020 13:50:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-06-2020 13:50:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-06-2020 13:50:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/6/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-06-2020 13:50:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP98K5	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

5.a Sample ID

Date	Location	User	Value	Reason
Oct-06-2020 13:50:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP98K5	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-06-2020 13:50:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BRTLKK	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-06-2020 13:50:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRTLKK	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-06-2020 13:50:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BRTLKL	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-06-2020 13:50:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRTLKL	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-06-2020 13:50:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BRTLKM	Initial Entry

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Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

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5.d Sample ID

Date	Location	User	Value	Reason
Oct-06-2020 13:50:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRTLKM	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Aug/17/2020

Form: DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History

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Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

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I. Date of Visit

Date	Location	User	Value	Reason
Nov-13-2020 13:58:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 9: Closed	Response satisfies query
Nov-13-2020 10:28:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 9: Answered	page updated
Nov-13-2020 09:56:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 9: Reissued :Opened	Page unfrozen please update
Nov-13-2020 07:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 9: Answered	please unfreeze to allow site to remove erroneous visit entry. This visit was done.
Nov-12-2020 00:36:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 9: Opened	DM: Visit is marked erroneous, however data present in OXYGENATION PARAMETERS and VITAL SIGNS - COVID forms. Please consider removing all data and adding form level comment "Not applicable".

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Aug/17/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

				Thank you.
Sep-23-2020 09:19:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 7: Closed	Response satisfies query
Sep-23-2020 06:27:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 8: Deleted	Query is invalid or does not apply
Sep-22-2020 10:33:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Closed	Response satisfies query
Sep-22-2020 07:17:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 7: Answered	Changed data per query
Sep-22-2020 07:05:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 8: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Sep-22-2020 06:45:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 7: Opened	DM: Thank you for your response. However, As visit is marked as erroneous visit. Please remove all data entered in this CRF and add form level comment as

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Aug/17/2020

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Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

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				"NOT APPLICABLE".
Sep-21-2020 15:43:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Answered	updated
Sep-21-2020 15:42:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 7: Candidate	Erroneous Visit is marked, but date of visit is entered. Please check whether other assessments are performed at this visit.
Sep-21-2020 11:19:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Reissued:Opened	Thank you for your reply. Please enter the data for the visit that was conducted over the phone and enter not collected for the visit that was deemed not needed and provide reason. Please contact CRA for any further assistance. Forms can't be left blank.
Sep-21-2020 07:58:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Answered	Visit conducted over the phone and self swab was deemed not needed
Sep-21-2020 02:07:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Reissued:Opened	DM1: Thanks for the response. However please refer to CCG section 8.29 and update both the forms by indicating

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Aug/17/2020

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Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

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				non-collection of sample by providing reason. Contact CRA for any further assistance.
Sep-20-2020 04:06:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Deleted	Alternate query present.
Sep-18-2020 09:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/17/ 2020	Transcription Error
Sep-18-2020 09:15:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 6: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Sep-18-2020 09:15:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/16/ 2020	Transcription Error
Sep-18-2020 08:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Answered	Swab not collected
Sep-18-2020 06:17:03 (UTC-06:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Opened	DM:Date of Visit is completed but Date of Collection in

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Aug/17/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Central Time (US & Canada)				both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Sep-17-2020 10:13:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Sep-17-2020 10:13:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/17/2020	Transcription Error
Sep-17-2020 01:32:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	As per site response.
Sep-16-2020 07:05:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Per PI and Sponsor, No Swab needed
Sep-16-2020 04:10:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued :Opened	DM1: Thank you for response. However per CCG 8.26 for Potential COVID-19 Illness Visit nasal swab self or nasal swab are expected. Please review and update as

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Aug/17/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1019

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Generated By: (b) (4)

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				appropriate. Else clarify.
Sep-16-2020 01:07:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Deleted	alternate query present in open state
Sep-15-2020 14:08:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 3: Closed	Auto closed by Validation Check: VC_SV001_02
Sep-15-2020 12:09:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Sep-15-2020 12:09:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Transcription Error
Sep-15-2020 12:09:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/27/ 2020	Transcription Error
Sep-15-2020 07:54:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	No nasal Swab conducted

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Aug/17/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Sep-15-2020 04:10:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 3: Opened	DMW4695564;The Date of Visit at Visit COVID_A is the same as the other Date of Visit at Visit V2_VAX2_L. Please review for duplication and update as appropriate.
Sep-14-2020 22:27:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Sep-14-2020 14:20:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Sep-14-2020 14:20:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Sep-14-2020 14:20:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Aug/17/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

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Generated By: (b) (4)

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Sep-14-2020 14:20:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/1/2020	Initial Entry
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2. Erroneous Visit

Date	Location	User	Value	Reason
Nov-13-2020 10:27:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-21-2020 15:42:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ERRONEOUS VISIT	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Sep-14-2020 14:20:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form Version: 21-Aug-2020 02:52

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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I. Date of Assessment:

Date	Location	User	Value	Reason
Sep-23-2020 00:44:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Deleted	Query is invalid or does not apply
Sep-23-2020 00:38:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 3: Candida te	DMW4777412;Date of Assessment is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Sep-22-2020 07:17:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Sep-22-2020 07:05:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-18-2020 09:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Sep-18-2020 09:15:29 (UTC-06:00) Central Time	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Date of assessment is not same as Date Visit. Please check and correct.

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

(US & Canada)				
Sep-17-2020 10:14:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-17-2020 10:14:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/17/2020	Transcription Error
Sep-17-2020 10:12:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date of assessment is not same as Date Visit. Please check and correct.
Sep-17-2020 10:12:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/16/2020	Transcription Error
Sep-16-2020 04:18:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM1: Kindly verify the date of assessment is not same as Date Visit. Per CCG 8.27 the date of assessment should correspond the initial assessment date. Please check and correct. Else clarify.
Sep-15-2020 12:10:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Pt informed site on 01 SEP 2020

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Canada)				
Sep-15-2020 12:09:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date of assessment is not same as Date Visit. Please check and correct.
Sep-14-2020 14:20:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/1/2 020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Sep-23-2020 00:44:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Query is invalid or does not apply
Sep-23-2020 00:41:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Candida te	DMW4777437;Date First Symptom Started is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Sep-22-2020 07:17:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not App licable	Initial Entry
Sep-22-2020 07:03:48 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit
on Aug/17/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF
Audit Trail History**Form Version:** 21-Aug-2020 02:52**Form Status:** Data Complete, Frozen, Verified**Site No:** 1019**Site Name:** (1019) Diagnostics Research Group**Subject No:** 10191010**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44

(US & Canada)				
Sep-18-2020 09:15:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/16/2020	Transcription Error
Sep-17-2020 10:14:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/17/2020	Transcription Error
Sep-17-2020 10:12:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/16/2020	Transcription Error
Sep-14-2020 14:20:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/1/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Sep-22-2020 07:17:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Sep-22-2020 07:03:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-14-2020 14:20:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Date of Last Symptom Resolved :	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:52**Form Status:** Data Complete, Frozen, Verified**Site No:** 1019**Site Name:** (1019) Diagnostics Research Group**Subject No:** 10191010**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44

Sep/2/2020

4.a

Date	Location	User	Value	Reason
Sep-22-2020 07:17:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: FEVER Symptom Present: Not Applicable	Initial Entry
Sep-22-2020 07:08:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: FEVER Symptom Present:	Transcription Error
Sep-14-2020 14:20:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: FEVER Symptom Present: NO	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Sep-14-2020 14:20:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Sep-22-2020 07:17:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Sep-22-2020 07:08:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-14-2020 14:20:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020**Form Version:** 21-Aug-2020 02:52**Site No:** 1019**Subject No:** 10191010**Generated By:** (b) (4)**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1019) Diagnostics Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:44

Sep-22-2020 07:17:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED COUGH Symptom Present: Not Applicable	Initial Entry
Sep-22-2020 07:09:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED COUGH Symptom Present:	Transcription Error
Sep-14-2020 14:20:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED COUGH Symptom Present: NO	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Sep-14-2020 14:20:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Sep-22-2020 07:17:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Sep-22-2020 07:09:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-14-2020 14:20:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.c

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form Version: 21-Aug-2020 02:52

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

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Sep-22-2020 07:17:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom Present: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: Not Applicable	Initial Entry
Sep-22-2020 07:14:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom Present: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present:	Transcription Error
Sep-14-2020 14:20:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom Present: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: NO	Initial Entry

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

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Subject Initials: ---

Generated By: (b) (4)

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4.c Symptoms:

Date	Location	User	Value	Reason
Sep-14-2020 14:20:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SHORTN ESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Sep-22-2020 07:17:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Sep-22-2020 07:14:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-14-2020 14:20:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Sep-22-2020 07:17:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: CHILLS Symptom Present: Not Applicabl e	Initial Entry
Sep-22-2020 07:14:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: CHILLS Symptom Present:	Transcription Error
Sep-14-2020 14:20:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: CHILLS Symptom Present: NO	Initial Entry

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

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Subject Initials: ---

Generated By: (b) (4)

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4.d Symptoms:

Date	Location	User	Value	Reason
Sep-14-2020 14:20:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Sep-22-2020 07:17:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry
Sep-22-2020 07:14:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Transcription Error
Sep-14-2020 14:20:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Sep-22-2020 07:17:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom NEW OR INCREASED MUSCLE PAIN Symptom Present: Not Applicable	Initial Entry
Sep-22-2020 07:15:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom NEW OR INCREASED MUSCLE PAIN Symptom Present:	Transcription Error
Sep-14-2020 14:20:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom NEW OR INCREASED MUSCLE PAIN Symptom Present: NO	Initial Entry

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Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

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4.e Symptoms:

Date	Location	User	Value	Reason
Sep-14-2020 14:20:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Sep-22-2020 07:17:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Sep-22-2020 07:15:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-14-2020 14:20:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Sep-22-2020 07:17:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms NEW LOSS OF TASTE OR SMELL Symptom Present: Not Applicable	Initial Entry
Sep-22-2020 07:15:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms NEW LOSS OF TASTE OR SMELL Symptom Present:	Transcription Error
Sep-14-2020 14:20:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms NEW LOSS OF TASTE OR SMELL Symptom Present: NO	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

4.f Symptoms:

Date	Location	User	Value	Reason
Sep-14-2020 14:20:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW LOSS OF TASTE OR SME LL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Sep-22-2020 07:17:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Sep-22-2020 07:15:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-14-2020 14:20:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Sep-22-2020 07:17:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom NEW OR INCREASED SORE THROAT Symptom Not Applicable Present:	Initial Entry
Sep-22-2020 07:15:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom NEW OR INCREASED SORE THROAT Symptom Present:	Transcription Error
Sep-14-2020 14:20:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom NEW OR INCREASED SORE THROAT Symptom NO Present:	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

4.g Symptoms:

Date	Location	User	Value	Reason
Sep-14-2020 14:20:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SORE T HROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Sep-22-2020 07:17:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Sep-22-2020 07:15:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-14-2020 14:20:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Sep-22-2020 07:17:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: DIARRHEA Symptom Present: Not Applicable	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

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4.h

Date	Location	User	Value	Reason
Sep-22-2020 07:15:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: DIARRHEA Symptom Present :	Transcription Error
Sep-14-2020 14:20:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: DIARRHEA Symptom Present YES :	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Sep-14-2020 14:20:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Sep-22-2020 07:17:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Sep-22-2020 07:15:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-14-2020 14:20:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.i

Date	Location	User	Value	Reason
Sep-22-2020 07:17:01	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	Symptoms: VOMITING Symptom Present: Not Applicable	
Sep-22-2020 07:15:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: VOMITING Symptom Present:	Transcription Error
Sep-14-2020 14:20:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: VOMITING Symptom Present: NO	Initial Entry

4.i Symptoms:

Date	Location	User	Value	Reason
Sep-14-2020 14:20:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Sep-22-2020 07:17:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Sep-22-2020 07:15:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-14-2020 14:20:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Aug/17/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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1. Actual Date of Collection:

Date	Location	User	Value	Reason
Sep-21-2020 15:39:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Sep-21-2020 15:39:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Sep-21-2020 15:39:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Sep-21-2020 15:39:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Sep-21-2020 15:39:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Sep-21-2020 15:39:57 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Aug/17/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Time (US & Canada)		(b) (4), (b) (6)	
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7. Test Result:

Date	Location	User	Value	Reason
Sep-21-2020 15:39:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Sep-21-2020 15:39:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Sep-21-2020 15:39:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Sep-21-2020 15:40:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-21-2020 15:40:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-21-2020 15:40:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Sep-21-2020 15:40:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Sep-21-2020 15:40:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-21-2020 15:40:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-21-2020 15:40:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Sep-21-2020 15:40:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Aug/17/2020**Form Version:** 15-Sep-2020 21:53**Form Status:** Data Complete, Frozen, Verified**Site No:** 1019**Site Name:** (1019) Diagnostics Research Group**Subject No:** 10191010**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)**I.a**

Date	Location	User	Value	Reason
Sep-17-2020 10:43:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: NO	Initial Entry
Sep-17-2020 10:43:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts:	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Sep-17-2020 10:43:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SPECIALIST	Initial Entry

I.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Sep-17-2020 10:43:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.b

Date	Location	User	Value	Reason
Sep-17-2020 10:43:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: EMERGENCY ROOM Occurrence of Visits or Contacts: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Aug/17/2020

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

1.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Sep-17-2020 10:43:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EMERGENCY ROOM	Initial Entry

1.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Sep-17-2020 10:43:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

1.c

Date	Location	User	Value	Reason
Sep-17-2020 10:43:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO	Initial Entry
Sep-17-2020 10:43:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts:	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Aug/17/2020

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

1.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Sep-17-2020 10:43:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

1.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Sep-17-2020 10:43:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.d

Date	Location	User	Value	Reason
Sep-17-2020 10:43:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner URGENT : CARE Occurrence of Visits NO or Contacts:	Initial Entry
Sep-17-2020 10:43:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner URGENT : CARE Occurrence of Visits or Contacts:	Initial Entry

1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Sep-17-2020 10:43:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Sep-17-2020 10:43:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Aug/17/2020

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Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

I.e

Date	Location	User	Value	Reason
Sep-17-2020 10:43:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: NO	Initial Entry
Sep-17-2020 10:43:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts:	Initial Entry

I.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Sep-17-2020 10:43:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: TELEPHONE CONSULTATION	Initial Entry

I.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Sep-17-2020 10:43:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.f

Date	Location	User	Value	Reason
Sep-17-2020 10:43:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OTH ER Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Aug/17/2020

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Sep-17-2020 10:43:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OTH ER Occurrence of Visits or Contacts:	Initial Entry
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1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Sep-17-2020 10:43:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Sep-17-2020 10:43:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Has the subject been hospitalized due to potential COVID-19 illness?

Date	Location	User	Value	Reason
Nov-11-2020 12:27:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Thank you!
Nov-11-2020 11:38:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	hospital data added
Nov-11-2020 05:10:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Op ened	[DM - please unfreeze CRF pages under this visit so site can add updated information on this hospitalization]CLINQUERY:Please enter on the relevant CRF form any available information(vital signs, pulse oxymet, respiratory treatment, lab results, imaging...)

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
on Aug/17/2020**Form Version:** 15-Sep-2020 21:53**Form Status:** Data Complete, Frozen, Verified**Site No:** 1019**Site Name:** (1019) Diagnostics Research Group**Subject No:** 10191010**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44

Nov-10-2020 19:04:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued: Candidate	[DM - please unfreeze CRF pages under this visit so site can add updated information on this hospitalization]CLINQUERY: Please enter on the relevant CRF form any available information (vital signs, pulse oxymet, respiratory treatment, lab results, imaging...)
Nov-10-2020 11:27:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	yes, please unfreeze CRF so site can update
Nov-10-2020 10:45:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued: Opened	CLINQUERY: Was subject hospitalized during this potential COV ILL visit period?
Nov-10-2020 07:21:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Subject was not hospitalized due to covid
Nov-09-2020 00:41:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINQUERY: Subject had COVID-19 illness and was hospitalized. Please enter on the relevant CRF form any available information (vital signs, pulse oxymet, respiratory treatment, lab results, imaging...). Please make every effort to obtain this
Nov-06-2020 17:50:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Candidate	CLINQUERY: Subject had COVID-19 illness and was hospitalized. Please enter on the relevant CRF form any available information (vital signs, pulse oxymet, respiratory treatment, lab results, imaging...). Please make every effort to obtain this
Oct-12-2020 20:35:32 (UTC-06:00)	ACV0PFEINFP6000	Rupal N Shah (b) (4)	Query 1: Closed	Response satisfies query

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Aug/17/2020

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Central Time (US & Canada)				
Oct-12-2020 10:25:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	crf updated
Oct-06-2020 23:14:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rupal N Shah (b) (4)	Query 1: Reissued:Open	thank you for your response. The query response indicates that the subject was hospitalized, however hospitalization CRF has not been completed. DOV CRF is also marked as erroneous. Please clarify.
Sep-29-2020 12:37:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	pt alerted site of hospital visit
Sep-29-2020 10:21:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rupal N Shah (b) (4)	Query 1: Opened	CLIQUEY: this visit is marked as Erroneous visit, please review and update this form as appropriate or else clarify,
Sep-17-2020 10:43:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Has the subject been in intensive care due to potential COVID-19 illness? NO	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HOSPITALIZATION DETAILS - Audit Trail
on Aug/17/2020

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Oct-12-2020 10:25:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HOSPITALIZATION DETAILS - eCRF Audit Trail History on Aug/17/2020

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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1. Hospitalization Category:

Date	Location	User	Value	Reason
Oct-12-2020 10:25:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: HOSPITALIZATION STATUS	Initial Entry
Oct-07-2020 10:18:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-21-2020 15:41:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Hospitalization Term:

Date	Location	User	Value	Reason
Oct-12-2020 10:25:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HOSPITAL	Initial Entry
Oct-07-2020 10:18:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-29-2020 10:20:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rupal N Shah (b) (4)	Query 1: Closed	Response satisfies query
Sep-29-2020 10:19:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rupal N Shah (b) (4)	Query 1: Opened	CLIQUEY: In the Healthcare utilization CRF, it indicates that the subject was hospitalized, therefore, this form is not expected to be completed as "not applicable". please complete the CRF as appropriate per CCG.
Sep-21-2020 15:41:08	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HOSPITALIZATION DETAILS - eCRF Audit Trail History
on Aug/17/2020

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	Not Applicable	
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3. Admission Date:

Date	Location	User	Value	Reason
Oct-12-2020 10:25:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/27/2020	Initial Entry
Oct-07-2020 10:18:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-21-2020 15:41:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Ongoing?

Date	Location	User	Value	Reason
Oct-12-2020 10:25:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Discharge Date: Aug/29/2020	Initial Entry
Oct-07-2020 10:18:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-21-2020 15:41:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: RESPIRATORY TREATMENT - eCRF Audit Trail History on Aug/17/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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1. What is the treatment Identifier?

Date	Location	User	Value	Reason
Sep-21-2020 15:41:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Concomitant Non-drug Treatment Pre-specified:

Date	Location	User	Value	Reason
Sep-21-2020 15:41:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Treatment:

Date	Location	User	Value	Reason
Sep-21-2020 15:41:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Treatment:

Date	Location	User	Value	Reason
Sep-21-2020 15:41:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Sep-21-2020 15:41:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Sep-21-2020 15:41:17 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History
on Aug/17/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Time (US & Canada)	(b) (4), (b) (6)
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Oct-24-2020 09:44:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Oct-24-2020 09:44:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Oct-22-2020 10:21:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILLNESS	Initial Entry
Oct-22-2020 10:21:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-21-2020 15:41:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Oct-25-2020 02:56:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Oct-24-2020 09:44:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Oct-24-2020 09:44:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Oct-24-2020 09:44:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Changed data per query
Oct-23-2020 13:13:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	Response is marked as 'No' but the visit is Erroneous visit.

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: ILLNESS DETAILS - eCRF Audit Trail History on Aug/17/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

		(b) (4), (b) (6)		Please review and update as appropriate.
Oct-22-2020 14:45:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-22-2020 10:21:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Initial Entry
Oct-22-2020 10:21:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
Oct-22-2020 10:21:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Oct-21-2020 15:35:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	Dm Query: Unfrozen. Per CCG, this form is a required CRF, please complete as appropriate. if Diagnosis is not obtained, answer the question as "NO" and enter toxicity grade between 1-5 as per CCG section.
Oct-21-2020 07:20:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	please unfreeze
Oct-20-2020 15:36:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Per CCG, this form is a required CRF, please complete as appropriate. if Diagnosis is not obtained, answer the question as "NO" and enter toxicity grade between 1-5 as per CCG section.

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: ILLNESS DETAILS - eCRF Audit Trail History on Aug/17/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Sep-29-2020 02:08:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rupal N Shah (b) (4)	Query 1: Closed	not needed
Sep-29-2020 02:08:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rupal N Shah (b) (4)	Query 1: Opened	CLIQUEY: per CCG, this form is a required CRF, please complete as appropriate. if Diagnosis is not obtained, answer the question as "NO" and enter toxicity grade between 1-5 as per CCG section 8.13.5 as it relates to Symptoms.
Sep-21-2020 15:41:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-24-2020 09:44:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Oct-24-2020 09:44:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Oct-22-2020 14:46:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-22-2020 10:21:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Oct-22-2020 10:21:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry
Oct-22-2020 10:21:05 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - eCRF Audit Trail History
on Aug/17/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Time (US & Canada)		(b) (4), (b) (6)		
Oct-21-2020 15:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Dm Query: Unfrozen.Per CCG, this form is a required CRF, please complete as appropriate. if Diagnosis is not obtained, answer the question as "NO" and enter toxicity grade between 1-5 as per CCG section.
Oct-21-2020 07:21:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	please unfreeze to be updated
Oct-20-2020 15:36:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Per CCG, this form is a required CRF, please complete as appropriate. if Diagnosis is not obtained, answer the question as "NO" and enter toxicity grade between 1-5 as per CCG section.
Sep-21-2020 15:41:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: ILLNESS DETAILS - SEVERE - eCRF Audit Trail History on Aug/17/2020

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Sep-21-2020 15:41:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Subcategory of Clinical Event:

Date	Location	User	Value	Reason
Sep-21-2020 15:41:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Was a diagnosis obtained?

Date	Location	User	Value	Reason
Sep-21-2020 15:41:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-21-2020 15:41:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Audit Trail

Form Version: 30-Jul-2020 21:27

Form Status:

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Nov-11-2020 10:19:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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1. Lab Panel:

Date	Location	User	Value	Reason
Nov-11-2020 10:19:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: CLINICAL CHEMISTRY	Initial Entry
Nov-11-2020 08:13:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-21-2020 15:41:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Nov-16-2020 11:02:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-16-2020 07:37:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Methodist and Children's Hospital, 7700 Floyd Curl Dr., San Antonio, Texas 78229	Transcription Error
Nov-16-2020 07:36:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-16-2020 07:36:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Methodist and Children's Hospitals 7700 Floyd Curl Dr. San Antonio, Texas 78229	Transcription Error
Nov-15-2020 11:29:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM :A carriage return is identified, please do not press enter key, just type lab name all in single line with comma separated.

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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit
on Aug/17/2020**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY -
eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:27**Form Status:** Data Complete, Frozen**Site No:** 1019**Site Name:** (1019) Diagnostics Research Group**Subject No:** 10191010**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44

Nov-11-2020 10:19:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Methodist and Children's Hospi tals 7700 Floyd Curl Dr. San Antonio, Texas 78229	Initial Entry
Nov-11-2020 08:13:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-21-2020 15:41:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Nov-11-2020 10:19:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/27/2020	Initial Entry
Nov-11-2020 08:13:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-21-2020 15:41:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Nov-11-2020 10:19:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLOOD	Initial Entry
Nov-11-2020 08:13:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-21-2020 15:41:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Nov-11-2020 10:19:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 329 Test:: Not Applicable Result:: Not Done:: NOT DONE Lab Normal Range:	Initial Entry
Nov-11-2020 08:13:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Not Applicable Result:: Not Done:: Lab Normal Range:	Initial Entry
Sep-21-2020 15:41:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

5.a Sponsor ID:

Date	Location	User	Value	Reason
Nov-11-2020 10:19:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 329	Initial Entry
Nov-11-2020 08:13:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-21-2020 15:41:49	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	Not Applicable	
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5.a Test:

Date	Location	User	Value	Reason
Sep-21-2020 15:41:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Nov-11-2020 08:13:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Sep-21-2020 15:41:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Nov-11-2020 10:19:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT DONE	Initial Entry
Nov-11-2020 08:13:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Sep-21-2020 15:41:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Nov-11-2020 08:13:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Sep-21-2020 15:41:49 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Time (US & Canada)	(b) (4), (b) (6)
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5.b

Date	Location	User	Value	Reason
Nov-11-2020 10:19:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 30 Test:: Not Applicable Result:: 23 Not Done:: Lab Normal Range: <i>Low</i> 13 <i>High</i> 61 <i>Unit</i> U/L	Initial Entry
Nov-11-2020 08:13:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Not Applicable Result:: Not Done:: Lab Normal Range:	Initial Entry
Sep-21-2020 15:41:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

5.b Sponsor ID:

Date	Location	User	Value	Reason
Nov-11-2020 10:19:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30	Initial Entry
Nov-11-2020 08:13:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Sep-21-2020 15:41:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Sep-21-2020 15:41:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Nov-11-2020 10:19:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 23	Initial Entry
Nov-11-2020 08:13:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Sep-21-2020 15:41:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Nov-11-2020 08:13:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Sep-21-2020 15:41:49	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	Not Applicable	
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5.b LNMT

Date	Location	User	Value	Reason
Nov-11-2020 10:19:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 13 <i>High</i> 61 <i>Unit</i> U/L	Initial Entry
Nov-11-2020 08:13:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-21-2020 15:41:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-11-2020 10:19:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 28 Test:: Not Applicable Result:: 22 Not Done:: Lab Normal Range: <i>Low</i> 15 <i>High</i> 37 <i>Unit</i> U/L	Initial Entry
Nov-11-2020 08:13:58 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

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Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Time (US & Canada)		(b) (4), (b) (6)	Sponsor-Defined Identifier: Test:: Not Applicable Result:: Not Done:: Lab Normal Range:	
Sep-21-2020 15:41:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

5.c Sponsor ID:

Date	Location	User	Value	Reason
Nov-11-2020 10:19:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 28	Initial Entry
Nov-11-2020 08:13:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Sep-21-2020 15:41:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Sep-21-2020 15:41:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Nov-11-2020 10:19:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 22	Initial Entry
Nov-11-2020 08:13:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Sep-21-2020 15:41:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Nov-11-2020 08:13:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Sep-21-2020 15:41:49	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
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5.c LNMT

Date	Location	User	Value	Reason
Nov-11-2020 10:19:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 15 <i>High</i> 37 <i>Unit</i> U/L	Initial Entry
Nov-11-2020 08:13:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-21-2020 15:41:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d

Date	Location	User	Value	Reason
Nov-11-2020 10:19:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 35 Test:: Not Applicable Result:: 98 Not Done:: Lab Normal Range: <i>Low</i> 45 <i>High</i> 117 <i>Unit</i> U/L	Initial Entry
Nov-11-2020 08:13:58 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

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Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Time (US & Canada)		(b) (4), (b) (6)	Sponsor-Defined Identifier: Test:: Not Applicable Result:: Not Done:: Lab Normal Range:	
Sep-21-2020 15:41:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

5.d Sponsor ID:

Date	Location	User	Value	Reason
Nov-11-2020 10:19:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 35	Initial Entry
Nov-11-2020 08:13:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-21-2020 15:41:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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5.d Test:

Date	Location	User	Value	Reason
Sep-21-2020 15:41:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Nov-11-2020 10:19:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 98	Initial Entry
Nov-11-2020 08:13:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-21-2020 15:41:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Nov-11-2020 08:13:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-21-2020 15:41:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Nov-11-2020 10:19:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Low 45 High 117	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

			Unit U/L	
Nov-11-2020 08:13:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-21-2020 15:41:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e

Date	Location	User	Value	Reason
Nov-11-2020 10:19:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Id 21 entifier: Test:: Not Applic able Result:: 0.6 Not Done:: Lab Normal Range: <i>Low</i> 0.2 <i>High</i> 1.0 <i>Unit</i> mg/dL	Initial Entry
Nov-11-2020 08:13:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id entifier: Test:: Not Applic able Result:: Not Done:: Lab Normal Range:	Initial Entry
Sep-21-2020 15:41:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id Not Applic entifier: able	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range:	Not Applicable	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

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Site No: 1019

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Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

5.e Sponsor ID:

Date	Location	User	Value	Reason
Nov-11-2020 10:19:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 21	Initial Entry
Nov-11-2020 08:13:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Sep-21-2020 15:41:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Sep-21-2020 15:41:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Nov-11-2020 10:19:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 0.6	Initial Entry
Nov-11-2020 08:13:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Sep-21-2020 15:41:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Nov-11-2020 08:13:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Sep-21-2020 15:41:49	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

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Site No: 1019

Site Name: (1019) Diagnostics Research Group

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Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	Not Applicable	
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5.e LNMT

Date	Location	User	Value	Reason
Nov-11-2020 10:19:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0.2 <i>High</i> 1.0 <i>Unit</i> mg/dL	Initial Entry
Nov-11-2020 08:13:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-21-2020 15:41:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f

Date	Location	User	Value	Reason
Nov-11-2020 10:19:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 47 Test:: Not Applicable Result:: 10 Not Done:: Lab Normal Range: <i>Low</i> 7 <i>High</i> 18 <i>Unit</i> mg/dL	Initial Entry
Nov-11-2020 08:13:58 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form Version: 30-Jul-2020 21:27

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Time (US & Canada)		(b) (4), (b) (6)	Sponsor-Defined Identifier: Test:: Not Applicable Result:: Not Done:: Lab Normal Range:	
Sep-21-2020 15:41:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

5.f Sponsor ID:

Date	Location	User	Value	Reason
Nov-11-2020 10:19:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 47	Initial Entry
Nov-11-2020 08:13:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Sep-21-2020 15:41:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Sep-21-2020 15:41:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Nov-11-2020 10:19:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 10	Initial Entry
Nov-11-2020 08:13:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Sep-21-2020 15:41:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Nov-11-2020 08:13:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Sep-21-2020 15:41:49	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
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5.f LNMT

Date	Location	User	Value	Reason
Nov-11-2020 10:19:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 7 <i>High</i> 18 <i>Unit</i> mg/dL	Initial Entry
Nov-11-2020 08:13:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-21-2020 15:41:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g

Date	Location	User	Value	Reason
Nov-11-2020 10:19:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 48 Test:: Not Applicable Result:: 1.01 Not Done:: Lab Normal Range: <i>Low</i> 0.6 <i>High</i> 1.3 <i>Unit</i> mg/dL	Initial Entry
Nov-11-2020 08:13:58 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form Version: 30-Jul-2020 21:27

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Time (US & Canada)		(b) (4), (b) (6)	Sponsor-Defined Identifier: Test:: Not Applicable Result:: Not Done:: Lab Normal Range:	
Sep-21-2020 15:41:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

5.g Sponsor ID:

Date	Location	User	Value	Reason
Nov-11-2020 10:19:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 48	Initial Entry
Nov-11-2020 08:13:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Sep-21-2020 15:41:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Sep-21-2020 15:41:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Nov-11-2020 10:19:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1.01	Initial Entry
Nov-11-2020 08:13:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Sep-21-2020 15:41:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Nov-11-2020 08:13:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

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5.g Not Done:

Date	Location	User	Value	Reason
Sep-21-2020 15:41:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Nov-11-2020 10:19:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0.6 <i>High</i> 1.3 <i>Unit</i> mg/dL	Initial Entry
Nov-11-2020 08:13:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-21-2020 15:41:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Audit Trail

Form Version: 30-Jul-2020 21:28

Form Status:

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

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Date	Location	User	Value	Reason
Nov-11-2020 10:34:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

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1. Lab Panel:

Date	Location	User	Value	Reason
Nov-11-2020 10:34:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: HEMATOLOGY	Initial Entry
Nov-11-2020 10:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Nov-16-2020 11:09:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-16-2020 07:37:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-16-2020 07:37:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Methodist and Children's Hospitals, 7700 Floyd Curl Dr., San Antonio, Texas 78229	Transcription Error
Nov-15-2020 11:30:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM :A carriage return is identified, please do not press enter key, just type lab name all in single line with comma separated.
Nov-11-2020 10:34:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Methodist and Children's Hospitals 7700 Floyd Curl Dr. San Antonio, Texas 78229	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:28**Form Status:** Data Complete, Frozen**Site No:** 1019**Site Name:** (1019) Diagnostics Research Group**Subject No:** 10191010**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44

Nov-11-2020 10:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Nov-11-2020 10:34:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/27/2020	Initial Entry
Nov-11-2020 10:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Nov-11-2020 10:34:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLOOD	Initial Entry
Nov-11-2020 10:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-11-2020 10:34:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Id 1 entifier:	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

			Test:: Not Applicable Result:: 12.6 Not Done:: Lab Normal Range: <i>Low</i> 12.0 <i>High</i> 16.0 <i>Unit</i> g/dL	
Nov-11-2020 10:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Not Applicable Result:: Not Done:: Lab Normal Range:	Initial Entry
Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

5.a Sponsor ID:

Date	Location	User	Value	Reason
Nov-11-2020 10:34:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry
Nov-11-2020 10:20:35 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Time (US & Canada)		(b) (4), (b) (6)		
Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Nov-11-2020 10:34:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 12.6	Initial Entry
Nov-11-2020 10:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Nov-11-2020 10:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Nov-11-2020 10:34:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Low 12.0	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:28**Form Status:** Data Complete, Frozen**Site No:** 1019**Site Name:** (1019) Diagnostics Research Group**Subject No:** 10191010**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44

			High 16.0 Unit g/dL	
Nov-11-2020 10:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-11-2020 10:34:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Id entifier: 2 Test:: Not Applic able Result:: 37.5 Not Done:: Lab Normal Range: <i>Low</i> 36.0 <i>High</i> 46.0 <i>Unit</i> %	Initial Entry
Nov-11-2020 10:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id entifier: Test:: Not Applic able Result:: Not Done:: Lab Normal Range:	Initial Entry
Sep-21-2020 15:42:11	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Generated By: (b) (4)

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(UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Sponsor-Defined Identifier:	Not Applicable
		Test::	Not Applicable
		Result::	Not Applicable
		Not Done::	Not Applicable
		Lab Normal Range:	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

5.b Sponsor ID:

Date	Location	User	Value	Reason
Nov-11-2020 10:34:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 2	Initial Entry
Nov-11-2020 10:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Nov-11-2020 10:34:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 37.5	Initial Entry
Nov-11-2020 10:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Nov-11-2020 10:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Sep-21-2020 15:42:11	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

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Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	Not Applicable	
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5.b LNMT

Date	Location	User	Value	Reason
Nov-11-2020 10:34:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 36.0 <i>High</i> 46.0 <i>Unit</i> %	Initial Entry
Nov-11-2020 10:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-11-2020 10:34:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 3 Test:: Not Applicable Result:: Not Done:: NOT DONE Lab Normal Range:	Initial Entry
Nov-11-2020 10:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Not Applicable Result:: Not Done::	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

			Lab Normal Range:	
Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

5.c Sponsor ID:

Date	Location	User	Value	Reason
Nov-11-2020 10:34:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 3	Initial Entry
Nov-11-2020 10:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Nov-11-2020 10:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Nov-11-2020 10:34:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT DONE	Initial Entry
Nov-11-2020 10:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Sep-21-2020 15:42:11	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	Not Applicable	
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5.c LNMT

Date	Location	User	Value	Reason
Nov-11-2020 10:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d

Date	Location	User	Value	Reason
Nov-11-2020 10:34:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 5 Test:: Not Applicable Result:: 322 Not Done:: Lab Normal Range: <i>Low</i> 150 <i>High</i> 400 <i>Unit</i> /uL	Initial Entry
Nov-11-2020 10:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Not Applicable Result:: Not Done:: Lab Normal Range:	Initial Entry
Sep-21-2020 15:42:11 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Time (US & Canada)	(b) (4), (b) (6)	Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable
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5.d Sponsor ID:

Date	Location	User	Value	Reason
Nov-11-2020 10:34:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry
Nov-11-2020 10:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

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5.d Test:

Date	Location	User	Value	Reason
Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Nov-11-2020 10:34:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 322	Initial Entry
Nov-11-2020 10:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Nov-11-2020 10:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Nov-11-2020 10:34:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Low 150 High 400	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

			Unit /uL	
Nov-11-2020 10:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e

Date	Location	User	Value	Reason
Nov-11-2020 10:34:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Id 7 entifier: Test:: Not Applic able Result:: Not Done:: NOT DON E Lab Normal Range:	Initial Entry
Nov-11-2020 10:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id entifier: Test:: Not Applic able Result:: Not Done:: Lab Normal Range:	Initial Entry
Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id Not Applic entifier: able Test:: Not Applic able Result:: Not Applic able Not Done:: Not Applic able	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

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Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

			Lab Normal Range: Not Applicable	
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

5.e Sponsor ID:

Date	Location	User	Value	Reason
Nov-11-2020 10:34:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 7	Initial Entry
Nov-11-2020 10:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Nov-11-2020 10:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Nov-11-2020 10:34:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT DONE	Initial Entry
Nov-11-2020 10:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Sep-21-2020 15:42:11	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry

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Header Text: c4591001

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Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	Not Applicable	
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5.e LNMT

Date	Location	User	Value	Reason
Nov-11-2020 10:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f

Date	Location	User	Value	Reason
Nov-13-2020 22:44:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Not Applicable Result:: 5.3 Not Done:: Lab Normal Range <i>Low</i> : 1.5 <i>High</i> 7.8 <i>Unit</i> /uL	Transcription Error
Nov-11-2020 10:34:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Not Applicable Result:: 5.3 Not Done::	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

			Lab Normal Range <i>Low</i> : 1.5 <i>High</i> 7.8	
Nov-11-2020 10:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Not Applicable Result:: Not Done:: Lab Normal Range:	Initial Entry
Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

5.f Sponsor ID:

Date	Location	User	Value	Reason
Nov-11-2020 10:34:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 608	Initial Entry
Nov-11-2020 10:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Nov-14-2020 09:30:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-13-2020 22:45:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	added units
Nov-13-2020 20:06:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erica Weaver (b) (4)	Query 2: Opened	units are missing for neutrophils, pls enter.
Nov-11-2020 12:39:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-11-2020 10:35:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	ranges are there
Nov-11-2020 10:34:52	ACV0PFEINFP6000	auto query	Query 1: Opened	Result is present,

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-06:00) Central Time (US & Canada)		(autoquery)		but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Nov-11-2020 10:34:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 5.3	Initial Entry
Nov-11-2020 10:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Nov-11-2020 10:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Nov-13-2020 22:44:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 1.5 <i>High</i> 7.8 <i>Unit</i> /uL	Transcription Error
Nov-11-2020 10:34:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 1.5	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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			High 7.8	
Nov-11-2020 10:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g

Date	Location	User	Value	Reason
Nov-11-2020 10:34:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Id 609 entifier: Test:: Not Applic able Result:: 0.8 Not Done:: Lab Normal Range: <i>Low</i> 0.0 <i>High</i> 6.0 <i>Unit</i> /uL	Initial Entry
Nov-11-2020 10:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id entifier: Test:: Not Applic able Result:: Not Done:: Lab Normal Range:	Initial Entry
Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id Not Applic entifier: able Test:: Not Applic able	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range:	Not Applicable	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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5.g Sponsor ID:

Date	Location	User	Value	Reason
Nov-11-2020 10:34:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 609	Initial Entry
Nov-11-2020 10:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Nov-11-2020 10:34:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 0.8	Initial Entry
Nov-11-2020 10:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Nov-11-2020 10:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
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5.g LNMT

Date	Location	User	Value	Reason
Nov-11-2020 10:34:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0.0 <i>High</i> 6.0 <i>Unit</i> /uL	Initial Entry
Nov-11-2020 10:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.h

Date	Location	User	Value	Reason
Nov-11-2020 10:34:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Id 612 entifier: Test:: Not Applicable Result:: 0.8 Not Done:: Lab Normal Range: <i>Low</i> 0.2 <i>High</i> 1.0 <i>Unit</i> /uL	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Nov-11-2020 10:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Not Applicable Result:: Not Done:: Lab Normal Range:	Initial Entry
Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

5.h Sponsor ID:

Date	Location	User	Value	Reason
Nov-11-2020 10:34:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 612	Initial Entry
Nov-11-2020 10:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Nov-11-2020 10:34:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 0.8	Initial Entry
Nov-11-2020 10:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.h Not Done:

Date	Location	User	Value	Reason
Nov-11-2020 10:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Sep-21-2020 15:42:11	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

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Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	Not Applicable	
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5.h LNMT

Date	Location	User	Value	Reason
Nov-11-2020 10:34:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0.2 <i>High</i> 1.0 <i>Unit</i> /uL	Initial Entry
Nov-11-2020 10:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.i

Date	Location	User	Value	Reason
Nov-11-2020 10:34:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 610 Test:: Not Applicable Result:: 0.1 Not Done:: Lab Normal Range: <i>Low</i> 0.0 <i>High</i> 0.1 <i>Unit</i> /uL	Initial Entry
Nov-11-2020 10:20:35 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Time (US & Canada)		(b) (4), (b) (6)	Sponsor-Defined Identifier: Test:: Not Applicable Result:: Not Done:: Lab Normal Range:	
Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

5.i Sponsor ID:

Date	Location	User	Value	Reason
Nov-11-2020 10:34:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 610	Initial Entry
Nov-11-2020 10:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.i Test:

Date	Location	User	Value	Reason
Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.i Result:

Date	Location	User	Value	Reason
Nov-11-2020 10:34:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 0.1	Initial Entry
Nov-11-2020 10:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.i Not Done:

Date	Location	User	Value	Reason
Nov-11-2020 10:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Sep-21-2020 15:42:11	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

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Generated Time (GMT): 29-Mar-2021 04:44

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	Not Applicable	
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5.i LNMT

Date	Location	User	Value	Reason
Nov-11-2020 10:34:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0.0 <i>High</i> 0.1 <i>Unit</i> /uL	Initial Entry
Nov-11-2020 10:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.j

Date	Location	User	Value	Reason
Nov-11-2020 10:34:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Id 611 entifier: Test:: Not Applicable Result:: 2.6 Not Done:: Lab Normal Range: <i>Low</i> 0.8 <i>High</i> 3.4 <i>Unit</i> /uL	Initial Entry
Nov-11-2020 10:20:35 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

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Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Time (US & Canada)		(b) (4), (b) (6)	Sponsor-Defined Identifier: Test:: Not Applicable Result:: Not Done:: Lab Normal Range:	
Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

5.j Sponsor ID:

Date	Location	User	Value	Reason
Nov-11-2020 10:34:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 611	Initial Entry
Nov-11-2020 10:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.j Result:

Date	Location	User	Value	Reason
Nov-11-2020 10:34:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2.6	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Form Status: Data Complete, Frozen

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Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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5.j Result:

Date	Location	User	Value	Reason
Nov-11-2020 10:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.j Not Done:

Date	Location	User	Value	Reason
Nov-11-2020 10:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.j LNMT

Date	Location	User	Value	Reason
Nov-11-2020 10:34:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0.8 <i>High</i> 3.4 <i>Unit</i> /uL	Initial Entry
Nov-11-2020 10:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-21-2020 15:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Audit Trail
on Aug/17/2020

Form Version: 30-Jul-2020 21:27

Form Status:

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

*** THIS REPEATING FORM HAS BEEN DELETED ***

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Date	Location	User	Value	Reason
Feb-04-2021 08:03:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error
Nov-11-2020 08:19:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History
on Aug/17/2020**Form Version:** 30-Jul-2020 21:27**Form Status:** Data Complete, Deleted**Site No:** 1019**Site Name:** (1019) Diagnostics Research Group**Subject No:** 10191010**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44

*** THIS REPEATING FORM HAS BEEN DELETED ***

[Back to Form](#)**I. Date:**

Date	Location	User	Value	Reason
Feb-03-2021 04:15:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-02-2021 19:39:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Updated data per query. Each day has single value recorded
Jan-23-2021 23:47:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 1: Opened	Check all assessments performed on 27 and 28th Aug2020. If multiple values were recorded on a single day, at a minimum the most abnormal should be recorded, i.e. the lowest Diastolic Blood Pressure & Systolic Blood Pressure and the highest HR and RR.
Nov-11-2020 08:19:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/27/2020	Initial Entry
Nov-11-2020 08:14:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-21-2020 15:42:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Aug/17/2020

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Form Status: Data Complete, Deleted

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Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

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*** THIS REPEATING FORM HAS BEEN DELETED ***

Nov-11-2020 08:19:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: Not Applicable Systolic:: 187 Diastolic:: 74 Respiratory Rate in respirations/minute: 20 Heart Rate in beats/minute: 69	Initial Entry
Nov-11-2020 08:14:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: Not Applicable Systolic:: Diastolic:: Respiratory Rate in respirations/minute: Heart Rate in beats/minute:	Initial Entry
Sep-21-2020 15:42:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: Not Applicable Systolic:: Not Applicable Diastolic:: Not Applicable Respiratory Rate in respirations/minute: Not Applicable Heart Rate in beats/minute: Not Applicable	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-21-2020 15:42:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a Systolic:

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Header Text: c4591001

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Form Status: Data Complete, Deleted

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

*** THIS REPEATING FORM HAS BEEN DELETED ***

Date	Location	User	Value	Reason
Nov-11-2020 22:03:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-11-2020 13:30:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	per hospital doctors NCS
Nov-11-2020 12:50:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM Q: Please confirm if Clinically significant or not clinically significant. Thank you
Nov-11-2020 08:19:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	per medical records
Nov-11-2020 08:19:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Systolic BP 187 is outside of Normal Range 90 - 140.
Nov-11-2020 08:19:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 187	Initial Entry
Nov-11-2020 08:14:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-21-2020 15:42:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Nov-11-2020 08:19:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 74	Initial Entry
Nov-11-2020 08:14:48 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Aug/17/2020

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Deleted

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

*** THIS REPEATING FORM HAS BEEN DELETED ***

Time (US & Canada)		(b) (4), (b) (6)		
Sep-21-2020 15:42:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Nov-11-2020 08:19:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 20	Initial Entry
Nov-11-2020 08:14:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-21-2020 15:42:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Nov-11-2020 08:19:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 69	Initial Entry
Nov-11-2020 08:14:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-21-2020 15:42:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Audit Trail
on Aug/17/2020

Form Version: 10-Oct-2020 15:59

Form Status:

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

*** THIS REPEATING FORM HAS BEEN DELETED ***

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Date	Location	User	Value	Reason
Feb-02-2021 09:37:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error
Nov-11-2020 08:20:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Audit Trail
on Aug/17/2020

Form Version: 10-Oct-2020 15:59

Form Status:

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

*** THIS REPEATING FORM HAS BEEN DELETED ***

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Date	Location	User	Value	Reason
Feb-02-2021 09:33:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error
Nov-11-2020 08:21:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Audit Trail
on Aug/17/2020

Form Version: 10-Oct-2020 15:59

Form Status:

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

*** THIS REPEATING FORM HAS BEEN DELETED ***

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Date	Location	User	Value	Reason
Feb-02-2021 09:29:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error
Nov-11-2020 08:24:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Audit Trail
on Aug/17/2020

Form Version: 10-Oct-2020 15:59

Form Status:

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

*** THIS REPEATING FORM HAS BEEN DELETED ***

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Date	Location	User	Value	Reason
Feb-02-2021 09:29:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error
Nov-11-2020 08:25:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Audit Trail
on Aug/17/2020

Form Version: 10-Oct-2020 15:59

Form Status:

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

*** THIS REPEATING FORM HAS BEEN DELETED ***

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Date	Location	User	Value	Reason
Feb-02-2021 08:44:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error
Nov-11-2020 08:26:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Audit Trail
on Aug/17/2020

Form Version: 10-Oct-2020 15:59

Form Status:

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Nov-11-2020 08:27:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Audit Trail
on Aug/17/2020

Form Version: 10-Oct-2020 15:59

Form Status:

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

*** THIS REPEATING FORM HAS BEEN DELETED ***

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Date	Location	User	Value	Reason
Feb-02-2021 09:37:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error
Nov-11-2020 10:36:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Audit Trail
on Aug/17/2020

Form Version: 10-Oct-2020 15:59

Form Status:

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

*** THIS REPEATING FORM HAS BEEN DELETED ***

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Date	Location	User	Value	Reason
Feb-02-2021 09:38:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error
Nov-11-2020 10:37:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Audit Trail
on Aug/17/2020

Form Version: 10-Oct-2020 15:59

Form Status:

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

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*** THIS REPEATING FORM HAS BEEN DELETED ***

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Date	Location	User	Value	Reason
Feb-02-2021 09:39:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error
Nov-11-2020 10:42:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Audit Trail
on Aug/17/2020

Form Version: 10-Oct-2020 15:59

Form Status:

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

*** THIS REPEATING FORM HAS BEEN DELETED ***

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Date	Location	User	Value	Reason
Feb-02-2021 19:39:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error
Nov-11-2020 10:54:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Audit Trail
on Aug/17/2020

Form Version: 10-Oct-2020 15:59

Form Status:

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

*** THIS REPEATING FORM HAS BEEN DELETED ***

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Date	Location	User	Value	Reason
Feb-02-2021 19:38:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error
Nov-11-2020 10:55:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Audit Trail
on Aug/17/2020

Form Version: 10-Oct-2020 15:59

Form Status:

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Feb-02-2021 09:43:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error
Nov-11-2020 10:57:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Audit Trail
on Aug/17/2020

Form Version: 10-Oct-2020 15:59

Form Status:

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

*** THIS REPEATING FORM HAS BEEN DELETED ***

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Date	Location	User	Value	Reason
Feb-02-2021 09:41:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error
Nov-11-2020 11:02:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Audit Trail
on Aug/17/2020

Form Version: 10-Oct-2020 15:59

Form Status:

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Nov-11-2020 11:02:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Audit Trail
on Aug/17/2020

Form Version: 10-Oct-2020 15:59

Form Status:

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Nov-11-2020 11:37:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Aug/17/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Deleted

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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I. Date:

Date	Location	User	Value	Reason
Nov-11-2020 08:21:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/27/2020	Transcription Error
Nov-11-2020 08:20:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/27/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-11-2020 08:20:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Systolic:: 16 2 Diastolic:: 73 Respiratory Rate in respirat 18 ions/minute: Heart Rate in beats/minute: 83	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-11-2020 08:20:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Nov-11-2020 22:05:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-11-2020 13:30:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	per hospital doctors NCS

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Aug/17/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Deleted

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

*** THIS REPEATING FORM HAS BEEN DELETED ***

Nov-11-2020 12:50:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM Q: Please confirm if Clinically significant or not clinically significant. Thank you
Nov-11-2020 08:20:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	per medical records
Nov-11-2020 08:20:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Systolic BP 162 is outside of Normal Range 90 - 140.
Nov-11-2020 08:20:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 162	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Nov-11-2020 08:20:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 73	Initial Entry

2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Nov-11-2020 08:20:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 18	Initial Entry

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Nov-11-2020 08:20:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 83	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Aug/17/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Deleted

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

*** THIS REPEATING FORM HAS BEEN DELETED ***

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1. Date:

Date	Location	User	Value	Reason
Nov-11-2020 08:21:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/27/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-11-2020 08:21:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Systolic:: 17 8 Diastolic:: 76 Respiratory Rate in respirat 18 ions/minute: Heart Rate in beats/minute: 77	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-11-2020 08:21:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Nov-11-2020 22:06:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-11-2020 13:30:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	per hospital doctors NCS
Nov-11-2020 12:50:56 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM Q: Please confirm if

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Aug/17/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Deleted

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

*** THIS REPEATING FORM HAS BEEN DELETED ***

Time (US & Canada)		(b) (4), (b) (6)		Clinically significant or not clinically significant. Thank you
Nov-11-2020 08:24:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	per medical records
Nov-11-2020 08:21:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Systolic BP 178 is outside of Normal Range 90 - 140.
Nov-11-2020 08:21:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 178	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Nov-11-2020 08:21:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 76	Initial Entry

2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Nov-11-2020 08:21:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 18	Initial Entry

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Nov-11-2020 08:21:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 77	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Aug/17/2020

Form Version: 10-Oct-2020 15:59

Form Status: Incomplete, Data Complete, Deleted

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

*** THIS REPEATING FORM HAS BEEN DELETED ***

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1. Date:

Date	Location	User	Value	Reason
Feb-02-2021 09:29:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Nov-11-2020 08:24:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/27/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Feb-02-2021 09:29:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Systolic:: Diastolic:: Respiratory Rate in respirati ons/minute: Heart Rate in beats/minute:	Transcription Error
Nov-11-2020 08:24:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Systolic:: 15 5 Diastolic:: 70 Respiratory Rate in respira tions/minute: 20 Heart Rate in beats/minute: 74	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-11-2020 08:24:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Systolic:

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Aug/17/2020

Form Version: 10-Oct-2020 15:59

Form Status: Incomplete, Data Complete, Deleted

Site No: 1019

Site Name: (1019) Diagnostics Research Group

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Generated By: (b) (4)

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*** THIS REPEATING FORM HAS BEEN DELETED ***

Date	Location	User	Value	Reason
Feb-02-2021 09:29:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Transcription Error
Nov-11-2020 22:06:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-11-2020 13:30:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	per hospital doctors NCS
Nov-11-2020 12:50:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM Q: Please confirm if Clinically significant or not clinically significant. Thank you
Nov-11-2020 08:25:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	per medical records
Nov-11-2020 08:24:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Systolic BP 155 is outside of Normal Range 90 - 140.
Nov-11-2020 08:24:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 155	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Feb-02-2021 09:29:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Transcription Error
Nov-11-2020 08:24:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 70	Initial Entry

2.a Respiratory Rate in respirations/minute:

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History
on Aug/17/2020

Form Version: 10-Oct-2020 15:59

Form Status: Incomplete, Data Complete, Deleted

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

*** THIS REPEATING FORM HAS BEEN DELETED ***

Date	Location	User	Value	Reason
Feb-02-2021 09:29:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Transcription Error
Nov-11-2020 08:24:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 20	Initial Entry

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Feb-02-2021 09:29:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Transcription Error
Nov-11-2020 08:24:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 74	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Aug/17/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Deleted

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

*** THIS REPEATING FORM HAS BEEN DELETED ***

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1. Date:

Date	Location	User	Value	Reason
Nov-11-2020 08:25:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/27/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-11-2020 08:25:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Systolic:: 17 5 Diastolic:: 78 Respiratory Rate in respirat ions/minute: 18 Heart Rate in beats/minute: 75	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-11-2020 08:25:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Nov-11-2020 22:07:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-11-2020 13:31:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	per hospital doctors NCS
Nov-11-2020 12:50:56 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM Q: Please confirm if

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Aug/17/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Deleted

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

*** THIS REPEATING FORM HAS BEEN DELETED ***

Time (US & Canada)		(b) (4), (b) (6)		Clinically significant or not clinically significant. Thank you
Nov-11-2020 08:25:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	per medical records
Nov-11-2020 08:25:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Systolic BP 175 is outside of Normal Range 90 - 140.
Nov-11-2020 08:25:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 175	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Nov-11-2020 08:25:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 78	Initial Entry

2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Nov-11-2020 08:25:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 18	Initial Entry

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Nov-11-2020 08:25:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 75	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Aug/17/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Deleted

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

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1. Date:

Date	Location	User	Value	Reason
Nov-11-2020 08:26:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/27/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-11-2020 08:26:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Systolic:: 17 7 Diastolic:: 10 9 Respiratory Rate in respirat 20 ions/minute: Heart Rate in beats/minute: 75	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-11-2020 08:26:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Nov-11-2020 22:08:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-11-2020 13:31:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	per hospital doctors NCS
Nov-11-2020 12:50:56	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM Q: Please

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Aug/17/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Deleted

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

*** THIS REPEATING FORM HAS BEEN DELETED ***

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)		confirm if Clinically significant or not clinically significant. Thank you
Nov-11-2020 08:26:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	per medical records
Nov-11-2020 08:26:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Systolic BP 177 is outside of Normal Range 90 - 140.
Nov-11-2020 08:26:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 177	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Nov-11-2020 22:07:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-11-2020 13:31:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	per hospital doctors NCS
Nov-11-2020 12:50:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM Q: Please confirm if Clinically significant or not clinically significant. Thank you
Nov-11-2020 08:26:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	per medical records
Nov-11-2020 08:26:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Diastolic BP 109 is outside of Normal Range 60 - 90.

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Aug/17/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Deleted

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

*** THIS REPEATING FORM HAS BEEN DELETED ***

Nov-11-2020 08:26:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 109	Initial Entry
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2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Nov-11-2020 08:26:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 20	Initial Entry

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Nov-11-2020 08:26:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 75	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Aug/17/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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I. Date:

Date	Location	User	Value	Reason
Feb-04-2021 23:55:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-04-2021 08:04:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Feb-04-2021 01:51:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 1: Opened	Check all assessments performed on 27Aug2020. If multiple values were recorded on a single day, at a minimum the most abnormal should be recorded, i.e. the lowest Diastolic & Systolic Blood Pressure and the highest Heart Rate & Respiratory rate
Nov-11-2020 08:27:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/27/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-11-2020 08:27:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Systolic:: 13 6 Diastolic:: 48 Respiratory Rate in respirat ions/minute: 20 Heart Rate in beats/minute: 66	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Aug/17/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-11-2020 08:27:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Nov-11-2020 08:27:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 136	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Nov-11-2020 22:08:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-11-2020 13:31:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	per hospital doctors NCS
Nov-11-2020 12:50:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM Q: Please confirm if Clinically significant or not clinically significant. Thank you
Nov-11-2020 08:27:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	per medical records
Nov-11-2020 08:27:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Diastolic BP 48 is outside of Normal Range 60 - 90.
Nov-11-2020 08:27:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 48	Initial Entry

2.a Respiratory Rate in respirations/minute:

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History
on Aug/17/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Nov-11-2020 08:27:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 20	Initial Entry

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Nov-11-2020 08:27:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 66	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Aug/17/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Deleted

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

*** THIS REPEATING FORM HAS BEEN DELETED ***

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1. Date:

Date	Location	User	Value	Reason
Nov-11-2020 10:36:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/27/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-11-2020 10:36:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Systolic:: 20 2 Diastolic:: 81 Respiratory Rate in respirat 22 ions/minute: Heart Rate in beats/minute: 69	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-11-2020 10:36:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Nov-12-2020 00:46:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-11-2020 13:31:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	per hospital doctors NCS
Nov-11-2020 12:50:56 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM Q: Please confirm if

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Aug/17/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Deleted

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

*** THIS REPEATING FORM HAS BEEN DELETED ***

Time (US & Canada)		(b) (4), (b) (6)		Clinically significant or not clinically significant. Thank you
Nov-11-2020 10:37:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	per medical records
Nov-11-2020 10:36:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Systolic BP 202 is outside of Normal Range 90 - 140.
Nov-11-2020 10:36:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 202	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Nov-11-2020 10:36:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 81	Initial Entry

2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Nov-11-2020 10:36:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 22	Initial Entry

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Nov-11-2020 10:36:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 69	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Aug/17/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Deleted

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date:

Date	Location	User	Value	Reason
Nov-11-2020 10:37:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/27/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-11-2020 10:37:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Systolic:: 19 2 Diastolic:: 78 Respiratory Rate in respirat 18 ions/minute: Heart Rate in beats/minute: 72	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-11-2020 10:37:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Nov-12-2020 00:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-11-2020 13:32:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	per hospital doctors NCS
Nov-11-2020 12:50:56 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM Q: Please confirm if

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Aug/17/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Deleted

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

*** THIS REPEATING FORM HAS BEEN DELETED ***

Time (US & Canada)		(b) (4), (b) (6)		Clinically significant or not clinically significant. Thank you
Nov-11-2020 10:38:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	per medical records
Nov-11-2020 10:37:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Systolic BP 192 is outside of Normal Range 90 - 140.
Nov-11-2020 10:37:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 192	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Nov-11-2020 10:37:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 78	Initial Entry

2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Nov-11-2020 10:37:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 18	Initial Entry

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Nov-11-2020 10:37:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 72	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Aug/17/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Deleted

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date:

Date	Location	User	Value	Reason
Nov-11-2020 10:42:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/27/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-11-2020 10:42:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Systolic:: 16 9 Diastolic:: 72 Respiratory Rate in respirat 18 ions/minute: Heart Rate in beats/minute: 72	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-11-2020 10:42:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Nov-12-2020 01:29:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-11-2020 13:32:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	per hospital doctors NCS
Nov-11-2020 12:50:56 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM Q: Please confirm if

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Aug/17/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Deleted

Site No: 1019

Site Name: (1019) Diagnostics Research Group

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Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

*** THIS REPEATING FORM HAS BEEN DELETED ***

Time (US & Canada)		(b) (4), (b) (6)		Clinically significant or not clinically significant. Thank you
Nov-11-2020 10:42:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	recorded per medical records
Nov-11-2020 10:42:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Systolic BP 169 is outside of Normal Range 90 - 140.
Nov-11-2020 10:42:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 169	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Nov-11-2020 10:42:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 72	Initial Entry

2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Nov-11-2020 10:42:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 18	Initial Entry

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Nov-11-2020 10:42:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 72	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Aug/17/2020

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Site No: 1019

Site Name: (1019) Diagnostics Research Group

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1. Date:

Date	Location	User	Value	Reason
Nov-11-2020 10:54:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/28/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-11-2020 10:54:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Systolic:: 14 6 Diastolic:: 67 Respiratory Rate in respirat 18 ions/minute: Heart Rate in beats/minute: 12 6	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-11-2020 10:54:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Nov-11-2020 22:09:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-11-2020 13:32:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	per hospital doctors NCS
Nov-11-2020 12:50:56	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM Q: Please

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Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Aug/17/2020

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Site No: 1019

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Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

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(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)		confirm if Clinically significant or not clinically significant. Thank you
Nov-11-2020 10:54:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	as per medical records
Nov-11-2020 10:54:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Systolic BP 146 is outside of Normal Range 90 - 140.
Nov-11-2020 10:54:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 146	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Nov-11-2020 10:54:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 67	Initial Entry

2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Nov-11-2020 10:54:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 18	Initial Entry

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Nov-12-2020 03:21:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-11-2020 13:32:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	per hospital doctors NCS
Nov-11-2020 12:50:56	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM Q: Please

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History
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(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)		confirm if Clinically significant or not clinically significant. Thank you
Nov-11-2020 10:55:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	as per medical records
Nov-11-2020 10:54:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Heart rate 126 is outside of Normal Range 0 - 120.
Nov-11-2020 10:54:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 126	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Aug/17/2020

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Form Status: Data Complete, Deleted

Site No: 1019

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Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

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1. Date:

Date	Location	User	Value	Reason
Nov-11-2020 10:55:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/28/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-11-2020 10:56:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Systolic:: 15 1 Diastolic:: 96 Respiratory Rate in respira 18 tions/minute: Heart Rate in beats/minute: 72	Transcription Error
Nov-11-2020 10:56:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Systolic:: 18 4 Diastolic:: 96 Respiratory Rate in respira 18 tions/minute: Heart Rate in beats/minute: 72	Transcription Error
Nov-11-2020 10:55:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Systolic:: 48 4 Diastolic:: 96 Respiratory Rate in respira 18 tions/minute: Heart Rate in beats/minute: 72	Initial Entry

2.a Record Identifier:

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

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Generated By: (b) (4)

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Date	Location	User	Value	Reason
Nov-11-2020 10:55:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Nov-11-2020 22:10:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-11-2020 13:32:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	per hospital doctors NCS
Nov-11-2020 12:50:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM Q: Please confirm if Clinically significant or not clinically significant. Thank you
Nov-11-2020 10:56:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	as per medical records
Nov-11-2020 10:56:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Systolic BP 151 is outside of Normal Range 90 - 140.
Nov-11-2020 10:56:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 151	Transcription Error
Nov-11-2020 10:56:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Systolic BP 184 is outside of Normal Range 90 - 140.
Nov-11-2020 10:56:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 184	Transcription Error
Nov-11-2020 10:55:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Systolic BP 484 is outside of Normal Range 90 - 140.

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Aug/17/2020

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Form Status: Data Complete, Deleted

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

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Nov-11-2020 10:55:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 484	Initial Entry
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2.a Diastolic:

Date	Location	User	Value	Reason
Nov-12-2020 03:20:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-11-2020 13:33:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	per hospital doctors NCS
Nov-11-2020 12:50:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM Q: Please confirm if Clinically significant or not clinically significant. Thank you
Nov-11-2020 10:55:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	as per medical records
Nov-11-2020 10:55:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Diastolic BP 96 is outside of Normal Range 60 - 90.
Nov-11-2020 10:55:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 96	Initial Entry

2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Nov-11-2020 10:55:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 18	Initial Entry

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
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Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History
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Nov-11-2020 10:55:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 72	Initial Entry
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Aug/17/2020

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1. Date:

Date	Location	User	Value	Reason
Nov-11-2020 10:57:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/28/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-11-2020 10:57:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Systolic:: 12 3 Diastolic:: 50 Respiratory Rate in respirat 16 ions/minute: Heart Rate in beats/minute: 78	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-11-2020 10:57:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Nov-11-2020 10:57:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 123	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Nov-12-2020 03:21:59 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History
on Aug/17/2020**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Deleted**Site No:** 1019**Site Name:** (1019) Diagnostics Research Group**Subject No:** 10191010**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44

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Time (US & Canada)				
Nov-11-2020 13:33:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	per hospital doctors NCS
Nov-11-2020 12:50:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM Q: Please confirm if Clinically significant or not clinically significant. Thank you
Nov-11-2020 11:01:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	as per medical records
Nov-11-2020 10:57:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Diastolic BP 50 is outside of Normal Range 60 - 90.
Nov-11-2020 10:57:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 50	Initial Entry

2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Nov-11-2020 10:57:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 16	Initial Entry

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Nov-11-2020 10:57:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 78	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Aug/17/2020

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Generated By: (b) (4)

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1. Date:

Date	Location	User	Value	Reason
Nov-11-2020 11:02:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/28/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-11-2020 11:02:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Systolic:: 14 9 Diastolic:: 71 Respiratory Rate in respirat ions/minute: 16 Heart Rate in beats/minute: 70	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-11-2020 11:02:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Nov-11-2020 22:08:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-11-2020 13:33:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	per hospital doctors NCS
Nov-11-2020 12:50:56 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM Q: Please confirm if Clinically

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Time (US & Canada)		(b) (4), (b) (6)		significant or not clinically significant. Thank you
Nov-11-2020 11:02:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	as per medical records
Nov-11-2020 11:02:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Systolic BP 149 is outside of Normal Range 90 - 140.
Nov-11-2020 11:02:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 149	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Nov-11-2020 11:02:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 71	Initial Entry

2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Nov-11-2020 11:02:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 16	Initial Entry

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Nov-11-2020 11:02:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 70	Initial Entry

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Header Text: c4591001

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Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

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1. Date:

Date	Location	User	Value	Reason
Nov-11-2020 11:02:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Aug/28/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-11-2020 11:02:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Record Identifier:: 1 Systolic:: 12 2 Diastolic:: 63 Respiratory Rate in respirat 16 ions/minute: Heart Rate in beats/minute: 73	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-11-2020 11:02:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Nov-11-2020 11:02:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 122	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Nov-11-2020 11:02:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 63	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History
on Aug/17/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Nov-11-2020 11:02:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 16	Initial Entry

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Nov-11-2020 11:02:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 73	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History
on Aug/17/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date:

Date	Location	User	Value	Reason
Nov-11-2020 11:37:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/29/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-13-2020 07:14:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Systolic:: 13 8 Diastolic:: 69 Respiratory Rate in respira 18 tions/minute: Heart Rate in beats/minute: 56	Transcription Error
Nov-11-2020 11:38:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Systolic:: 13 8 Diastolic:: 69 Respiratory Rate in respira 18 tions/minute: Heart Rate in beats/minute: 18	Transcription Error
Nov-11-2020 11:38:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Systolic:: 13 8 Diastolic:: 69 Respiratory Rate in respira 18 tions/minute: Heart Rate in beats/minute: 0	Transcription Error
Nov-11-2020 11:37:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1	Transcription Error

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Aug/17/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

			Systolic:: 13 8 Diastolic:: 69 Respiratory Rate in respirations/minute: 56 Heart Rate in beats/minute: 0	
Nov-11-2020 11:37:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Systolic:: 13 8 Diastolic:: 69 Respiratory Rate in respirations/minute: 0 Heart Rate in beats/minute: 0	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-11-2020 11:37:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Nov-11-2020 11:37:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 138	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Nov-11-2020 11:37:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 69	Initial Entry

2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Nov-11-2020 11:38:02 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 18	Transcription Error

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Aug/17/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Time (US & Canada)		(b) (4), (b) (6)		
Nov-11-2020 11:37:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 56	Transcription Error
Nov-11-2020 11:37:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 0	Initial Entry

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Nov-13-2020 12:34:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-13-2020 07:14:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-13-2020 07:14:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 56	Transcription Error
Nov-12-2020 17:46:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: Please confirm that this data value matches source documentation.
Nov-11-2020 11:38:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 18	Transcription Error
Nov-11-2020 11:37:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 0	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Audit Trail
on Aug/17/2020

Form Version: 30-Jul-2020 21:28

Form Status:

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

*** THIS REPEATING FORM HAS BEEN DELETED ***

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Date	Location	User	Value	Reason
Feb-02-2021 08:11:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error
Nov-11-2020 08:28:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Deleted

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

*** THIS REPEATING FORM HAS BEEN DELETED ***

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I. Date:

Date	Location	User	Value	Reason
Feb-03-2021 00:52:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-02-2021 08:11:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Jan-23-2021 23:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 2: Opened	Please check the assessments performed on 27Aug2020. If multiple values were recorded on a single day, at a minimum the most abnormal should be recorded, i.e. the lowest Oxygen Saturation for the day. Hence enter only one entry and delete other one.
Nov-16-2020 10:51:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-16-2020 07:59:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Nov-15-2020 07:34:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 1: Opened	Please check all assessments performed on 27 and 28th Aug2020. If multiple values were recorded on a single day, at a minimum the most abnormal should be

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020**Form:** VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:28**Form Status:** Data Complete, Deleted**Site No:** 1019**Site Name:** (1019) Diagnostics Research Group**Subject No:** 10191010**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44

*** THIS REPEATING FORM HAS BEEN DELETED ***

				recorded, i.e. the lowest Oxygen Saturation for the day. Hence enter only one entry and delete others
Nov-11-2020 08:28:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/27/2020	Initial Entry
Nov-11-2020 08:28:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-21-2020 15:42:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-11-2020 08:28:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: Unknown Oxygen Saturation: 100.0	Initial Entry
Nov-11-2020 08:28:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: Unknown Oxygen Saturation:	Initial Entry
Sep-21-2020 15:42:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: Unknown Oxygen Saturation: Unknown	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-21-2020 15:42:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

2.a SPO2 Pulse Oximetry %

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

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Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Deleted

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

*** THIS REPEATING FORM HAS BEEN DELETED ***

Date	Location	User	Value	Reason
Nov-11-2020 08:28:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 100.0	Initial Entry
Nov-11-2020 08:28:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Sep-21-2020 15:42:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Audit Trail
on Aug/17/2020

Form Version: 10-Oct-2020 16:04

Form Status:

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

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Date	Location	User	Value	Reason
Nov-16-2020 07:57:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error
Nov-11-2020 08:28:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Audit Trail
on Aug/17/2020

Form Version: 10-Oct-2020 16:04

Form Status:

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

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Date	Location	User	Value	Reason
Nov-16-2020 07:57:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error
Nov-11-2020 08:28:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Audit Trail
on Aug/17/2020

Form Version: 10-Oct-2020 16:04

Form Status:

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

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Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

*** THIS REPEATING FORM HAS BEEN DELETED ***

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Date	Location	User	Value	Reason
Nov-16-2020 07:56:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error
Nov-11-2020 08:28:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Audit Trail
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Form Version: 10-Oct-2020 16:04

Form Status:

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

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Generated By: (b) (4)

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*** THIS REPEATING FORM HAS BEEN DELETED ***

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Date	Location	User	Value	Reason
Nov-16-2020 07:55:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error
Nov-11-2020 08:29:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Audit Trail
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Form Status:

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

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Generated By: (b) (4)

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Date	Location	User	Value	Reason
Nov-16-2020 07:39:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error
Nov-11-2020 08:29:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Audit Trail
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Form Status:

Site No: 1019

Site Name: (1019) Diagnostics Research Group

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Generated By: (b) (4)

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Date	Location	User	Value	Reason
Nov-11-2020 08:29:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Audit Trail
on Aug/17/2020

Form Version: 10-Oct-2020 16:04

Form Status:

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

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Generated By: (b) (4)

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Date	Location	User	Value	Reason
Nov-16-2020 07:38:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error
Nov-11-2020 08:41:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Audit Trail
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Form Version: 10-Oct-2020 16:04

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Site No: 1019

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Date	Location	User	Value	Reason
Nov-16-2020 07:59:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error
Nov-11-2020 11:24:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Audit Trail
on Aug/17/2020

Form Version: 10-Oct-2020 16:04

Form Status:

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

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Generated By: (b) (4)

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Date	Location	User	Value	Reason
Nov-16-2020 07:59:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error
Nov-11-2020 11:24:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Audit Trail
on Aug/17/2020

Form Version: 10-Oct-2020 16:04

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Date	Location	User	Value	Reason
Nov-16-2020 07:58:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error
Nov-11-2020 11:25:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Audit Trail
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Form Version: 10-Oct-2020 16:04

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Site No: 1019

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Subject No: 10191010

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Generated By: (b) (4)

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*** THIS REPEATING FORM HAS BEEN DELETED ***

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Date	Location	User	Value	Reason
Nov-16-2020 07:57:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error
Nov-11-2020 11:25:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Audit Trail
on Aug/17/2020

Form Version: 10-Oct-2020 16:04

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Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

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Date	Location	User	Value	Reason
Nov-11-2020 11:26:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Audit Trail
on Aug/17/2020

Form Version: 10-Oct-2020 16:04

Form Status:

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

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Date	Location	User	Value	Reason
Nov-11-2020 11:35:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020 Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Deleted, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

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1. Date:

Date	Location	User	Value	Reason
Nov-11-2020 08:28:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/27/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-11-2020 08:28:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Oxygen Saturation: 98.0	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-11-2020 08:28:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Nov-11-2020 08:28:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 98.0	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Deleted, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

*** THIS REPEATING FORM HAS BEEN DELETED ***

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1. Date:

Date	Location	User	Value	Reason
Nov-11-2020 08:28:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/27/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-11-2020 08:28:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Oxygen Saturation: 100.0	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-11-2020 08:28:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Nov-11-2020 08:28:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 100.0	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Deleted, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

*** THIS REPEATING FORM HAS BEEN DELETED ***

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1. Date:

Date	Location	User	Value	Reason
Nov-11-2020 08:28:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Aug/27/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-11-2020 08:28:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Record Identifier:: 1 Oxygen Saturation: 99.0	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-11-2020 08:28:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Nov-11-2020 08:28:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 99.0	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Deleted, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

*** THIS REPEATING FORM HAS BEEN DELETED ***

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1. Date:

Date	Location	User	Value	Reason
Nov-11-2020 08:29:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Aug/27/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-11-2020 08:29:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Record Identifier:: 1 Oxygen Saturation: 99.0	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-11-2020 08:29:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Nov-11-2020 08:29:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 99.0	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Deleted, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

*** THIS REPEATING FORM HAS BEEN DELETED ***

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1. Date:

Date	Location	User	Value	Reason
Nov-11-2020 08:29:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Aug/27/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-11-2020 08:29:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Record Identifier:: 1 Oxygen Saturation: 99.0	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-11-2020 08:29:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Nov-11-2020 08:29:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 99.0	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date:

Date	Location	User	Value	Reason
Nov-11-2020 08:29:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Aug/27/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-11-2020 08:30:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Record Identifier:: 1 Oxygen Saturation: 95.0	Transcription Error
Nov-11-2020 08:29:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Record Identifier:: 1 Oxygen Saturation: 99.0	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-11-2020 08:29:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Nov-11-2020 08:30:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 95.0	Transcription Error
Nov-11-2020 08:29:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 99.0	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Aug/17/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail
History

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Deleted, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

*** THIS REPEATING FORM HAS BEEN DELETED ***

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1. Date:

Date	Location	User	Value	Reason
Nov-11-2020 08:41:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/27/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-11-2020 08:41:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Oxygen Saturation: 100.0	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-11-2020 08:41:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Nov-11-2020 08:41:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 100.0	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Deleted, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

*** THIS REPEATING FORM HAS BEEN DELETED ***

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1. Date:

Date	Location	User	Value	Reason
Nov-11-2020 11:24:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Aug/28/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-11-2020 11:24:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Record Identifier:: 1 Oxygen Saturation: 97.0	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-11-2020 11:24:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Nov-11-2020 11:24:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 97.0	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Deleted, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

*** THIS REPEATING FORM HAS BEEN DELETED ***

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1. Date:

Date	Location	User	Value	Reason
Nov-11-2020 11:24:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/28/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-11-2020 11:24:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Oxygen Saturation: 99.0	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-11-2020 11:24:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Nov-11-2020 11:24:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 99.0	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Deleted, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

*** THIS REPEATING FORM HAS BEEN DELETED ***

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1. Date:

Date	Location	User	Value	Reason
Nov-11-2020 11:25:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/28/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-11-2020 11:25:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Oxygen Saturation: 99.0	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-11-2020 11:25:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Nov-11-2020 11:25:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 99.0	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Aug/17/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail
History

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Deleted, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

*** THIS REPEATING FORM HAS BEEN DELETED ***

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1. Date:

Date	Location	User	Value	Reason
Nov-11-2020 11:25:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/28/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-11-2020 11:25:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Oxygen Saturation: 99.0	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-11-2020 11:25:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Nov-11-2020 11:25:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 99.0	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date:

Date	Location	User	Value	Reason
Nov-11-2020 11:26:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/28/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-11-2020 11:26:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Oxygen Saturation: 96.0	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-11-2020 11:26:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Nov-11-2020 11:26:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 96.0	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date:

Date	Location	User	Value	Reason
Nov-11-2020 11:35:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/29/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-11-2020 11:35:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Oxygen Saturation: 93.0	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-11-2020 11:35:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Nov-11-2020 11:35:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 93.0	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: OXYGENATION PARAMETERS - eCRF Audit Trail History on Aug/17/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date Time of Assessment:

Date	Location	User	Value	Reason
Nov-11-2020 09:05:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Sep-21-2020 15:42:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

2. Arterial Blood Gases PaO2 (mmHg):

Date	Location	User	Value	Reason
Nov-11-2020 09:05:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Sep-21-2020 15:42:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

3. FiO2 (Fraction of Inhaled Oxygen):

Date	Location	User	Value	Reason
Nov-11-2020 09:05:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Sep-21-2020 15:42:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

090177e196ae3e27\Final\Final On: 01-Apr-2021 04:47 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History**Form Version:** 06-Jul-2020 21:55**Form Status:** Data Complete, Frozen, Verified**Site No:** 1019**Site Name:** (1019) Diagnostics Research Group**Subject No:** 10191010**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Sep-21-2020 15:42:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Sep-21-2020 15:42:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Sep-21-2020 15:42:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Sep-21-2020 15:42:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Sep-21-2020 15:42:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6. Ongoing?

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Sep-21-2020 15:42:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: IMAGING - eCRF Audit Trail History on Aug/17/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Assessment:

Date	Location	User	Value	Reason
Sep-21-2020 15:43:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Location of Assessment:

Date	Location	User	Value	Reason
Sep-21-2020 15:43:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Type of Imaging Exam:

Date	Location	User	Value	Reason
Sep-21-2020 15:43:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Assessment:

Date	Location	User	Value	Reason
Sep-21-2020 15:43:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-06-2020 13:23:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/6/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-06-2020 13:23:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-06-2020 13:23:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

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Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Dec-02-2020 13:51:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/2/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Dec-02-2020 13:51:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Dec-02-2020 13:52:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-02-2020 13:51:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Response to "Status" is LOST TO FOLLOW-UP but "Specify Status" is missing.
Dec-02-2020 13:51:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LOST TO FOLLOW-UP	Initial Entry

4. Specify Status:

Date	Location	User	Value	Reason
Dec-02-2020 13:52:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: lost to follow up	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

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Date	Location	User	Value	Reason
Sep-02-2020 07:32:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Sep-18-2020 09:30:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1019) Diagnostics Research Group

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Date	Location	User	Value	Reason
Oct-06-2020 13:19:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Not Complete

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Category:

Date	Location	User	Value	Reason
Sep-02-2020 07:32:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Sep-02-2020 07:32:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Sep-15-2020 10:03:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	CLINICAL - 14 Sep 2020 email from Salim Bouguermouh that SARS-COV-2 testing on 11 Aug 2020 and 01 Sep 2020 at the central lab were both Negative.
Sep-15-2020 07:49:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Sep-14-2020 14:44:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	NCS per PI
Sep-14-2020 14:21:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	completed
Sep-14-2020 12:08:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	CLINICAL SAE report of CT scan results report bilat lower lung nodules. Consider clinical

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Not Complete

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

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				significance and if needed, report as an adverse event
Sep-14-2020 11:13:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Opened	Clin: Per protocol Amendment 5 - Section 8.3.7., COVID-19 related event "DIARRHEA" does not qualify as AE and please should be documented ALSO on the COVID Illness CRF form. A Nasal SWAB will not be collected since the symptoms ended on 29Aug2020.
Sep-14-2020 11:13:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Clin: Per protocol Amendment 5 - Section 8.3.7., COVID-19 related event "DIARRHEA" does not qualify as AE and please should be documented ALSO on the COVID Illness CRF form. A Nasal SWAB will not be collected since the symptoms ended on 29Aug2020.
Sep-03-2020 14:55:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: Per protocol Amendment 5 - Section 8.3.7., COVID-19 related event "DIARRHEA" does not qualify as AE and please should be documented only on the COVID Illness

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Header Text: c4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Not Complete

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

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				CRF form. A Nasal SWAB will not be collected since the symptoms ended on 29Aug2020.
Sep-02-2020 07:32:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Diarrhea	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-18-2020 15:08:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-18-2020 15:08:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Sep-18-2020 14:09:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/17/2020 00:00	Transcription Error
Sep-18-2020 09:30:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	2nd AE entered to clarify
Sep-18-2020 09:30:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	2nd AE added to clarify
Sep-18-2020 07:53:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	ClinQuery SAE information states diarrhea began 8/17 & required hospitalization on 8/27. To report onset of diarrhea, consider a 2nd AE entry of diarrhea (non-serious) for 8/17-26, with appropriate grade.
Sep-18-2020 04:36:21 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: AER#2020339743

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Header Text: c4591001

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Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Not Complete

Site Name: (1019) Diagnostics Research Group

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Time (US & Canada)		(b) (4), (b) (6)		
Sep-02-2020 07:32:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/27/2020 00:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-21-2020 11:06:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Aug/27/2020 00:00	Transcription Error
Sep-21-2020 11:05:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Aug/29/2020 00:00	Transcription Error
Sep-21-2020 11:05:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Aug/27/2020 00:00	Transcription Error
Sep-02-2020 07:32:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Aug/29/2020 00:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-02-2020 07:32:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

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Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Not Complete

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

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Date	Location	User	Value	Reason
Oct-28-2020 23:27:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Query closed; will follow for SAE update with the requested COVID test info
Oct-28-2020 13:18:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	Follow-up form submitted.
Oct-25-2020 20:28:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	COVID testing has not been reported in the SAE submitted to safety. Please submit a follow-up SAE form [#2020339743] to provide whether COVID testing was performed (yes/no) and if yes, the results.
Sep-20-2020 08:31:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Deleted	Close Auto Query
Sep-18-2020 14:09:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Candidate	For AE Diarrhea: Response to "Is the adverse event serious?" is 'No' but "Serious Adverse Event Number" is present.
Sep-18-2020 14:09:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Transcription Error
Sep-03-2020 06:02:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Sep-02-2020 07:33:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query

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Site No: 1019

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Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Not Complete

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<p>Sep-02-2020 07:33:18 (UTC-06:00) Central Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p>Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? NO Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event YES</p>	<p>Transcription Error</p>
<p>Sep-02-2020 07:32:47 (UTC-06:00) Central Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>auto query (autoquery)</p>	<p>Query 2: Candidate</p>	<p>For AE Diarrhea: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.</p>
<p>Sep-02-2020 07:32:47 (UTC-06:00) Central Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>auto query (autoquery)</p>	<p>Query 1: Opened</p>	<p>'Is the adverse event serious?' is marked as YES, but responses to all of the seriousness criteria are NO. At</p>

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Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Not Complete

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

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				least one seriousness criterion is expected to be YES for serious events. Please review and update as appropriate.
Sep-02-2020 07:32:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>NO</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>NO</p>	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
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Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Not Complete

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

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Sep-02-2020 07:32:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-18-2020 14:10:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> Pre-Existing conditions	Transcription Error
Sep-02-2020 07:32:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> Unknown	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-02-2020 07:32:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-02-2020 07:32:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
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Site Name: (1019) Diagnostics Research Group

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Subject Initials: ---

Generated By: (b) (4)

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Sep-02-2020 07:32:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Sep-02-2020 07:32:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Sep-02-2020 07:32:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Sep-20-2020 08:31:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	AE 1 was updated to non serious and AE #2 was updated as Serious event
Sep-03-2020 06:02:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2020339743	Initial Entry

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Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Answered Queries

Site Name: (1019) Diagnostics Research Group

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1. Category:

Date	Location	User	Value	Reason
Oct-05-2020 14:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry
Sep-30-2020 07:20:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Sep-18-2020 09:30:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-05-2020 14:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry
Sep-30-2020 07:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Done	Initial Entry
Sep-30-2020 07:20:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Sep-18-2020 09:30:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Dec-17-2020 10:17:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 7: Closed	Response satisfies query

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Subject No: 10191010

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Answered Queries

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Subject Initials: ---

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Dec-17-2020 10:16:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Clo sed	Response satisfies query
Dec-17-2020 07:58:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 7: Ans wered	Updated SAE sent
Dec-17-2020 07:58:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Ans wered	updated SAE sent
Dec-06-2020 09:55:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 7: Ope ned	CLINICAL SAE report contains no relevant Med Hx conditions for event of Diarrhea; however Med Hx CRF contains potentially relevant conditions diabetes, diabetic neuropathy, chronic constipation (on Macrogel). Please review, and update SAE as appropriate
Dec-06-2020 09:49:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Rei ssued: Ope ned	CLINICAL Thank you. Updated SAE reports a primary infection (although site Unk); however, no anti-infective treatment was administered. Please update with the evidence for infection, or

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Subject No: 10191010

Generated By: (b) (4)

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				remove.
Dec-02-2020 13:10:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Ans wered	SAE submitted to address query
Nov-25-2020 09:56:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Ope ned	CLINICAL Please submit a SAE (#2020339743) followup with info on diarrhea treatment, & clarify statement "The primary infection site was known (as reported)"; eg which infection/what site/what was the workup for diarrhea & 'primary infection'
Oct-06-2020 22:14:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 5: Clo sed	Response satisfies query
Oct-05-2020 14:20:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry</u> : Diarrh ea	Initial Entry
Oct-05-2020 14:20:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry</u> :	Initial Entry
Oct-05-2020 14:02:39	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Ans	entered data

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(UTC-06:00) Central Time (US & Canada)			wered	
Oct-05-2020 07:51:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Clo sed	Response satisfies query
Oct-05-2020 07:25:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Clo sed	Clin query addresses this
Oct-01-2020 15:31:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 5: Ope ned	Clin: My apologies for the error. This SAE with no COVID positive result should be reported on both Covid visit and AE CRF forms to allow data reconciliation with safety database. Please enter the data a second time.
Oct-01-2020 09:53:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Ans wered	please delete entry. Per prior query. AE has been removed and moved to COVID illness CRF
Sep-30-2020 12:23:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 4: Ope ned	Null Term: Verbatim term must not be null/blank.
Sep-30-2020 10:49:59	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 3: Clo	Discrepancy has been closed.

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(UTC-06:00) Central Time (US & Canada)			sed	
Sep-30-2020 09:33:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Ans wered	please delete per prior query
Sep-30-2020 09:33:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Not A pplica ble	Initial Entry
Sep-30-2020 08:52:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 3: Ope ned	Null Term: Verbatim term must not be null/blank.
Sep-30-2020 07:20:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Ans wered	Transcription Error
Sep-30-2020 07:20:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry :	Transcription Error
Sep-30-2020 02:12:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Rei ssued: Ope ned	Clin: Per protocol COVID-19 listed symptom DIARRHEA should be please documented ONLY on the COVID Illness CRF form irrespective of other

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				diagnostics and regardless if a Nasal Swab was collected or SARS-COV-2 test was done
Sep-29-2020 12:54:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	No nasal swab was needed per PI. Per Medical Records, no SARS-COV-2 test was done.
Sep-29-2020 10:41:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Reissued: Opened	Clin: potential Covid illness visit CRF completed as ERRONEOUS VISIT, please clarify. Please confirm and provide the reason why no NASAL SWAB was collected. Please confirm that no SARS-COV-2 test was done since the subject was hospitalized.
Sep-29-2020 07:17:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	potential covid illness visit crf completed
Sep-23-2020 07:35:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Reissued: Opened	Clin: please COVID-19 protocol listed symptom DIARRHEA should HAVE triggered a COVID illness Visit irrespective of other potential diagnosis
Sep-21-2020 11:29:16	ACV0PFEINFP6000	Erica Weaver (b) (4)	Query 2: Closed	Site updated 1st outcome to 27/Aug,

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(UTC-06:00) Central Time (US & Canada)			sed	feels this is correct, do not requery for overlap, is ok with clinical.
Sep-21-2020 07:54:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Ans wered	AE entered to differentiate between Serious AE to Normal AE. Added per Clinical Trial team instruction
Sep-21-2020 07:39:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Ans wered	Per trial management team, Seperate AE needed to bridge time between normal AE to Serious AE
Sep-21-2020 01:04:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Ope ned	DMW4747349;This AE appears to be a duplicate with overlapping dates with another AE recorded on line 1. Please review if any updates are needed. If no updates are required, please clarify.
Sep-20-2020 21:41:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Ope ned	Clin: Per protocol COVID-19 listed symptom DIARRHEA should be please documented ONLY on the COVID Illness CRF form irrespective of other diagnostics. A NASAL SWAB will not be collected (symptom ended on 29Aug2020).
Sep-18-2020 09:30:20	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry	Initial Entry

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(UTC-06:00) Central Time (US & Canada)			Diarrhea
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4. Start Date Time:

Date	Location	User	Value	Reason
Oct-05-2020 14:01:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/27/2020 UNK:UNK	Initial Entry
Sep-30-2020 07:20:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-18-2020 09:30:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/27/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-05-2020 14:01:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Aug/29/2020 UNK:UNK	Initial Entry
Sep-30-2020 07:21:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-18-2020 09:30:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Aug/29/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-05-2020 14:01:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 4	Initial Entry

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Sep-30-2020 07:21:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-18-2020 09:30:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry

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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Mar-12-2021 13:47:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	FU SAE has been submitted.
Mar-08-2021 14:20:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Reissued:Opened	GPDCLIN: Please ensure a FU SAE is submitted if this serious criteria was not included in previous report.
Mar-08-2021 07:41:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	New Information
Mar-08-2021 07:41:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity?	New Information

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			NO Is this serious event life threatening? YES Other medically important serious event YES	
Mar-07-2021 23:41:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	GPDCLIN: Grade 4 event is a life threatening event however, answer to question: Is this serious event life threatening? is NO. Please review and clarify.
Mar-05-2021 06:54:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Candidate	GPDCLIN: Grade 4 event is a life threatening event however, answer to question: Is this serious event life threatening? is NO. Please review and clarify.
Mar-05-2021 06:54:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	re issued as candidate.
Mar-05-2021 06:46:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	GPDCLIN: Grade 4 event is a life threatening event however, answer to question: Is this serious event life threatening? is NO. Please review and clarify.
Oct-05-2020 14:01:12 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

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Time (US & Canada)		(b) (4), (b) (6)	<p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>YES</p>	
Sep-30-2020 07:21:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-20-2020 08:36:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Sep-18-2020 09:31:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-18-2020 09:31:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect?	Transcription Error

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			<p>h defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>NO</p>	
Sep-18-2020 09:30:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	For AE Diarrhea: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Sep-18-2020 09:30:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	'Is the adverse event serious?' is marked as YES, but responses to all of the seriousness criteria are NO. At least one seriousness criterion is expected to be YES for serious events.

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				Please review and update as appropriate.
Sep-18-2020 09:30:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry: YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>NO</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>NO</p>	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Oct-05-2020 14:01:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry: NO</p>	Initial Entry

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Sep-30-2020 07:21:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-18-2020 09:30:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-05-2020 14:01:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> Unknown	Initial Entry
Sep-30-2020 07:21:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-21-2020 13:24:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Samuel Dychter (b) (4)	Query 1: Closed	Response satisfies query
Sep-21-2020 07:56:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Sep-21-2020 07:56:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> Unknown	Transcription Error
Sep-18-2020 14:20:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Samuel Dychter (b) (4)	Query 1: Opened	GPD Clin: Can you please elaborate on what pre-existing

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				condition the SAE is related to?
Sep-18-2020 09:30:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> pre-existing condition	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-05-2020 14:01:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry
Sep-30-2020 07:21:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-18-2020 09:30:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Mar-10-2021 03:44:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-09-2021 14:23:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Mar-09-2021 14:23:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Transcription Error
Mar-09-2021 09:35:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	GPDCLIN: concomitant medication as well

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Form Version: 22-Apr-2020 21:02

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Answered Queries

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				as non-drug therapy are listed as NO. Please confirm no treatment was required.
Oct-05-2020 14:01:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
Sep-30-2020 07:21:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-18-2020 09:30:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-05-2020 14:01:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
Sep-30-2020 07:22:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-18-2020 09:30:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Oct-05-2020 14:01:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry
Sep-30-2020 07:22:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-18-2020 09:30:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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Subject No: 10191010

Generated By: (b) (4)

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Form Status: Data Complete, Answered Queries

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14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-05-2020 14:01:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
Sep-30-2020 07:22:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-18-2020 09:30:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Sep-20-2020 08:36:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2020339743	Initial Entry

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Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

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Form Status: Data Complete, Locked, Frozen

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1. Category:

Date	Location	User	Value	Reason
Oct-06-2020 13:19:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-06-2020 13:19:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-13-2020 14:45:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-13-2020 13:39:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	unable to clarify medical term. AE term will remain as written
Nov-13-2020 12:31:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	GPDClin: please clarify if there is a more precise medical term that can be provided. thank you
Nov-13-2020 07:10:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Pt was unable to recall what was stated a minute or two ago while talking on the phone. This is documented in a progress note
Nov-10-2020 23:35:25	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	GPDClin: Please

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(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)		consider further clarifying what was the exact change in mental status that was identified and update the term accordingly to allow accurate coding.
Nov-10-2020 09:27:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Candidate	GPDCLIN: Please consider further clarifying what was the exact change in mental status that was identified and update the term accordingly to allow accurate coding.
Oct-06-2020 13:19:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mental State Status Change	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-06-2020 13:19:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/2/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-06-2020 13:19:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/2/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-06-2020 13:19:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

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Form Status: Data Complete, Locked, Frozen

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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Oct-06-2020 13:19:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Oct-06-2020 13:19:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-06-2020 13:19:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment (s), this event is due to: OTHER If Other, specify: unknown	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-06-2020 13:19:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
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Site No: 1019

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Subject Initials: ---

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Oct-06-2020 13:19:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-06-2020 13:19:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Oct-06-2020 13:19:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-06-2020 13:19:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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1. Subject Status

Date	Location	User	Value	Reason
Dec-02-2020 13:51:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Initial Entry
Oct-06-2020 13:23:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-11-2020 16:03:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-11-2020 14:31:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Dec-02-2020 13:51:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Dec/2/2020	Initial Entry
Oct-06-2020 13:23:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/6/2020	Initial Entry
Aug-11-2020 16:03:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/11/2020	Initial Entry
Aug-11-2020 14:31:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/11/2020	Initial Entry

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Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1019

Subject No: 10191010

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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I. Casebook Signature

Date	Location	User	Value	Reason
Sep-15-2020 15:24:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry

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