16.1.10 Documentation of Interlaboratory Standardization Methods and Quality Assurance Procedures if Used

The following central laboratory was used in the study:

PPD Global Central Laboratory
2 Tesseneer Drive
Highland Heights, KY 41076
United States

The following additional local laboratories were used in the study:

Viracor Eurofins Laboratories
1001 NW Technology Drive
Lee's Summit, MO 64086
United States

PPD Vaccine Laboratory
PPD BioA Richmond
2256 C Dabney Road
Richmond, VA 23230
United States

NIH NIAID Vaccine Immunology Program
Vaccine Immunology Program
9 West Watkins Mill Road
Gaithersburg, MD 20878
United States

Battelle/BBRC – JS-3
1425 State Route 142
West Jefferson, OH 43162
United States

Duke University Medical Center
SORF Building
915 S. LaSalle Street
Durham, NC 27710
United States

Genotyping analysis of SARS-CoV-2 variants

Monogram Biosciences
345 Oyster Point Boulevard
South San Francisco, CA 94080
United States

Viracor Eurofins
1001 NW Technology Drive
Lee's Summit, MO 64086
United States

The following documents are provided in this section:

PPD Central Laboratory Manual, version 3.0 dated 10 Aug 2021

PPD Collection Flow Chart, version 7.0 dated 11 Mar 2021

PPD Collection Flow Chart, version 6.0B dated 05 Jan 2021

Central Laboratory Manual

Moderna TX, Inc.

mRNA-1273-P301

Laboratory Manual

Version 3.0

10AUG2021

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1 INTRODUCTION TO OUR SERVICES

1.1 WELCOME

PPD®Laboratories maintains state-of-the-art central laboratories that specialize in highly standardized safety, efficacy and biomarker testing services, as well as biorepository services. We provide flexible global lab services, including a wide spectrum of routine and sophisticated laboratory analyses. Our laboratory services are combined with expertise in clinical protocol design, data management and logistics to consistently deliver the performance needed for successful completion of Phase I-IV clinical trials.

Our representatives are able to assist with the following routine queries: copies of lab reports, requests for supplies, questions regarding specimen processing, corrections, and updates. If you should have any questions, please do not hesitate to contact us.

PPD Laboratories – US (for North, South and Latin America):

2 Tesseneer Drive
Highland Heights, KY 41076, USA
Email: siteservices.us@ppdi.com
Phone: +1 800 323 2996 or
+1 859 781 8877
Select Option 1 for Help Desk
Select Option 2 for Supplies
Fax: +1 859 781 9310
Hours of Operation: Mon-Fri: 07:30 – 18:00 (EST)
Saturday 08:00-14:00 (EST)

1.2 TOLL FREE PHONE ACCESS

The toll-free numbers listed below can be used to contact our Global Site Services help desk.

A specific code needs to be used when contacting the help desk-
Site Services help desk US (supports North America): (b) (4)

If your country is not listed, please use the general phone numbers in section 1.1.
***: Wait for second dial tone**

COUNTRY	WORLDWIDE TOLL-FREE ACCESS #
United States	(b) (4)

1.3 GLOSSARY OF LAB MANUAL ABBREVIATIONS AND TERMINOLOGY

- **Accession Number** – A unique, non-repeated identifier assigned to a data point or a set of data. There are accession numbers to define; patient-level data (which are 7 alpha-numeric digits and sample-level data (which are 11 alpha-numeric digits). Patient-level accession numbers can be found at the top left side of the laboratory reports. Sample-level accession numbers are reflected as sample barcodes throughout the study. Note, the barcode found on the top right of the requisition form is not a sample-level or patient-level accession number, but rather this is an identifier assigned to that particular Laboratory Kit.
- **Ambient Temperatures** – Typical room temperatures, without refrigeration or freezers involved. Extremely high temperatures should be avoided.
- **AWB** – Air waybill. A document completed by the site when shipping samples to a defined location via a shipping courier.
- **Bulk Supplies** – Any supplies provided in bulk to a site, outside of the laboratory kits.
- **CBC** – Complete Blood Count. Typically, this is a reference to a Hematology Panel with either an Automated or Manual Differential cell count.
- **CFC** – Collection Flow Chart. A document providing the schedule of laboratory events, including expected samples per visit, processing instructions, kit assignments, estimated blood volumes and other critical sample information. This document is provided to sites with their initial lab supplies.
- **Collection Kit** – Also called a Laboratory Kit. A pre-packaged, built-to-order set of laboratory supplies utilized to collect a specific set of samples for a designated visit. Each kit contains a Requisition Form which pairs with the specific containers and barcoded items found within that kit. Some visits require more than one kit and/or bulk supplies additionally to complete all necessary collections for a visit. A packing list of included supplies can also be found in each kit. Refer to the PPD Collection Flow Chart for details per study.
- **CCS** – Courier Contact Sheet. A form provided to sites in each region containing courier contact information, pickup times and transit times for the designated courier. Some couriers will provide a Site Specific Instructional Letter to sites directly in lieu of this Courier Contact Sheet which is provided by PPD Laboratories for other couriers.
    - Most EMEA sites (except few countries, ex. Israel, Russia, Ukraine) need to complete the Dry Ice Order Form (DIOF) or Site Specific Booking Form and send it to the designated email/fax number mentioned on the form.
      For TNT only: Once dry ice is delivered to the site, site would need to book a collection via local Healthcare phone number mentioned on the CCS.
    - Russia, Ukraine, Israel and APAC sites need to call the local Healthcare helpdesk as per received CCS or Site Specific Instructional Letter and book dry ice/collection.
- **Critical Values** – Also referred to as Voice Alerts. These are laboratory results which indicate a potential, serious patient safety concern.
- **DCR** – Demographic Changes Request Form. A document provided to sites with their initial supply which the site can fax or email to PPD Site Services in order to correct data points for a patient or lab collection event.
- **DSR** – Daily Site Report (also known as a Laboratory Report)
- **Exception** – Also referred to as a Query. A request for clarification regarding information and/or samples received from a site due to a potential discrepancy in expected data.
- **Flags** – Notifications added to specific Laboratory Report results according to protocol requirements, reference range deviations and/or other important criteria. Flags are meant to draw attention to specifics of interest or concern, but do not define eligibility for a patient. As such, these are informative, but the Investigator and Sponsor must make actual patient eligibility decisions. PPD Laboratories does not determine patient eligibility.
- **Frozen Temperatures** – Typically, a range from -20° Celsius or colder
- **IATA** - International Air Transport Association.
- **Preclarus® Investigator Site Portal**– This is an online web-portal provided by PPD Laboratories for sites to be able to online accession, access their laboratory reports, view their site-specific open queries and to view supplies on hand and reorder further supplies.
- **Laboratory Kit** – Also called a Collection Kit. A pre-packaged, built-to-order set of laboratory supplies utilized to collect a specific set of samples for a designated visit. Each kit contains a Requisition Form which pairs with the specific containers and barcoded items found within that kit. Some visits require more than

one kit and/or bulk supplies additionally to complete all necessary collections for a visit. A packing list of included supplies can also be found in each kit. Refer to the PPD Collection Flow Chart for details per study.

- **Packing List** – An informative document provided within each Laboratory Kit noting all supplies found within that kit, including any specific barcodes applied to containers in that kit.
- **PPD help desk** – Also referred to as PPD Global Site Services. A dedicated team supporting sites globally for general questions, supply orders, query resolution and data updates for each study. There are regional team locations supporting defined regions as described in this Laboratory Manual. Contact information for each regional team can also be found at the bottom of the Collection Flow Chart for the study.
- **PPD Global Site Services** – Also referred to as the PPD help desk. A dedicated team supporting sites globally for general questions, supply orders, query resolution and data updates for each study. There are regional team locations supporting defined regions as described in this Laboratory Manual. Contact information for each regional team can also be found at the bottom of the Collection Flow Chart for the study.
- **PPD US** – PPD's Laboratory facility in the United States of America, located in Highland Heights, Kentucky
- **Query** – Also referred to as an Exception. A request for clarification regarding information and/or samples received from a site due to a potential discrepancy in expected data.
- **Reference Range** – The normal range of laboratory results according to PPD Laboratories for a specific assay and population.
- **Refrigerated Temperatures** – 2° to 8° Celsius
- **Requisition Form** – A two-part (white top page, yellow second page) document provided within Laboratory Kits which sites complete and submit with samples found within that kit to PPD Laboratories. The information received from this document is loaded into the PPD Laboratory database for that patient and lab event. The white, top copy should be submitted to PPD Laboratories with the first shipment of samples per visit. The yellow copy should be retained at the site. When submitting frozen samples on a subsequent basis for a visit with samples already submitted previously, a second copy of the same form should not be re-submitted again to PPD Laboratories.
- **RPM** – Revolutions per Minute.
- **Specimen Received Statement** – A report provided to sites after submission of samples to PPD Laboratories. Upon receipt of the requisition form for a visit, this report will be sent to sites to note all samples which have been received as well as any expected samples for that visit which have not yet been received. Sites should retain these reports for their records and follow up with PPD Laboratories for any samples expected but not yet received.
- **Supply Reorder Form** – A document provided to sites with their initial supply which the site can fax or email to PPD Site Services to re-order supplies.
- **Voice Alerts** – Also referred to as Critical Values. These are laboratory results which indicate a potential, serious patient safety concern.

1.4 HOLIDAY SCHEDULE

PPD Laboratories will be closed and unable to receive shipments on the holidays listed below. Please consider these holidays, as well as transit times from your site, when scheduling subject visits around these days.

Please check with your courier regarding local holidays, as these vary between regions and may affect shipments from your site, even if PPD Laboratories is open and able to receive samples.

PPD Laboratories US

New Year's Day	01 Jan 2020	01 Jan 2021	01 Jan 2022
Memorial Day	25 May 2020	31 May 2021	30 May 2022
Independence Day	04 Jul 2020	04 Jul 2021	04 Jul 2022
Labor Day	07 Sep 2020	06 Sep 2021	05 Sep 2022
Thanksgiving Day	26 Nov 2020	25 Nov 2021	24 Nov 2022
Christmas Day	25 Dec 2020	25 Dec 2021	25 Dec 2022

1.5 Preclarus® Investigator Site Portal

Preclarus® Investigator Site Portal is a secure web portal for:

- Online accessioning of samples (at the collection site) to strengthen chain of custody and make samples available for testing sooner.
- On-site biorepository tools to help manage samples and track them to their final destinations.
- Simplified subject registration with real-time error checking and resolution to ensure data integrity.
- Automatic alerts for critical values to facilitate patient management.
- Online collection kit ordering and inventory management.
- Built-in reports to help trend lab results and manage patients.

The portal can be accessed at: http://preclaruslabdata.ppdi.com

User Account Activation

Upon initial site address entry performed by **PPD® Laboratories Database**, an activation email is sent to the Principal Investigator's and/or Study Coordinator's email address.

The Principal Investigator or Study Coordinator is required to complete the following steps to activate the account:

- Click on the link within the email to activate site
- USER ID = email address
- Create password and enter your name at prompt
- Email account activation link will expire after seven calendar days after receipt.
- Contact the local Investigator Services help desk if activation has expired in order to have another activation email sent.
- Log into account using the newly created password and the user id (email address)

The complete User Guide and videos are available online and can be accessed by selecting the Help tab within the portal.

1.5.1 Electronic Lab Requisition(EREQ):

Register a new subject for clinical study

Enter the details in the online requisition and sample accessioning form

View the existing requisition form for a clinical study

1.5.2 Reports:

View Lab reports

1.5.3 Views

Patient level results trending
Result filtering
Graphs and Charts
Subject Demographics

1.5.4 Queries Center:

View, print and respond to queries raised by **PPD® Laboratories Central Labs** pertaining to any discrepancies in a particular study

1.5.5 Supplies:

Request re-supply order

Inventory management tools

Order Tracking

Alerts and Reminders

1.5.6 Documents:

View and print investigator manuals and other site documents available

1.5.7 Shipments:

Create Shipments and assign air waybills
Shipment History

1.5.8 User Details:

The User Details tab is available for all users with administrator access, the Study Coordinator does not have access to the User Management 'Investigator Role' unless the PI grants access.

1.5.9 User Management:

The administrator account access will allow the user to Add/Remove account access for site personnel.

1.5.10 Contact US:

Display contact information for PPD® Laboratories Central Labs across the globe.

1.5.11 Help:

User guides and training materials

1.5.12 Alert Box:

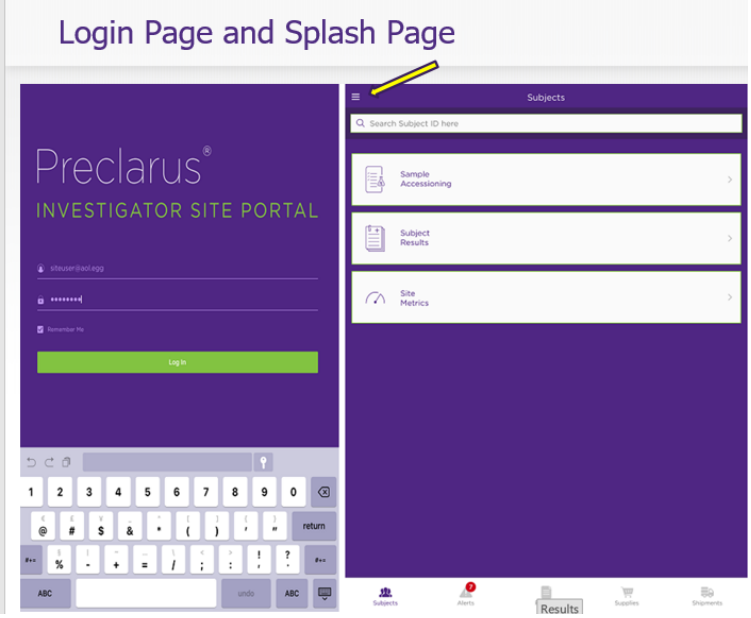
Critical Alerts- section shows the number of critical reports with an out of reference range value that requires attention. Click the link to view the critical reports
Open queries -section shows the number of queries that require a response. Click the link to view the Query Center page
Unshipped Samples- section shows the number of samples not shipped to PPD® Laboratories Central Labs. Click link to view the unshipped samples report.
View Missing Samples -link allows you to view a list of samples not recorded in the subject's visit. Click the link to view the missing samples report. In addition, you can update the status for the missing samples and generate a printed report
New subject- results section shows the number of subject reports not viewed across all authorized, protocols and site during the last 5 days

1.5.13 News Ticker:

This section displays latest news related to PPD® Laboratories Central Labs, highlighting all the latest and current happenings.

1.5.14 Mobile Application:

- For Site Members Only.
- Downloadable Mobile application available:
  - Google Play store (Android or Android Tablet 5+)
  - Apple iTunes application store (IOS for phone or tablet 10+)



Accounts are created just the same as Preclarus Lab Data for SITE USERS!

1.5.15 Preclarus Contingency Plan:

Contact PPD Global Site Services help desk by phone or email if you are not able to use Preclarus (see section 1.1) or your local site service help desk (see section 1.2)

Site service help desk can support:

- Closure of queries
- Acknowledgement of critical alerts
- Re-ordering of supplies and demographic change requests
- Online accessioning
- Shipping samples with a paper requisition from please refer to Appendix III REQUISITION FORMS
- To register samples on line please refer to 4.1 ONLINE ACCESSION

2 LABORATORY SUPPLIES

KEY POINTS FOR THIS SECTION:

- Initial Supplies are triggered by the clinical team. Kits required later in the study are not included in the initial supply and need to be ordered by the site closer to date of actual need.
- Resupply Orders are triggered by the site. These can be made through the Preclarus® Investigator Site Portal.
- **PPD Laboratories requires a minimum of 5 business days to process an order with an additional 3-5 business days for transit time based on courier requirements and location of site (see section 2.4.2).**
- Please note it is the site's responsibility to monitor supplies for quantity and expiration dates. PPD Laboratories does not automatically send resupplies to sites.
- **Do Not Use Expired Kits.** If samples are collected in an expired kit results may not be reported.

2.1 VISIT-SPECIFIC COLLECTION KITS

At study start you will be provided with visit-specific PPD Laboratories collection kits. It is possible that multiple visits will use the same kit type or that a single visit will use multiple kit types.

Each kit type (A, B, C, …), or a combination of kits will contain all tubes and requisition forms needed for the collection of all samples for a certain visit. The kit box, which contains the collection supplies, doubles as the ambient mailer for the return shipment of samples to the central lab. Instructions pertaining to sample packaging are found in Section 5.

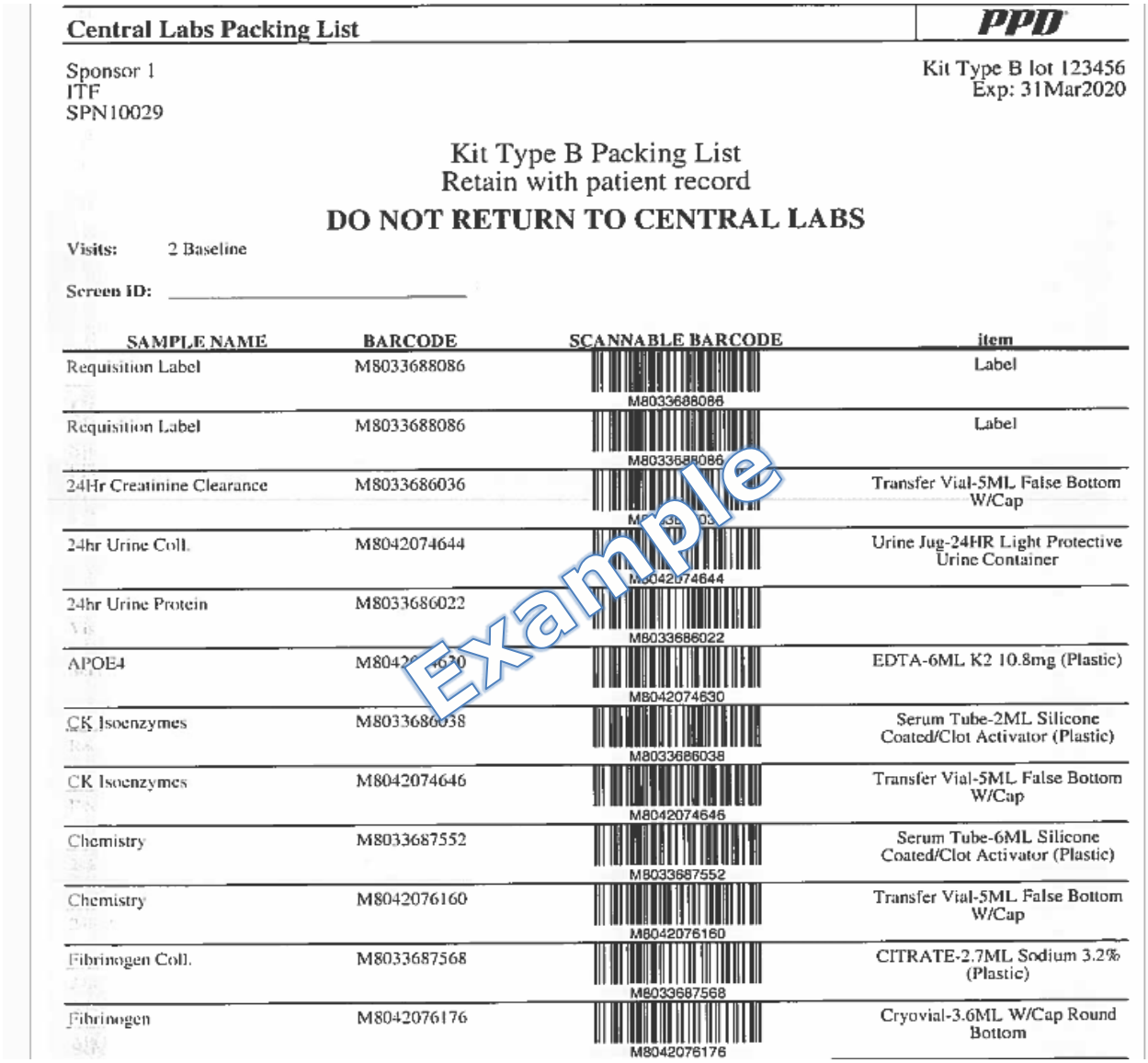
On the Collection Flow Chart provided to you separately, you can find information on which kit(s) to use for which visit.

Expiry dates will be clearly marked on the label that is placed on the outside of the collection kit box. The expiry date is always reflective of the tube that expires the earliest. The expiry date displayed on the label is good to the last day of the month displayed unless otherwise noted

Each kit is labeled with the following information **but not limited to:**

- Protocol reference
- Visit(s)
- Kit lot number
- Expiration date

A packing list will be included within each kit detailing the kit contents. When the kit is selected for use, enter the patient identifier and retain the list on site for your records.



Central Labs Packing List PPD

Sponsor 1
ITF
SPN10029

Kit Type B lot 123456
Exp: 31Mar2020

Kit Type B Packing List
Retain with patient record

DO NOT RETURN TO CENTRAL LABS

Visits: 2 Baseline

Screen ID: _____

SAMPLE NAME	BARCODE	SCANNABLE BARCODE	item
Requisition Label	M8033688086	M8033688086	Label
Requisition Label	M8033688086	M8033688086	Label
24Hr Creatinine Clearance	M8033686036		Transfer Vial-5ML False Bottom W/Cap
24hr Urine Coll.	M8042074644	M8042074644	Urine Jug-24HR Light Protective Urine Container
24hr Urine Protein	M8033686022	M8033686022	
APOE4	M804 4630	M8042074630	EDTA-6ML K2 10.8mg (Plastic)
CK Isoenzymes	M8033686038	M8033686038	Serum Tube-2ML Silicone Coated/Clot Activator (Plastic)
CK Isoenzymes	M8042074646	M8042074646	Transfer Vial-5ML False Bottom W/Cap
Chemistry	M8033687552	M8033687552	Serum Tube-6ML Silicone Coated/Clot Activator (Plastic)
Chemistry	M8042076160	M8042076160	Transfer Vial-5ML False Bottom W/Cap
Fibrinogen Coll.	M8033687568	M8033687568	CITRATE-2.7ML Sodium 3.2% (Plastic)
Fibrinogen	M8042076176	M8042076176	Cryovial-3.6ML W/Cap Round Bottom

Example

2.2 INITIAL SUPPLIES

PPD Laboratories will provide you with the supplies required to collect, prepare and ship samples for this study. Initial Supply orders are ordered/requested by the Clinical Team.

Initial supplies may include the following:

- PPD Laboratories Collection Kits – enough for a pre-determined amount of subjects and visits
- Courier Information and pre-printed air waybills
- Laboratory Manual
- Collection Flow Chart
- Shipping boxes and material (if applicable)
- General bulk ancillary supplies (if applicable)

Please note that kits required later in the study may not be included in the initial supply and will need to be ordered by the site closer to the date for which they will be required.

2.3 RE-ORDERING OF SUPPLIES

You will be alerted via the Preclarus® Investigator Site Portal if your inventory drops below a pre-defined threshold so that you can determine if you need to order additional supplies.

Supplies can be reordered:

1. Through the Preclarus® Investigator Site Portal **(Recommended)**
2. Investigator Site Services will accept phone orders as well as email orders

   Note: Please refer to section 1.5.15 Preclarus Contingency Plan if a re-supply order form is needed

When ordering supplies through the Preclarus® Investigator Site Portal (see Section 1.5 Preclarus® Investigator Site Portal), a confirmation email will be sent automatically to your site's email address.

Re-orders should be placed enough in advance of need to allow for processing and shipment of the order. PPD requires 5 business days to process orders (see section 2.4.2 for transit times)

2.4 DELIVERY TRANSIT TIMES

2.4.1 Supplies are shipped from:

PPD US: North America

2.4.2 Expected transit times *:

North America 3-5 business days

Actual delivery times may vary due to custom constraints, special documentation requirements or weather-related issues beyond our control. Countries in need of importation approvals will be processed 5 business days after importation approval is received from the clinical team.

3 SPECIMEN COLLECTION GUIDE

KEY POINTS FOR THIS SECTION:

- Respect good phlebotomy practices to obtain good quality specimens.
- Check if your subject is to be fasting based on the protocol.
- The subject is to be seated at least five minutes prior to blood collection.
- Refer to the Collection Flow Chart for the order of draw, specimen processing and shipping instructions.

3.1 PHLEBOTOMY

It is the responsibility of the principal investigator and/or site coordinator to assure that the person(s) performing phlebotomy are appropriately trained per local regulations and are using good phlebotomy technique.

Tips for Good Phlebotomy:

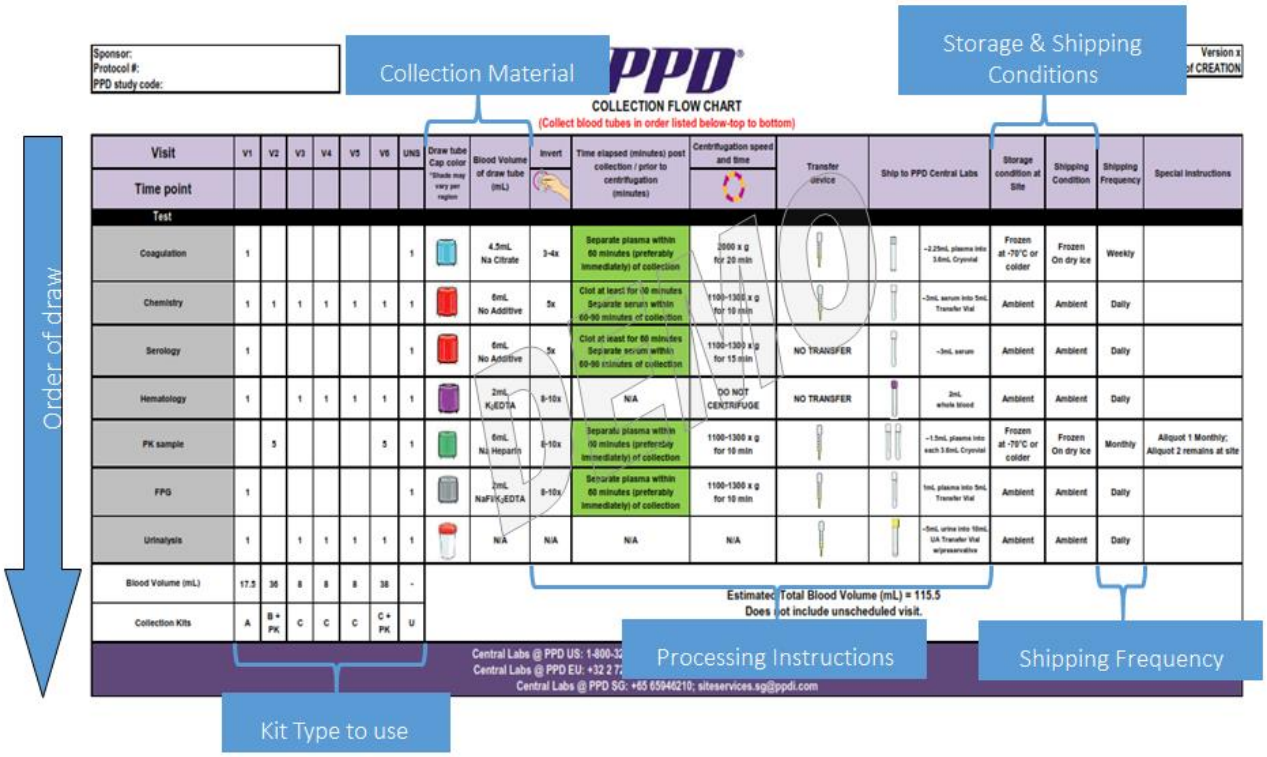
- Place Tourniquet 7 to 10 cm above the venipuncture site. If using a blood pressure cuff as a tourniquet, inflate to 40 mm Hg.
- Tourniquet application for preliminary vein selection should not exceed one minute as localized stasis with hemoconcentration and blood infiltration into tissue may occur. This may result in erroneously elevated protein-based analytes.
- The subject may close their fist but should NOT pump their fist. This may cause changes in certain analytes such as potassium.
- Clean the area with a 70% isopropyl alcohol pad using a circular motion from the center to the periphery. ***Allow the area to air dry*** to prevent hemolysis and to prevent the subject from experiencing a burning sensation.
- Needle selection:
  - Use the needle provided in the kit.
  - In the case of using a butterfly needle make sure to fill first a discard tube to allow the dead volume of 0.5ml to be eliminated before collecting the tubes for this study
- Release the tourniquet as soon as possible after the blood begins to flow
- Allow the tube to fill completely. Under filling may cause erroneous results, especially for coagulation studies.
- Immediately mix each tube as defined on the Collection Flow Chart.

3.2 SPECIMEN COLLECTION

You have been provided a **Collection Flow Chart** with your initial supplies. This flow chart is a separate document from the PPD Laboratories Manual. The flow chart will provide you an overview of the collections needed for this study at designated visits.

Blood collection tubes must be **drawn in the order displayed** on your Collection Flow Chart to avoid cross contamination between different types of tubes (with or without additives).

The following is only an example.



3.3 CENTRIFUGATION SPEED

For best results, please centrifuge your samples as per the instructions on the Collection Flow Chart provided for this study.

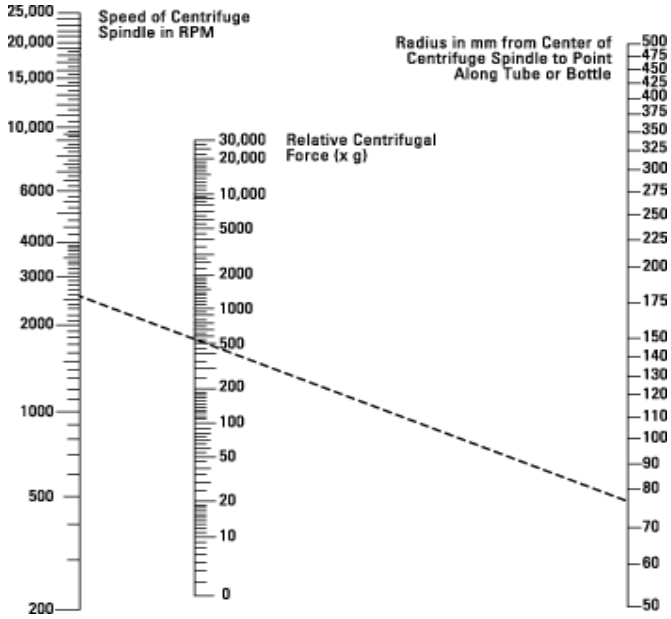
As the relative centrifugal force varies with the radius of the centrifuge, the table below will assist with determining the right speed setting of the centrifuge. Measure the distance from the center of the centrifuge (rotating axis) to the end of the tube (radius).

Determine the right speed (rpm) using the table below:

$$RCF = 1.12 \times 10^{-5} \times r \times (RPM)^2$$

$$RPM = \sqrt{\frac{RCF}{1.12 \times 10^{-5} \times r}}$$

- RPM: revolutions per minute (speed of the centrifuge)
- RCF: relative centrifugal force (the centrifugal force generated = g)
- r (radius, in cm): the distance from the center of the centrifuge head to the bottom of the tube holder in the centrifuge bucket



4 SAMPLE LABELING & IDENTIFICATION

KEY POINTS FOR THIS SECTION:

- Draw tubes and transfer tubes will be provided pre-labeled.
- Write clearly on each label in English.
- Complete the secondary ID on every tube (typically this is the full patient Screening #). Incomplete or missing information could delay reporting.
- Prepare a Requisition form for every kit used. Note, a paper requisition form is not required when using the Preclarus® Investigator Site Portal to accession samples on-line.
- Once a kit has been used, the remaining tubes in the kit must be discarded.
- The first shipment of every kit should include the white portion of the requisition form.
- Keep the yellow portion of the Requisition form at the site.
- The visit and patient information on the requisition form is critical to accession samples.
- Incomplete or missing requisition forms will delay testing and put your lab report on hold!
- Retain the PPD Laboratories Packing List (inside each kit box) at the site for your record. Please do not ship to back to PPD Laboratories.
- Additional tubes may be used from another kit provided the sample name is EXACTLY the same. The entire kit must be discarded after removal of any pre-labeled items. Send the requisition form from each kit and discard unused tubes from the additional kit.

4.1 PPD PRE-LABELED TUBES

Please use requisition form(s) provided per kit. The kit contains all pre-labeled tubes required for a particular visit. All specimens shipped to PPD Laboratories need to be identified with a secondary ID.

Each label has a unique 11-digit identifier (barcode): e.g. A1234567890.

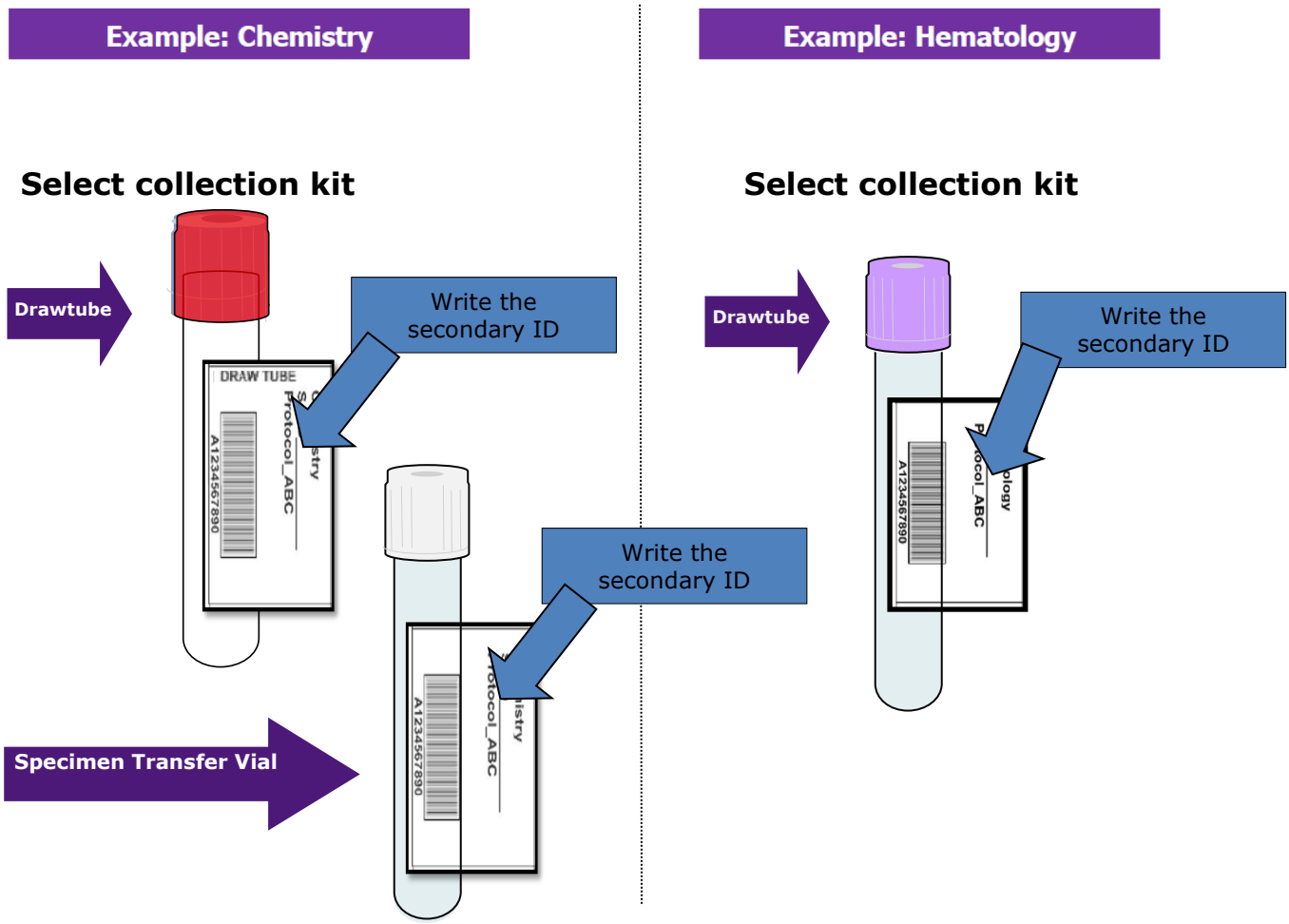
4.1.1 Tube labeling

Both the collection tubes and/or transfer vials are provided pre-labeled. Write the secondary identifier clearly using a blue or black pen only (AP material use markers) on both the draw tube and transfer vial to prevent mix up. The word draw tube will be specified on the draw tube label.

For some samples where the draw tube is required to be processed at the site, this should be discarded after the processed sample has been aliquoted into the appropriate transfer tube. For other samples, the draw tube will not be processed at site and will need to be sent to PPD Laboratories. Instructions for this will be located on the collection flowchart to advise which tubes should be sent to PPD Laboratories.

a) Example of a specimen with a transfer vial

b) Example of a specimen without a transfer vial



4.2 ELECTRONIC LAB REQUISITION(EREQ)

The Preclarus® investigator site portal was designed to make it easier for clinical trial sites to manage their PPD trials. The reports and tools within the Preclarus investigator site portal simplify every process including: adding patients to the trial; ordering sample collection kits; reviewing lab results; managing patients and critical values; and accessioning and shipping samples to PPD® Laboratories central lab.

The Preclarus investigator site portal provides:

- ✓ Up to 67% reduction in queries and data discrepancies when Preclarus is activated and in use.
- ✓ Electronic Lab Requisition(EREQ) of samples (at the collection site) to strengthen chain of custody and make samples available for testing sooner.
- ✓ Onsite bio-repository tools to help manage samples and track them to their final destinations.
- ✓ Simplified subject registration with real-time error checking and resolution to ensure data integrity and make it easy to add new subjects to the trial.
- ✓ Automatic alerts for critical values to facilitate patient management.
- ✓ Online collection kit ordering and inventory management to ensure the right kit is there when needed.
- ✓ Built-in reports with the ability to export data tables and graph results.
- ✓ Site metrics and feedback for a useful view into key activities.

Video Part 1 (Overview)
https://www.youtube.com/watch?v=Y7jtpV_098k

- Electronic Lab Requisition(EREQ)
- Registration & Requisitions
- Reporting
- Viewing Results & Subject Demographics
- Resolving Queries
- Ordering & Tracking Supplies
- Downloading Documents
- Preparing Sample Shipments
- Subject Search
- Help Section

Video Part 2
https://www.youtube.com/watch?v=mmiTfUewPrg

- Viewing PDF Reports
- Managing Supplies
- Using the Query Center
- Viewing Documents

5 SITE STORAGE OF SAMPLES PRIOR TO SHIPMENT

Follow the PPD Laboratories Collection Flow Chart for each study regarding appropriate storage temperatures and length of storage prior to shipping for each sample type.

PPD Laboratories is not involved in monitoring of site storage unit temperature logs and/or notifications of excursions from expected temperatures for samples stored on-site.

Sites should maintain appropriate temperature records for their refrigeration and freezer units on-site, including any necessary documentation for temperature excursions that occur.

The study sponsor and clinical monitoring team should be notified accordingly by the site if the refrigeration or freezer units utilized on site have temperature excursions outside of sponsor-defined ranges acceptable for those units while containing laboratory samples for each study.

KEY POINTS FOR THIS SECTION:

- Refer to your courier contact sheet or site specific instructional letter for all information on how to organize a shipment.
- Respect last call times to ensure that your pick-up still occurs on the same day.
- Your kit box can be used as an ambient shipping box [apply air waybill (AWB) on the bottom].
- Ship ambient samples according to the Collection Flow Chart instructions, typically on the day of collection.
- Avoid shipping frozen samples over the weekend.
- Dry ice delivery on Monday is not possible for all sites in US.
    - Dry ice can be ordered for delivery on Friday and keep at site until Monday shipment but should be avoided when possible.
- PPD is able to receive samples from Monday through Saturday.

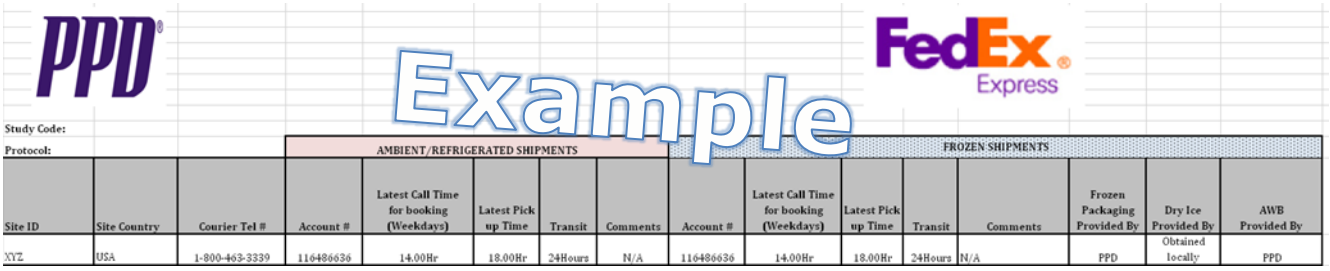
DO NOT forget to apply a Saturday Delivery sticker on your shipping box (ambient or frozen) for all sites in EU and US when shipped on a Thursday (sites in 48hr zone) or Friday (sites in 24hr zone).

5.1 COURIER INFORMATION

Depending on your courier you will receive a Courier Contact Sheet or site specific instructional letter separately or within your initial lab supply shipment that will contain the following site-specific courier information:

- Courier booking center telephone number
- Courier account number
- Last call time for booking to ensure same day pick-up
- Who to contact to obtain shipping materials
- How to order dry ice – (Sites located in the USA will obtain dry ice locally.)

Note: Sites located in the USA will receive packaging supplies from PPD and must contact their local FedEx for information on last call in times.



Study Code:
Protocol:

			AMBIENT/REFRIGERATED SHIPMENTS					FROZEN SHIPMENTS							
Site ID	Site Country	Courier Tel #	Account #	Latest Call Time for booking (Weekdays)	Latest Pick up Time	Transit	Comments	Account #	Latest Call Time for booking (Weekdays)	Latest Pick up Time	Transit	Comments	Frozen Packaging Provided By	Dry Ice Provided By	AWB Provided By
XYZ	USA	1-800-463-3339	116486636	14.00Hr	18.00Hr	24Hours	N/A	116486636	14.00Hr	18.00Hr	24Hours	N/A	PPD	Obtained locally	PPD

5.1.1 Frozen samples

We recommend sending dry ice shipments Monday through Wednesday to ensure arrival before the weekend. Remember to include the amount of dry ice in kgs on your frozen shipper and use a dry ice waybill (UN1845 preprinted on waybill).

5.2 ORGANIZING A PICK-UP

1) Call/email/fax the courier at the number/email address specified on your courier contact sheet or site specific instructional letter before the last calling time.
2) Provide the account number.
3) Pack your samples as detailed in the "Packaging instructions".
4) Provide shipping box to courier at pick-up. Retain a copy of the air waybill (AWB) and/or AWB number on site.

5.3 ORDERING DRY ICE

1) North America

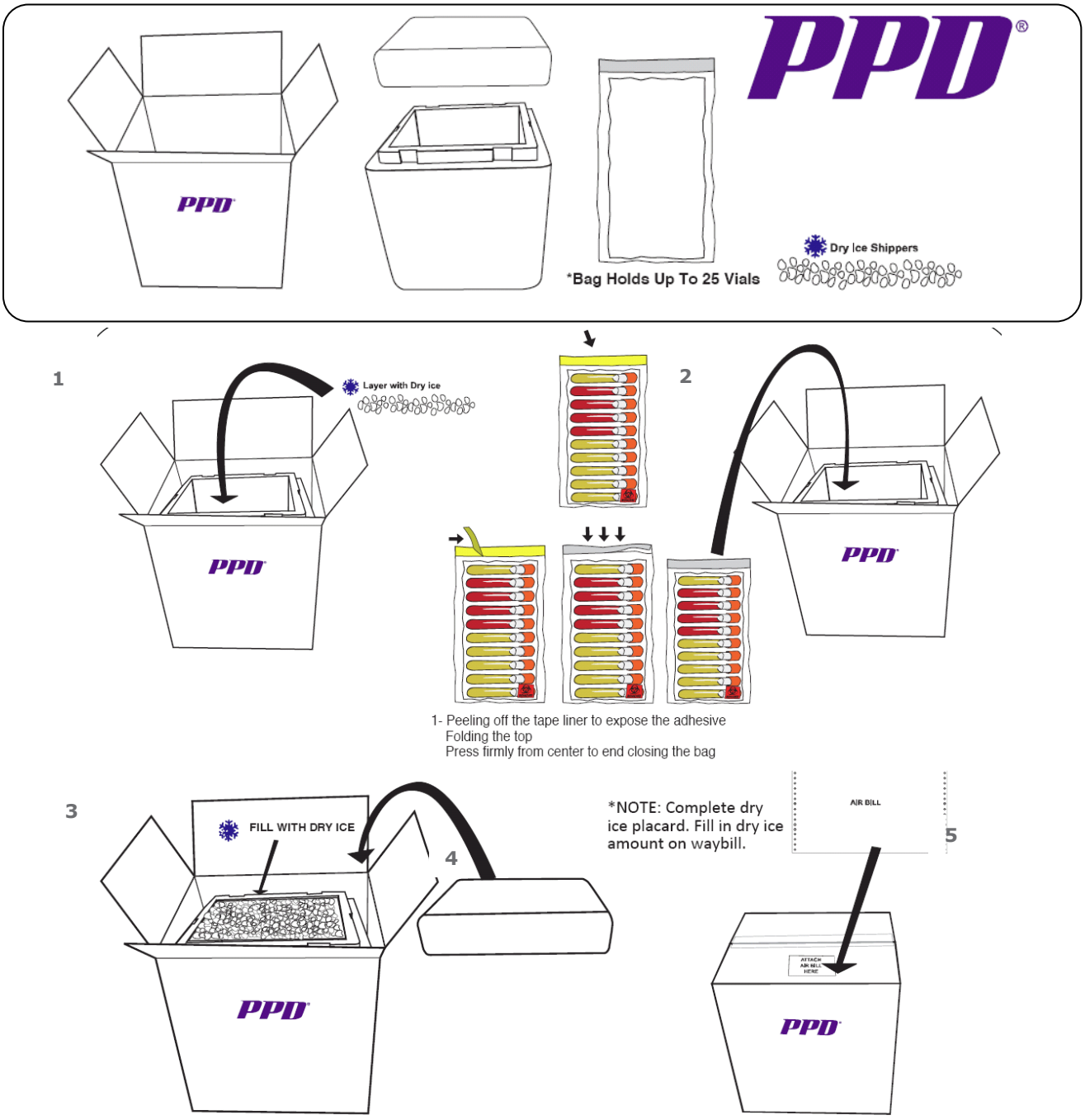
- Dry ice is to be obtained locally unless otherwise specified by PPD Laboratories per study.
- When dry ice is NOT available in your location, additional arrangements are available. Please contact your local Site Services help desk for assistance.
- Shipping boxes will be provided to you by PPD.
- Air waybills (AWB) will be provided to you by PPD. Note that when supply orders indicate "DIRECT–SHIP", PPD will order the waybills for your site which will be shipped directly to you via the courier instead of PPD.

5.4 PACKAGING INSTRUCTIONS

5.4.1 Frozen Specimens (Dry Ice)

The list of contents may have been printed on your shipping box for your convenience. Please complete the applicable fields where indicated.

When using PPD box:



1. Directly prior to packing, insert the frozen vials into the specimen bag(s) and seal tightly.
2. Place the sealed specimen bag(s) into the inner box.
3. Layer the bottom of the inner box with dry ice and place the sealed specimen bag(s) into the inner box. Note that each dry ice shipper comes with the appropriate, maximum number of sample bags that should be utilized for that shipper. Each sample bag holds up to a maximum of 25 samples per bag. Do not exceed the number of samples per bag or the number of specimen bags per shipper beyond what is provided with each shipper. If this guidance is not followed, there may be insufficient dry ice for the transport and the samples may be thawed during transit.

IMPORTANT NOTE: If samples are received at the incorrect condition at PPD Labs from the site, the site will be notified via query of the issue. The site should work with the sponsor and CRO team to determine if the sample must be replaced or re-drawn due to the error.

4. Add additional dry ice until the box is completely filled. Ensure that an appropriate amount of dry ice, including at least the minimum amount described below per dry ice shipper type, is included in the box.
5. Place the Styrofoam lid on top of the inner box and place the list of contents on top of the lid along with a copy of the requisition form. Ensure that the requisition form is NOT placed inside the container with the dry ice itself or it may be damaged during transit, resulting in potential issues on receipt.
6. Note that if your frozen shipper has the list of contents printed on the inner flap of the box it will not be necessary to complete the list of contents form, simply fill in the information on where applicable.
7. Close the outer cardboard box.
8. Apply the AWB to the top of the box. When dry ice weight is not already pre-filled, entry of the weight is required to be hand entered prior to the courier accepting the package.

North America: Dry Ice Shipper Capacities (typically provided by PPD Labs)

Description of Shipping Box (Refer to PPD Site Portal description per box if ordered via PPD)	Min Amount of Dry Ice	Max Wt of Shipper	Maximum # of Samples	Number of Transit Hrs Sample Remains Frozen Assuming Filled with Dry Ice Weight Required
Box-Frozen Shipper-5lb. W/(1) Sample Bag Max/25 Samples	5 lbs	6 lbs	25	36 Hours
Box-Frozen Shipper-10lb. W/(2) Sample Bags Max/50 Samples	7 lbs	10 lbs	50	48 Hours
Box-Frozen Shipper-20lb. W/(3) Sample Bags Max/75 Samples	15 lbs	20 lbs	75	60 Hours
Box-Frozen Shipper-40lb. W/(4) Sample Bags Max/100 Samples	32 lbs	40 lbs	100	98 Hours
Box-Frozen Shipper-50lb. W/(8) Sample Bags Max/200 Samples	40 lbs	50 lbs	200	100 Hours

5.5 IATA REGULATIONS FOR SHIPPING HUMAN BIOLOGICAL SUBSTANCES

IATA rules list the training requirements for persons involved with hazardous materials, including the packaging of human biological specimens for shipment to a clinical laboratory. PPD Laboratories does not provide IATA training; however, we will provide all materials for compliance with IATA regulations packing instructions 650. It is the shippers (site's) responsibility to have all employees responsible for packaging and shipping biological specimens IATA trained. For information regarding IATA requirements please refer to the official resources to obtain additional information/training: www.icao.int http://www.saftpak.com http://www.highqllc.com www.ercweb.com www.dgitraining.com.

5.6 SPECIMEN PRESERVATION (DISASTER CONTINGENCY PLAN)

This PPD Laboratories contingency plan has been established to give your site instructions on how to proceed should air travel be disrupted for a period of time.

Please note that this is the general PPD disaster contingency plan and should unforeseen events prevent shipment of samples long term, you will be informed at that time for study specific actions to take for your samples. **The below details are informative.**

1) Frozen samples

Specimens that are required to be frozen and shipped with dry ice should remain at the site in a non-frost free freezer at -20°C or below until notification is received from the sponsor or PPD Laboratories that safe transport of specimens is certain.

2) Non-frozen samples

Specimens already drawn should be kept at site unless the sponsor has directed your site to have these tests performed locally. If you are required to perform a test locally, the sponsor will notify you in writing. For short term storage:

- Hematology (CBC): the specimens are stable for a maximum of 3 days at ambient temperature. Shipment of samples on a Friday in regions where transit may result in delivery on a Monday can lead to sample loss due to lack of stability.
- Specimens for safety chemistry, lipid profile (if applicable for the study) and other specimens that are ordinarily shipped at ambient temperature or with ice refrigerant packs should be refrigerated at 2-8°C. These specimens are stable for at least one week.

If safe transport of specimen cannot be assured within 5 calendar days of collection, the sponsor may notify you to do one or more of the following:

- Perform Hematology / urinalysis / hemoglobin A1c in your local laboratory (if applicable for the study)
- Perform safety chemistry in your local laboratory if indicated by the subject's condition (if applicable for the study)
- Freeze lipid profile plasma and reserve sample vials in a non-frost free freezer at –15°C to –20°C or below (if applicable for the study).

Freeze serum vials in a non-frost free freezer at –15°C to –20°C or below (if applicable for the study).

Contact PPD Laboratories or the sponsor regarding the handling of any other specimens.

6 SPECIMEN PROCESSING AT THE CENTRAL LABORATORY

KEY POINTS FOR THIS SECTION:

- Inform PPD immediately if your site details change.
- Queries are sent out via the **Preclarus® Investigator Site Portal** on the day of receipt of your samples.
- **Laboratory Reports will not available on the Preclarus® Investigator Site Portal if you have pending queries.**
- Data for safety samples are available on the **Preclarus® Investigator Site Portal** on the day of receipt of the samples (unless there are pending queries).
- All protocol defined exclusion/inclusion/discontinuation criteria are flagged on the laboratory report. For appropriate actions always refer to the protocol!
- Critical Values are sent out to the sites via the **Preclarus® Investigator Site Portal** and are **not** delayed by pending queries. They require acknowledgement of receipt by site via the **Preclarus® Investigator Site Portal** within 1 business day. (Please refer to section 1.5.15 Preclarus Contingency Plan if needed)

6.1 SITE INFORMATION

For each site, the following information is set up in our database

- Site number
- Supply delivery address
- Sample pick up address
- Site contact name (other than PI)
- Phone number
- Fax number
- PI Email Address-Must have PI email address in order to activate the **Preclarus® Investigator Site Portal**

In order to maintain effective communication, please proactively inform our Global Site Services help desk (see section 1.1) should any of the details related to the above information change during study conduct.

6.2 SITE QUERIES AND EXCEPTIONS

When samples are received in the laboratory an evaluation is performed on the requisition and the samples to ensure completeness and accuracy of information. When demographic information is missing, unreadable, or discrepant on the tube label or the requisition form, queries are generated, and the following process occurs:

1) An exception is created by our database which blocks the laboratory report and the results cannot be provided to the site.
2) PPD Global Site Services help desk will query the site via the **Preclarus® Investigator Site Portal** (see section 1.5), requesting the missing information. After the initial query is sent, new queries are faxed after 2 business days to allow the site time to respond. Sites will then be queried every 1 business day until a confirmation of the missing information is received.
3) Sites are also able to view their queries online through the **Preclarus® Investigator Site Portal** (see section 1.5).

4) The site must respond to the query on-line through the **Preclarus® Investigator Site Portal** and the Global Site Services Help Desk will process your comments. (Please refer to section 1.5.15 Preclarus Contingency Plan if needed)
5) Upon receipt on-line comments, the exception is resolved, and the Laboratory Report is released.
6) The site will receive the laboratory report via the **Preclarus® Investigator Site Portal**.

It is imperative that all queries be resolved quickly to assure results are received in a timely manner. Otherwise open queries will keep the reports/results from being available.

6.3 LABORATORY REPORTS

The laboratory reports will be provided to the sites on the Preclarus® Investigator Site Portal

6.3.1 Specimen Received Statement

- This statement will list the subject information in the header and all of the samples expected for the visit in the body of the statement.
- The statement lists specimen status as either Received or Not Received. **If the site did not collect the sample, you can request the Global Site Services help desk to change the status to Not Collected. Otherwise, the sample will appear as Missing and will be listed for follow up with the Study Management team.**
- When utilizing the **Preclarus® Investigator Site Portal** you can update the status on-line for the missing samples to Not Collected, additionally you can print the list of missing samples for your convenience.

Sponsor: SponsorName
Protocol Number: SN12345
PPD Study Code: SPNR0001
Investigator Site ID: 001
Principle Investigator: Test User
Site Coordinator: Test User

Global Central Labs
2 Tesseneer Drive
Highland Heights, KY 41076

Report Generated: 06-Sep-2017

PPD

Example

SUBJECT INFORMATION

Screening ID: 001001	Gender: Female	Visit: Day 1
Randomization ID: 12345	YOB: 1974	Timepoint: Baseline
Accession Number: A012345		Drawdate: 01-Sep-2017

Demographic information

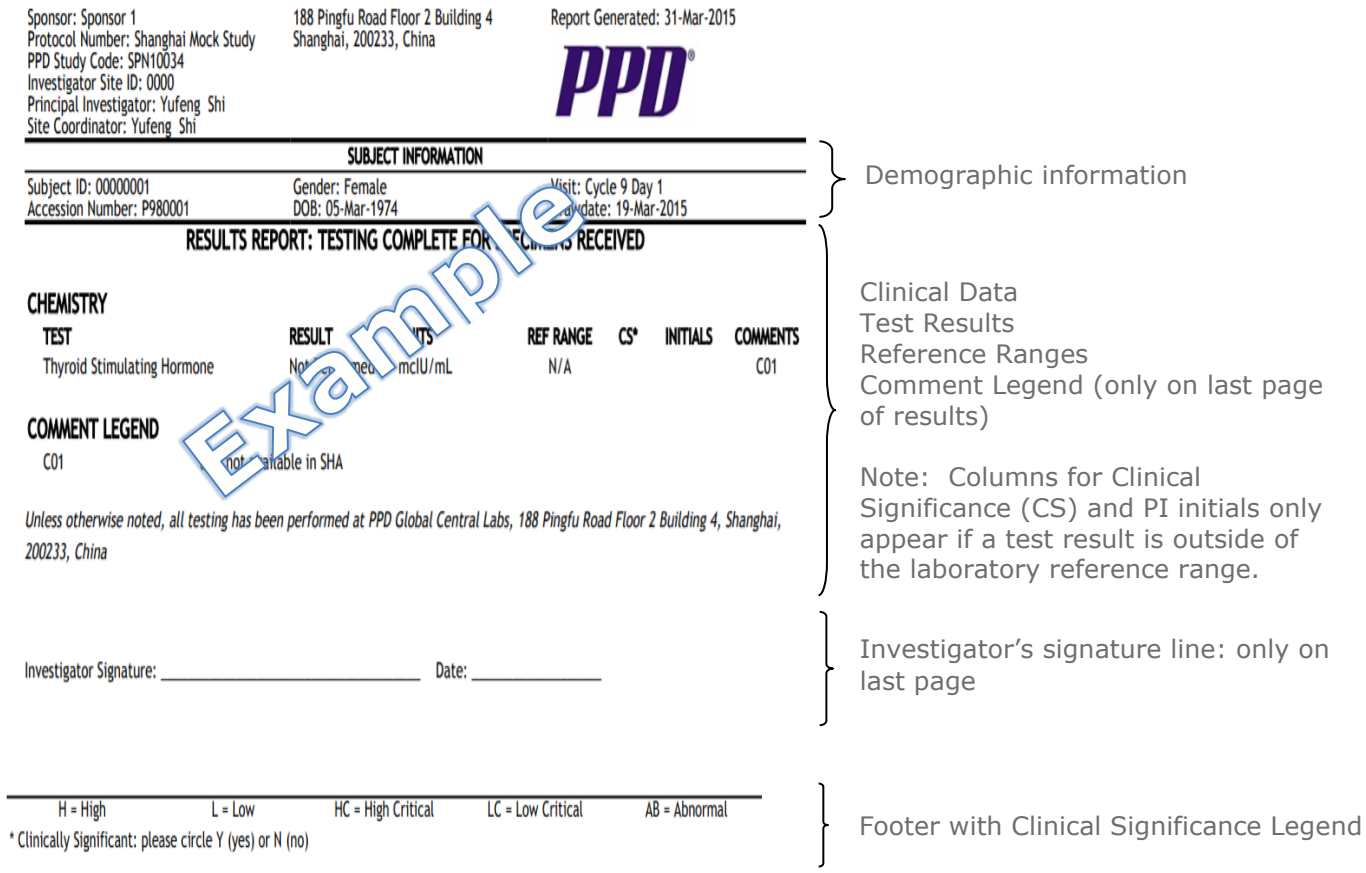
SPECIMEN RECEIVED STATEMENT

Specimen	Status	Collected	Received	Identifier
Serum ADA Set A	**Received**	**01-Sep-2017**	**06-Sep-2017**	**A0134567890**
Serum ADA Set B	Not Received	N/A	N/A	A0145678901
Plasma Biomarker Set A	**Received**	**01-Sep-2017**	**06-Sep-2017**	**A0156789012**
Plasma Biomarker Set B	Not Received	N/A	N/A	A0167890123

Sample information:
- Received
- Not Received
- Collection Date
- Received Date
- Sample Accession Number

6.3.2 Results Reports (also called DSRs)

- List of all test results, reference ranges, units and flags.


Sponsor: Sponsor 1
Protocol Number: Shanghai Mock Study
PPD Study Code: SPN10034
Investigator Site ID: 0000
Principal Investigator: Yufeng Shi
Site Coordinator: Yufeng Shi

188 Pingfu Road Floor 2 Building 4
Shanghai, 200233, China

Report Generated: 31-Mar-2015

PPD

SUBJECT INFORMATION

Subject ID: 00000001
Accession Number: P980001

Gender: Female
DOB: 05-Mar-1974

Visit: Cycle 9 Day 1
Collection Date: 19-Mar-2015

RESULTS REPORT: TESTING COMPLETE FOR ALL SPECIMENS RECEIVED

CHEMISTRY

TEST	RESULT	UNITS	REF RANGE	CS*	INITIALS	COMMENTS
Thyroid Stimulating Hormone	Not detected	mcIU/mL	N/A			C01

COMMENT LEGEND

C01 not available in SHA

Unless otherwise noted, all testing has been performed at PPD Global Central Labs, 188 Pingfu Road Floor 2 Building 4, Shanghai, 200233, China

Example

Investigator Signature: _____ Date: _____

H = High L = Low HC = High Critical LC = Low Critical AB = Abnormal

* Clinically Significant: please circle Y (yes) or N (no)

Demographic information

Clinical Data
Test Results
Reference Ranges
Comment Legend (only on last page of results)

Note: Columns for Clinical Significance (CS) and PI initials only appear if a test result is outside of the laboratory reference range.

Investigator's signature line: only on last page

Footer with Clinical Significance Legend

6.3.3 Revised Reports

- Revised Results: show the revised current result, the previous test results, reference ranges, units and flags.
- Revised Demographic/Clinical Data: show revised data specific to a visit with current and previous values (e.g. weight or fasting status).
- Revised subject data: shows revised data for the subject with current and previous values (e.g. Subject ID or gender) and all visits affected by this revision.
- Shows all visits affected by the revision.

6.4 Critical Values

There are 4 types of results:

1) Normal result within reference range.
2) Result outside of laboratory reference ranges: **L (Low)** or **H (High)** reported next to test result (value) on the laboratory report.
3) Protocol-specific result annotation: symbol (e.g. S01) reported next to test result (value) additional comment on cover page indicating the **protocol-specific rules/flagging.**

4) Critical value: **LC (Low Critical)** or **HC (High Critical)** reported next to test result (value) on Laboratory report without additional comment on cover page.

Critical Value: an extremely high or low value which is considered to be life threatening. These cut-off values are defined by the PPD medical / laboratory directors and are independent of protocol. They can be found on the reference ranges table in appendix 1. In the event a Critical Value is reported, PPD will contact the site to inform them of the critical value for that subject:

1) A notification is sent out via the **Preclarus® Investigator Site Portal** automatically to the site to inform them of the critical value for a certain subject/visit/test.
2) **Acknowledgement of receipt of critical value alert by site or sponsor is required to be provided to PPD Laboratories within 24 hours.**
3) If the site is using the Preclarus® Investigator Site Portal online (Please refer to section 1.5.15 Preclarus Contingency Plan if needed).
4) Critical values are not put on hold due to pending queries.
5) Investigator sites will be notified of critical values regardless of blinding.
6) A revised laboratory report will be available in the **Preclarus® Investigator Site Portal**

7 SPECIMEN DESTRUCTION REQUEST FORM SUBMISSION GUIDE

KEY POINTS FOR THIS SECTION:

Please be sure to follow the instructions carefully. Issues with form completion will result in the request to be returned to the requestor for resubmission and DELAY in destruction.

- The form must ONLY be opened and completed using Adobe Acrobat.
- Respect Good Documentation Practice (GDP). Use of quotation marks and/or lines, arrows to represent duplicate information is not acceptable per GDP.
- All fields must be completed and formatted correctly, with the applicable information and signatures, for the request to be actionable (i.e. a destruction service work order can be generated)
- If a field is not applicable, it must be marked 'N/A'
- Turn-around time is a minimum of 30 calendar days from receipt of an actionable request.
- There is a fee for this service.

The Sample Destruction Request Form can be found on the Preclarus® Investigator Site Portal in the Document Repository.

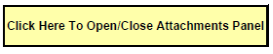
1. Place form on your computer's desktop
2. Right click and Open with Adobe® Acrobat Reader
   a) Current version is free at: https://get.adobe.com/reader/
   b) All data provided must be in electronic format; ONLY Wet Signature Pages will be processed in a scanned format!!!

All information needed to complete sections A and B can be found on the Specimen Received Status Report or on the Samples Received Report/Virtual Biorepository Report pulled from Preclarus® Investigator Site Portal/Preclarus® Lab Data Portal

3. Complete section A: Study Details
   a) **Sponsor Name:** Complete as it appears on the **Specimen Received Statement** (see **pink 1a** below).
   b) **Protocol Number:** Complete as it appears on the **Specimen Received Statement** (see **pink 1b** below).
   c) **PPD Study Code**: Complete as it appears on the **Specimen Received Statement** (see **pink 1c** below).

4. Complete section B: Sample Details (25,000 Sample Listing Maximum)

Access the Destruction List Template located in the attachments panel using the steps below. This template must be used to compile the relevant sample data for all samples to be destroyed. There must be no duplicate rows and the **data compiled must match the data in the study database exactly for each sample listed.**

a. Open attachments panel by clicking the 

button OR by clicking the  icon on the left-side panel of the form
b. Right click on and save to desktop
c. Open template from desktop and enter/paste sample data into file; MUST USE THE 'PASTE AS VALUES' OPTION!!!

a. **Lab Location:** This is the PPD location where the sample currently resides. This information can be obtained from the Preclarus® Portal in the Virtual Biorepository. It can also be found as the address on the Specimen Received Statement (GCL-US, GCL-EU, GCL-SG, or GCL-SH). Lastly, PPD GCL assigned study Project Assistant (PA) or Project Manager (PM) can provide
b. **Site ID**: This is the site number associated to the samples. The site number is the Investigator Site ID on the Specimen Received Statement (see **2a** below) OR Site ID in the Samples Received Report/Virtual Biorepository
c. **Screening ID:** Each sample requires the Screening ID to be entered [this is the value assigned to subject at screening; nomenclature may vary by study (e.g. – Subject ID, Patient ID]. If this number does not exist for the study and/or subject, field should be marked as 'NA'. See Specimen Received Statement (see **2b** below), Preclarus® Portal View Subject Demographics, OR Samples Received Report/Virtual Biorepository
d. **Randomization ID:** Samples may or may not have an associated Randomization ID. Where applicable, they must be entered [this is the value assigned to subject at randomization; nomenclature may vary by study (e.g. – Allocation Number, Baseline Number)]. If this number does not exist for the study and/or subject, field should be marked as 'NA'. See Specimen Received Statement (see **2c** below), Preclarus® Portal View Subject Demographics, OR Samples Received Report/Virtual Biorepository
e. **Complete Visit Name:** This is the visit name as it appears on the Specimen Received Statement (see **2d** below) OR Samples Received Report/Virtual Biorepository
f. **Collection Date:** This is the date the sample was collected. See Specimen Received Statement (see **2e** below) OR Samples Received Report
g. **Sample Identifier (Accession Number/Barcode):** This is the alpha-numeric identifier (minimum 11-characters) associated to the sample barcode. Each sample has a unique sample identifier that appears under the scannable barcode on the physical sample label. This identifier can be retrieved from the Specimen Received Statement (see **2f** below) OR Samples Received Report/Virtual Biorepository
h. **Sample Names:** This is the full sample name as it appears on the Specimen Received Statement (see **2g** below)
i. **Sample Status:** This is the Status as it appears on the Specimen Received Statement (see **2h** below) OR Samples Received Report

1a Sponsor: Sponsor Name
1b Protocol Number: SN12345
1c PPD Study Code: SPNR0001
2a Investigator Site ID: 001
Principal Investigator: Test User
Site Coordinator: Test User

Lab Director: Dr. Test User
Global Central Labs
2 Tesseneer Drive
Highland Heights, KY 41076
+1 859 781 8877

Report Generated: 06-Jul-2019

PPD

SUBJECT INFORMATION

2b Screening ID: 1001
2c Randomization ID: 12345
Accession Number: A012345

Gender: Female
DOB: 01-Jan-1995

2d Visit 3
2e Drawdate: 01-Sep-2017

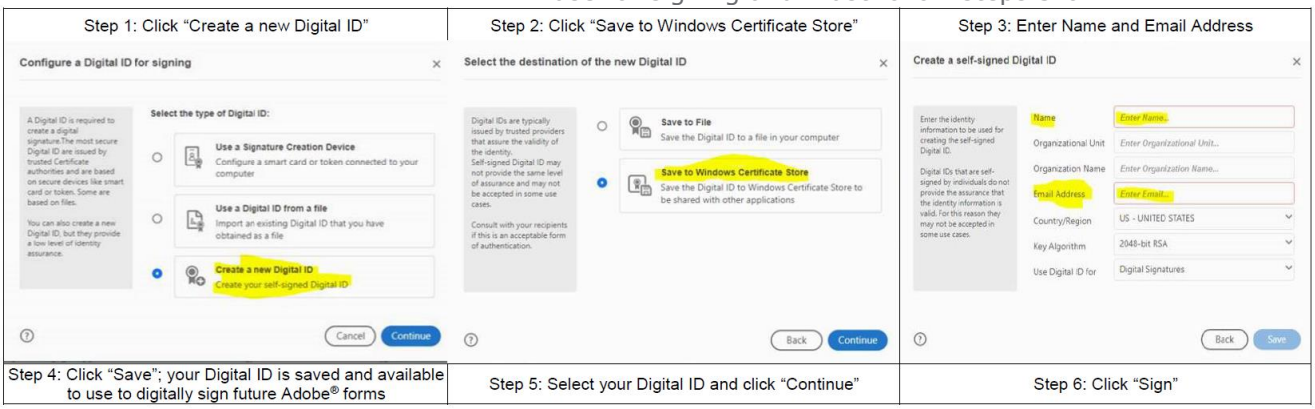
SPECIMEN RECEIVED STATEMENT

Specimen	Status	Collected	Received	Identifier
2g CHEM TRANSFER	2h Received	01-Sep-2017	07-Sep-2017	2f TESTFDA0019
CHEMISTRY	Received	01-Sep-2017	07-Sep-2017	TESTFDA0020
COAGULATION	Received	01-Sep-2017	07-Sep-2017	TESTFDA0021
FLUORIDE SAMPLE	Received	01-Sep-2017	07-Sep-2017	TESTFDA0022
HEMATOLOGY	Received	01-Sep-2017	07-Sep-2017	TESTFDA0023
HEME	Received	01-Sep-2017	07-Sep-2017	TESTFDA0024
HEME CITRATE	Received	01-Sep-2017	07-Sep-2017	TESTFDA0025
SERUM SAMPLE	Received	01-Sep-2017	07-Sep-2017	TESTFDA0026

d. Use "Click Here to Attach Sample List, Wet Signatures Page, Etc." button to attach Destruction Listing to the request form

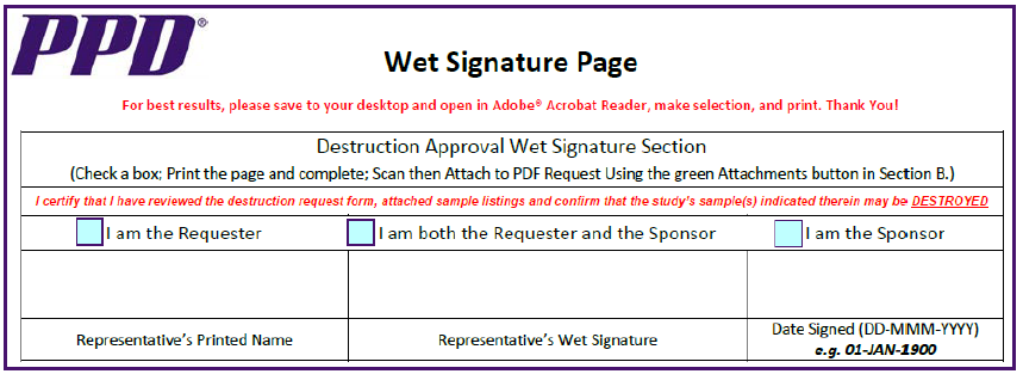
a. Attachments may be removed by opening attachments panel, selecting desired file, and pressing "Delete" on your keyboard

5. Complete Section C: Requester Information
   a) Name and email are required and must be completed; Telephone number is optional; if not entered, field should be marked as 'NA'
   b) Date of the request and reason for destruction are required and must be completed
      i. If the Requester is also the Sponsor, Select the "Check if the Requestor is also the Sponsor" checkbox. This will populate Sponsor Approval section (Section E) with information from Requestor Information section (Section C) and disable related fields until checkbox is unchecked.
      ii. Sponsor Approval section (Section E) can be skipped
   c) Copy the auto-generated filename (in bold, green letters). Use this filename when saving the form
      i. Right-Click the filename and click "Select All" and copy using Ctrl-C
      ii. Use the selection tool ( ) to highlight and copy using Ctrl-C
   d) Sign Section C using 1 of the following options:
      i. **E-Sign (recommended):** The built in Adobe® Digital Signature field does not require any external eSignature software, such as DocuSign. Adobe® Reader will create an encrypted Digital ID that will sign the form based on your individual computer's credentials, linked to your personal login. The Digital ID is unique to you and can only be recreated from your computer with your login credentials
         1. Click in the "Requester's Digital Signature" field; a pop-up window will appear with further instructions
            a. First time users are prompted to "Configure New Digital ID" and must follow steps 1-6
            b. Returning users will be prompted to select the Digital ID to use for signing and must follow steps 5-6



ii. Wet Signature

1. Select the "Check if Wet Signature Page used instead of digital signature" checkbox
2. Open attachments panel by clicking the yellow "Click Here to Open/Close Attachments Panel" button OR by clicking the icon on the left-side panel of the form
3. Open the file named Wet Signature Page Template_v11192019.pdf
4. Select the appropriate checkbox (checkboxes are mutually exclusive; only 1 can be checked)
5. Print, use wet ink to enter Name, Signature, and Date
6. Scan completed Wet Signature Page back to desktop
7. Use "Click Here to Attach Sample List, Wet Signatures Page, Etc." button to attach to the request form



PPD®

Wet Signature Page

For best results, please save to your desktop and open in Adobe® Acrobat Reader, make selection, and print. Thank You!

Destruction Approval Wet Signature Section (Check a box; Print the page and complete; Scan then Attach to PDF Request Using the green Attachments button in Section B.)		
I certify that I have reviewed the destruction request form, attached sample listings and confirm that the study's sample(s) indicated therein may be DESTROYED		
☐ I am the Requester	☐ I am both the Requester and the Sponsor	☐ I am the Sponsor
Representative's Printed Name	Representative's Wet Signature	Date Signed (DD-MMM-YYYY) ***e.g. 01-JAN-1900***

6. Save the file using auto-generated filename (copied in 5c)
7. Click green submit button that reads **Click to Submit Form to PPD GCL Project Assistants**
   a) If necessary, select your email account in pop-up dialog; send auto-generated email

NOTE: Only submit forms using the "Click to Submit Form to PPD GCL Project Assistants" button. Use of this button will notify the user of any fields that have been completed incorrectly.

The remaining fields will be completed and followed up by PPD.

The form will be reviewed by PPD GCL Project Assistants and Project Managers for completion of Section D. PPD BioA Principle Investigators (PI) must complete this section if samples requested for destruction reside at a BioA facility. Once Section D is completed, the form will proceed for Sponsor Approval.

Once Sponsor Approval is acquired, the destruction form will be reviewed once more and the destruction job will be initiated at PPD (completion of Section F). PPD Sample Coordinators will sign the form in Section G, providing certification that the requested samples have been destroyed.

The completed Destruction Form will be returned to the Requestor, Sponsor, PPD Project Management team and PPD BioA Principle Investigators for study file archiving, as applicable.

Study Specific Information

APPENDIX I TESTING OVERVIEW

1. Laboratory of receipt:

Samples will need to be sent to the following location(s) depending on your location:

PPD US: North America

Viracor: North America

2. Turnaround time and stability:

Test	Receipt Location	Testing Location	Temperature	Stability	TAT from sample receipt
COVID PCR Swab	Viracor	Viracor	Store at -70°C prior to shipment (Can be stored at -20°C until shipped same day if -70°C freezer is not available) If collected on Weekend: Can be stored at -20 C until Monday shipment Ship on Dry Ice	1 Month	2 Days
COVID PCR Saliva	Viracor	Viracor	Store at -70°C prior to shipment (Can be stored at -20°C until shipped weekly if -70°C freezer is not available) If collected on Weekend: Can be stored at -20 C until Monday shipment Ship on Dry Ice	1 Month	2 Days
Biofire RPS	Viracor	Viracor	Store at -70°C prior to shipment (Can be stored at -20°C until shipped same day if -70°C freezer is not available) Ship on Dry Ice	30 Days	2 Days

3. Sample Management Samples:

Sample Name	Shipment Frequency to PPD GCL	Storage and Shipping Temperature	Storage Location
Immuno Coll 1 – 8 (includes Anti-Sars Cov-2 sample)	Please ship Aliquots 1-10 in the first shipment and Aliquots 11-24 in the next shipment. Do not ship the two shipments on the same day. Sites will be shipping samples to GCL 2x per week	Store at -70°C prior to shipment (Can be stored at -20°C until shipped weekly if -70°C freezer is not available) Ship on Dry Ice	PPD
SARS CoV2 Blood Coll 1 -4	Daily Please ship Aliquots 1-4 in first shipment, and Aliquots 5-8 in second shipment Do not ship the two shipments on the same day.	Store at -70°C prior to shipment (Can be stored at -20°C until shipped weekly if -70°C freezer is not available) Ship on Dry Ice	PPD

Notes:

- If the testing is not performed at the laboratory of receipt, transit time to the testing laboratory will increase the turnaround time.
- Whole blood samples are retained 7 days after testing. All other samples are retained 10 business days after testing

APPENDIX II REQUISITION FORMS

Electronic Lab Requisition (E-Req) should be used for this study! See section 4.2 of this Lab Manual for additional details.

A paper requisition form is provided with every kit and should only be used for emergency reasons.

For samples shipping directly to Viracor:

Print out the E-Req Form and include in the sample shipping box.

If you forget to send e-Req please send to Viracor at:

(b) (6)

(b) (6)

APPENDIX III SWAB COLLECTION

Prior to Swab sample collection don appropriate Personal Protective Equipment.

COVID PCR Swab Collection (Visit 01 Baseline Month 0, Visit 02 Month 1, and Illness Day 1)

Note: Do not use calcium alginate swab or wood shafted swab.

1. Insert a swab into nostril parallel to the palate. Swab should reach depth equal to distance from nostrils to outer opening of the ear. Leave swab in place for several seconds to absorb secretions. Slowly remove swab while rotating it.
2. Place sterile swab immediately in 2 mL viral transport media VTM tube.
3. Ship on day of collection on dry ice, Monday through Friday to Viracor. Include printed eReq.

BioFire RPS Swab Collection (Illness Day 1)

Note: **The VTM media tubes are included in Illness Day 1 Kits (Kit Type C) and will no longer be provided as a bulk supply**
Note: Do not use calcium alginate swab or wood shafted swab.

1. Insert a swab into nostril parallel to the palate. Swab should reach depth equal to distance from nostrils to outer opening of the ear. Leave swab in place for several seconds to absorb secretions. Slowly remove swab while rotating it.
2. Place sterile swab immediately in 2 mL viral transport media (VTM) tube
3. Ship on day of collection on dry ice, Monday through Friday to Viracor. Include printed eReq.

APPENDIX IV SALIVA COLLECTION AT ILLNESS VISITS

A COVID Positive result at Illness D1 will require all saliva collections on Days 3, 5, 7, 9, 14, 21, and 28.

If COVID Negative result on Illness D1, instruct subject to stop collecting saliva samples. Any previously collected samples should be shipped to Viracor.

Saliva Sample Handling instructions:

Prior to sending saliva collection supplies home to subject, the site MUST fill out Subject ID on all 6 labels and on all 6 copies of the Sample Requisition Form in the Illness D3-D21 Kit.

1. Subject collects saliva sample and fills out collection date on Sample Requisition Form
2. Subject places saliva sample and Sample Requisition Form in provided Biohazardous bag at Room Temperature – DO NOT REFRIGERATE
3. Site picks up saliva sample at subject's home on day of collection and transports back to site in Styrofoam shipper at Room Temperature – DO NOT REFRIGERATE
4. Site accessions sample into Preclarus and prints out E-requisition to send with samples to Viracor.
5. Site freezes samples at -70C or below
6. Site batch ships all saliva samples weekly (If a saliva sample was collected on D1, it should ship on the day of collection).

The subject-facing sample collection instructions provided in the Illness Visit kits can be found on the following page of this manual.

Instructions for Home Saliva Collection

Important Notes:

- Store your saliva selection kits at room temperature and out of reach of children. **DO NOT REFRIGERATE OR FREEZE**
- Saliva must be collected to the "4mL FILL TO" line.
- Ideally, saliva collection should occur in the morning, BEFORE eating, drinking, smoking, brushing teeth, chewing gum, or any other types of oral intake. If this collection cannot occur first thing in the morning, **you should not eat, drink, smoke, brush teeth or chew gum for a minimum of 30 minutes before sample collection.**
- Try not to cough or sniffle prior to saliva collection. Saliva should be gently expelled from the mouth into the collection tube, no forceful spitting is required. It may take between 2 and 5 minutes to fill the tube to the 4mL fill line.

Procedure

1. Disinfect/Wash hands before opening collection materials.
2. Select correct collection tube and funnel from bag in kit. If the solution is cloudy, warm the tube gently in your hands for a few minutes until clear.
   Note: Do not swallow or touch stabilizing solution. If stabilizing solution comes into contact with skin or eyes, wash with plenty of water.
3. Carefully unscrew the cap from the collection tube being careful not to spill the liquid. Place the cap aside upside down on a clean surface for use later. *(page 7; picture 1)*
4. Screw the collection funnel on to the collection tube gently. Do not overtighten.
5. Gently expel saliva into the cup until level of the liquid in the collection tube (not including bubbles) reaches the **"4 mL FILL TO line"** on the collection tube. *(page 7; picture 2)*
   Note:
   a. If saliva does not flow easily into the tube, unscrew the funnel slightly.
   b. If needed, saliva production can be encouraged through thinking about food (favorite foods, upcoming meals etc.). Saliva production can be stimulated by rubbing the inside of cheek with the tongue, or gently massaging the outside of the cheeks.
6. Unscrew the collection funnel and replace the tube cap onto the collection tube tightly. *(page 7; picture 3)*
7. Discard the funnel.
8. Shake the collection tube several times to mix the saliva with the solution. *(page 7; picture 4)*
9. Write in date of collection on Requisition Form in your kit
10. Place tube in biohazard bag provided with completed Requisition Form.
    Keep sample at room temperature. **DO NOT REFRIGERATE**
11. **Contact clinical study staff for sample pickup immediately**

Green Label indicated "FILL TO" line

6

Illness Visit Instruction - V0.3 29Jun20

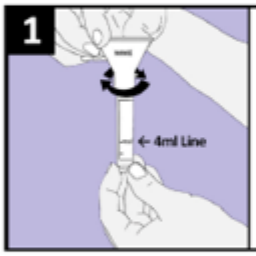
Instructions for Home Saliva Collection

GeneFix

Patient Instructions for Saliva Collection

REF GFX-02

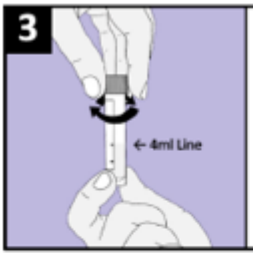
Do not eat, drink, smoke, brush your teeth or chew gum for 30 minutes before use.
Check fluid level is at 2ml line before opening.



1. Remove the cap from the tube.
   Keep cap for later use.
   Screw collection funnel on to the tube.

2. Spit into the funnel until the level of the liquid in the tube, not including bubbles, **reaches the 4ml line.**

   Delivery of saliva will take between 2 and 5 minutes.



3. Unscrew the collection funnel and replace the tube cap tightly.
   Discard the funnel.

4. Shake the collection tube several times to mix the saliva with the solution.

Precautions: Do not swallow. If stabilising solution comes into contact with skin or eyes, wash with plenty of water. Tube cap may be a choking hazard to small children.

Isohelix

www.isohelix.com

Version May 2020

CE 15°C 30°C

Illness Visit Instruction - V0.3 29Jun20 7

APPENDIX V KIT AND BULK SUPPLIES

1. Visit Kits

Visit Name	Kit Type	Quantity Provided at Start-up
Visit 01 Baseline Month 0 Visit 02 Month 1	Kit A	300
Visit 03 Month 2 Visit 04 Month 7 Visit 05 Month 13 Visit 06 End of Study	Kit B	
Illness D1	Kit C	25
Illness D3-D21	Kit D	25
Illness D28	Kit E	
Unscheduled	Kit UV	30

2. Bulk Supplies

Item Description	Quantity Provided at Start-up
URINE CUPS (25/SLEEVES)	12 PER SITE
URINE PREGNANCY KITS QUICK VUE (25/BOX)	12 PER SITE
VTM Transfer Tubes	25

APPENDIX VI LAB MANUAL CHANGE LOG

Amendments to the Laboratory Manual:

AMENDMENT #: 2	
DATE OF REQUEST:	REQUESTED BY:
10AUG2021	PPD Clinical
DESCRIPTION OF CHANGE	
CHANGE # 1 : Swab Collection clarification	
SECTION:	Appendix III Swab Collection
PAGE:	41
ORIGINAL VERBIAGE:	Place sterile swab immediately in 2 ml sterile buffered saline tube
UPDATED VERBIAGE:	Place sterile swab immediately in 2ml viral transport media (VTM) tube.
CHANGE # 2 :	
SECTION:	Appendix III Swab Collection
PAGE:	41
ORIGINAL VERBIAGE:	The VTM media is stored at 4C as bulk supply.
UPDATED VERBIAGE:	The VTM media tubes are included in Illness Day 1 Kits (Kit Type C) and will no longer be provided as a bulk supply
CHANGE # 3 :	
SECTION:	Appendix III Swab Collection
PAGE:	41
ORIGINAL VERBIAGE:	Place sterile swab immediately in 2ml viral transport media (VTM) tubes (which has been stored at 4C as bulk supply
UPDATED VERBIAGE:	Place sterile swab immediately in 2ml viral transport media (VTM) tube,

Documentation

CURRICULUM VITAE

1. Lab Director PPD Laboratories-US

SR. LABORATORY MEDICAL DIRECTOR
Basel Kashlan, M.D., FCAP, FASCP

EDUCATION

Fellowship-Transfusion Medicine, 2000-2001
University of Connecticut, Storrs, CT, USA

Internal Medicine Residency Program, 1995-1996
Louisiana State University, Baton Rouge, LA, USA

Post Graduate Training-Anatomical and Clinical Pathology Residency Program and Cytology Program, 1991-1995
University of Alabama, Birmingham, AL, USA

M.D.- Medical College, 1977-1983
Damascus University, Damascus, Syria

PROFESSIONAL EXPERIENCE

PPD, Highland Heights, KY, USA *Sr. Laboratory Medical Director* *Jul 2018-Present*

Sr. Laboratory Medical Director:
Oversees all aspects of management of medical laboratory operations and ensures productivity, efficiency and quality of the work is maintained and financial goals of the business are achieved. Allocates resources, facilities and personnel where necessary. Plans and develops laboratory policies and ensures proper implementation. Provides technical leadership and mentors lab management staff. Develops and maintains client relationships.

- Negotiates and executes project contracts, defines project scope, pricing and business and contractual interactions with clients, business development and inside sales. Supports sales/marketing efforts and builds and maintains client relations.
- Manages and directs work responsibilities of staff, assigns and prioritizes tasks and resources.
- Financial management of projects, revenues and costs and ensures the financial goals for the business are met; strategic planning and capabilities development.
- Oversees laboratory operations and ensures compliance to company SOPs and policies and client requirements.
- Procures and allocates personnel and analytical instrumentation, IT, and space needs to appropriate areas based on business needs.
- Manages staff, which may include interviewing and selection, job description preparation, professional development, goal setting, performance management, coaching and mentoring, employee counseling, and separations. Approves courses of action on salary administration, hiring, corrective action, and terminations. Reviews and approves time records, expense reports, requests for leave, and overtime.
- Establishes policies appropriate for the function. Interprets and recommends modifications to company-wide policies and practices. Develops and is responsible for budgets, schedules, and performance standards.

Positions Prior to PPD:

Human Longevity, Inc., San Diego, CA, USA
Medical Director *Jun 2018-Nov 2018*

- Interpreted whole genome sequencing testing.
- Performed whole exome for the identification of germ line and somatic variants within targeted regions of the human genome.

Quest Diagnostics Nichols Institute, Valencia, CA, USA
Medical Director *Feb 2015-Feb 2018*

- Oversaw esoteric laboratory operations with a team of three for a $13.7B, Fortune 500 clinical laboratory services company.
- Optimized quality of life and patient services by leading medical innovation and monitoring quality performance indicators for laboratory services.
- Identified and implemented key laboratory improvement metrics using the Six Sigma process.
- Analyzed customer and employee surveys, audits, and process measures to ensure performance optimization.
- Held position as Director of Quality Assurance.
- Implemented validating lab developed tests for pain management and clinical toxicology.
- Interpreted hemoglobinopathies electrophoresis and material serum screening and disaccharidase test.
- Provided medical consultations for clients and physicians.

Ovagene Oncology, Irvine, CA, USA
Medical Director *Nov 2011-Nov 2017*

- Performed molecular diagnostics for gynecological cancers.
- Provided innovative personalized gynecological cancer care through the introduction of molecular diagnostic tools that improve treatment outcome and patient survival.
- Interpreted next generation sequencing.
- Interpreted predictive and prognostic markers.

Q2 Solutions, Valencia, CA, USA
Assistant Director *Jan 2011-May 2017*

- Led advanced clinical trial operations for the world's second largest clinical laboratory services provider through a joint venture between Quintiles and Quest Diagnostics.
- Completed biopharmaceutical projects, diagnostic biomarkers, and cytogenetic studies for cancer patients.
- Collaboratively expedited quality manufactured products via client-focused results.
- Interpreted predictive and prognostic markers.
- Interpreted florescence in situ hybridization (FISH)

Quest Diagnostics Nichols Institute, Valencia, CA, USA
Associate Medical Director *Aug 2011-Jan 2015*

- Held position as Scientific Director of the Oncology Department.
- Served as Director of Quality Assurance, improving quality metrics of clinical laboratory testing and services.
- Oversaw Anatomical and Clinical Laboratory services, Molecular Pathology, Hematopathology, and Immunohistochemistry markers.

- Conducted consultations for Coagulations studies.

Specialty Laboratories, Valencia, CA, USA
Laboratory Director and Pathologist *Aug 2007-Jun 2011*

- Held positions of Co-laboratory Director/Pathologist (2007-2010) and Laboratory Director/Pathologist (2010-2011).
- Performed duties of Scientific Director of Oncology Services, including flow cytometry, coagulation, and hemoglobin electrophoresis.
- Oversaw and interpreted surgical pathology consults with immunohistochemistry markers.
- Conducted Laboratory Developed Testing (wide range of high complexity assays) for physicians to assist in patient diagnosis.
- Interpreted floresecence in situ hybridization (FISH) and UroVysion diagnostic tests.
- Interpreted flow cytometry studies.
- Completed and interpreted coagulation medical consults.

Oncotech, Tustin, CA, USA
Senior Pathologist *Jul 2003-Aug 2007*

- Completed several clinical trials in Oncology and Molecular Pathology.
- Assessed, validated, and interpreted predictive and prognostic biomarkers, as well as drug resistance assays for cancer patients.

PathNet Esoteric Laboratory Institute/LabCorp America, Van Nuys, CA, USA
Cytopathologist *Sep 2002-Sep 2011*

- Performed Pathologist duties for one of the highest volume independent cytology laboratories in the United States.
- Provided Cytology and Histopathology services for women's health (Pap smears and biopsies)
- Interpreted non-gynecological cytology fine needle aspirations.

Hahnemann University Hospital/Graduate Hospital, Philadelphia, PA, USA
Assistant Professor *Jul 2001-Nov 2002*

- Oversaw transfusion medical services at Hahnemann University Hospital.
- Performed stem cell collection for transplant patients, blood donor selection, and therapeutic plasmapheresis and photopheresis.
- Taught Pathology residents and medical students of the Medical College of Pennsylvania.
- Worked at Graduate Hospital, focused on surgical pathology and cytology services.
- Presented cases for the tumor board review.

LICENSES & CERTIFICATIONS

- Medical Licensure (California, Louisiana, Alabama, Pennsylvania, Tennessee, Connecticut, and Florida)
- DEA Licensure
- Board Certified in Anatomical and Clinical Pathology
- New York Certificate of Qualifications (Molecular Pathology, Oncology, Chemistry, Bacteriology, Clinical Toxicology, Blood Lead, Cellular Immunology, Cytopathology, Diagnostic Immunology, Fetal Defect Markers, Hematology, Histopathology, Mycobacteriology, Mycology, Parasitology, and Virology)
- Controlled Substance Registration
- CPR and AED Certification
- Certified as a Specialist in Cytology
- Certified as College of American Pathologists Inspector
- Board eligible in Clinical Toxicology
- Board eligible in Transfusion Medicine and Immunohematology

PROFESSIONAL DEVELOPMENT

Training while employed at PPD is available upon request.

PROFESSIONAL AFFILIATIONS

Member of the American Society of Clinical Pathologists (ASCP)
Member of College of American Pathology (CAP)
Member of American Society of Quality (ASQ)
Member of Society of Forensic Toxicologists (SOFT)
Member of American Medical Association (AMA)
Member of American Association for Clinical Chemistry (AACC)
Member of American Association of Blood Bank (AABB)
Member of United States and Canadian Academy of Pathology (USCAP)
Member of American Society of Addiction Medicine (ASAM)
Member of International Society of Blood Transfusion (ISBT)

PUBLICATIONS AND PRESENTATIONS

Publications:

F. Spencer Chivers, MD, Ken Jaffee, MD, B. Kashlan, MD – "Ankle Pain and Swelling in a 24 Year Old Woman"- Clinical Orthopedics and Related Research 1996; V323, pp338-344.

B, Kashlan, MD, H, Silver, MD, G. Tsongalis, PH.D. – "Review of Paternity Testing'.

H. Silver, MD, B. Kashlan, MD, I Drozdal, SBB – "Preparation of Aliquots for Neonatal Transfusion".

LANGUAGES

Native Tongue is English

I have reviewed this document and confirm that the information is accurate and complete.

Signed: (b) (6)

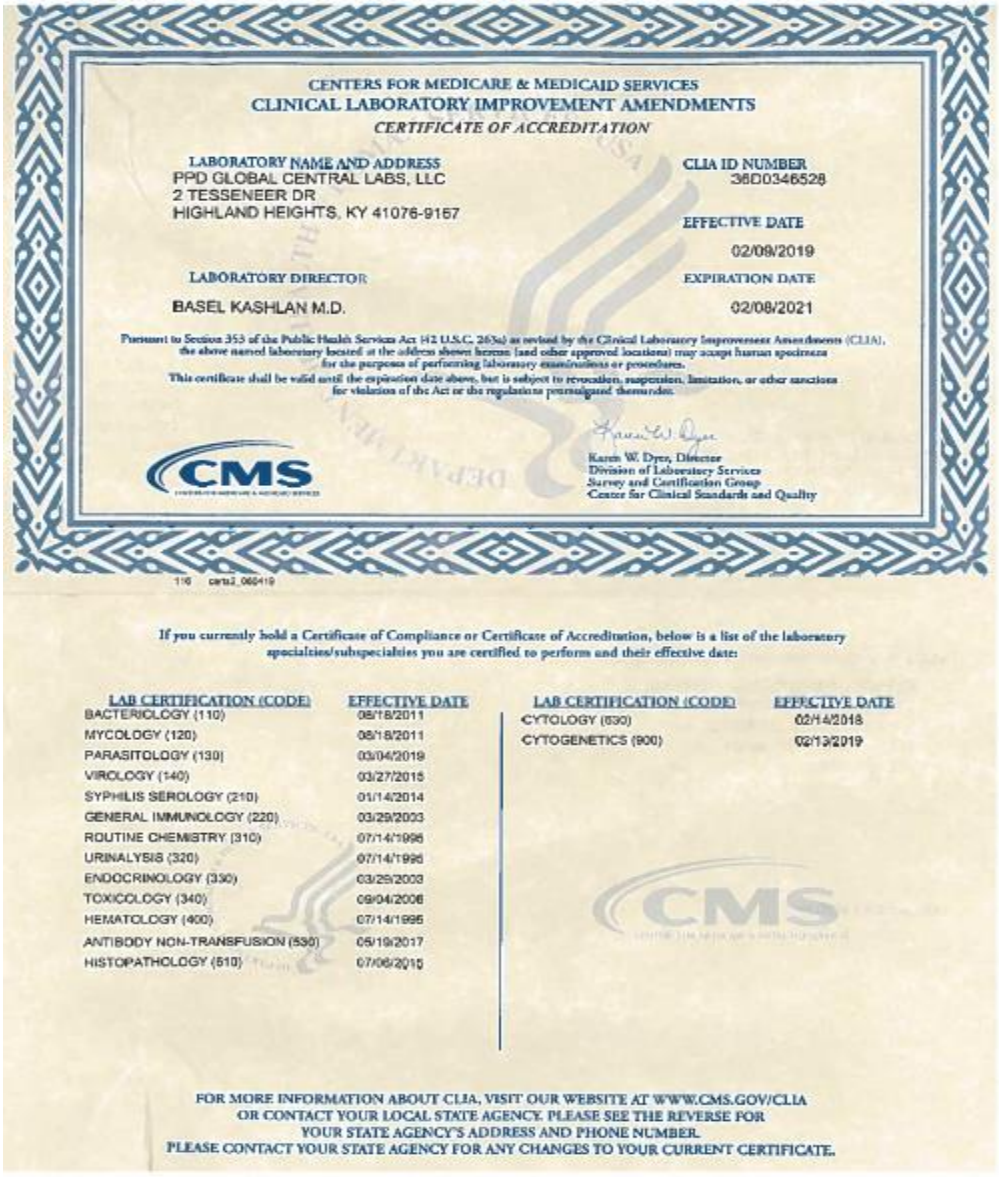
Date: _____

CAP AND CLIA CERTIFICATIONS

- PPD Central Labs certifications are provided in this manual for your site's reference. As a note, the most current laboratory certifications are posted and available at http://www.ppdi.com under the Services / Laboratories / Central Labs / Certifications sub-category. Please file these certifications where appropriate when the current certifications in your manual expire.

- Regulatory Accreditation Programs are continual processes: a laboratory remains accredited until otherwise notified. While a certificate provides effective and expiration dates, laboratories remain accredited while they wait for the receipt of a new certificate, even if the expiration date has passed. New certificates are posted on the website as soon as they are made available by the Regulatory/Accrediting Agency.

1. CLIA Certification – PPD Laboratories US



CENTERS FOR MEDICARE & MEDICAID SERVICES
CLINICAL LABORATORY IMPROVEMENT AMENDMENTS
CERTIFICATE OF ACCREDITATION

LABORATORY NAME AND ADDRESS
PPD GLOBAL CENTRAL LABS, LLC
2 TESSENEER DR
HIGHLAND HEIGHTS, KY 41076-9167

CLIA ID NUMBER
36D0346528

EFFECTIVE DATE
02/09/2019

LABORATORY DIRECTOR
BASEL KASHLAN M.D.

EXPIRATION DATE
02/08/2021

Pursuant to Section 353 of the Public Health Service Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown herein (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.
This certificate shall be valid until the expiration date above, but is subject to revocation, suspension, limitation, or other sanctions for violation of the Act or the regulations promulgated thereunder.

Karen W. Dyer, Director
Division of Laboratory Services
Survey and Certification Group
Center for Clinical Standards and Quality

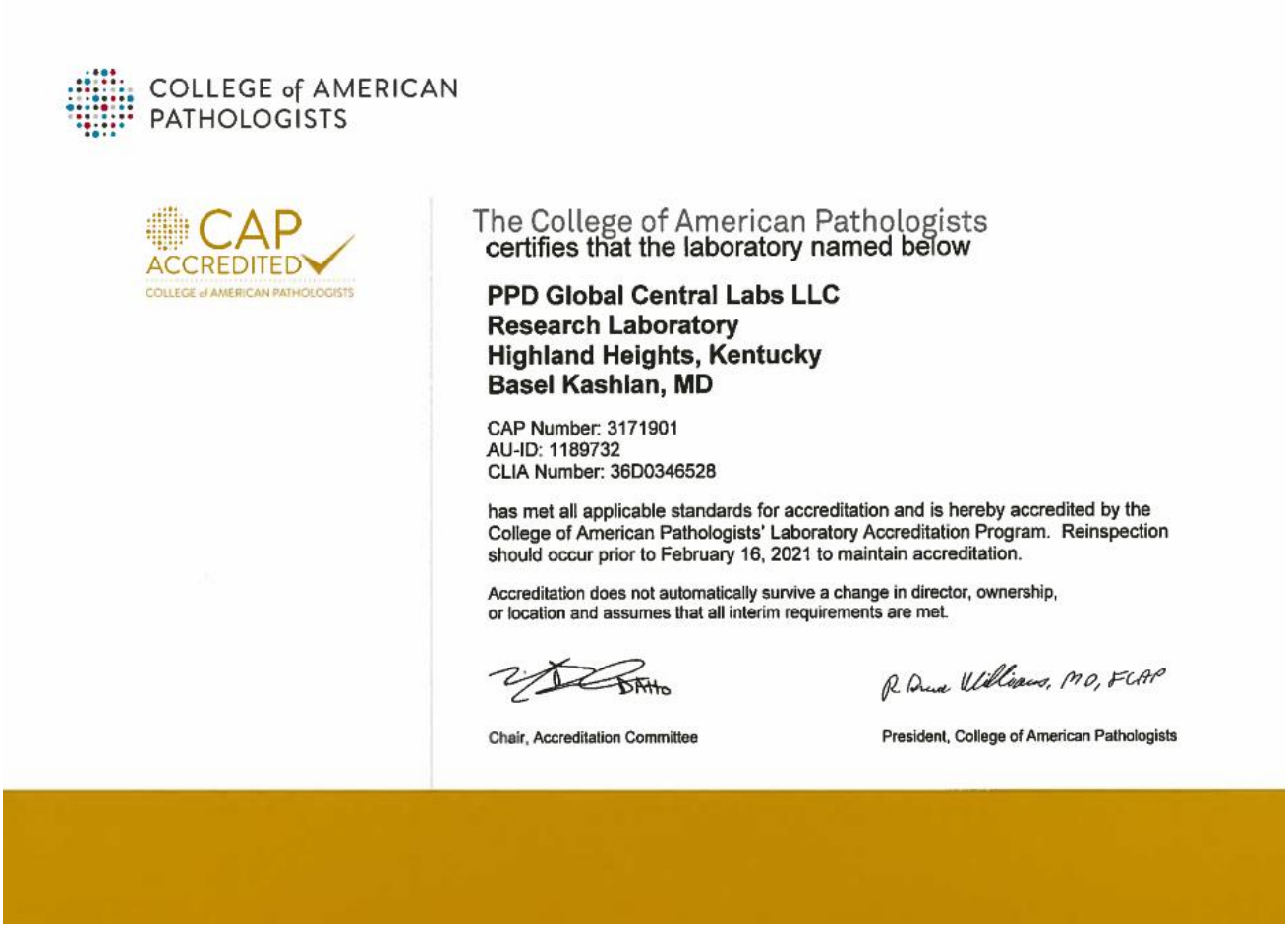
If you currently hold a Certificate of Compliance or Certificate of Accreditation, below is a list of the laboratory specialties/subspecialties you are certified to perform and their effective date:

LAB CERTIFICATION (CODE)	EFFECTIVE DATE
BACTERIOLOGY (110)	08/18/2011
MYCOLOGY (120)	08/18/2011
PARASITOLOGY (130)	03/04/2019
VIROLOGY (140)	03/27/2015
SYPHILIS SEROLOGY (210)	01/14/2014
GENERAL IMMUNOLOGY (220)	03/29/2003
ROUTINE CHEMISTRY (310)	07/14/1998
URINALYSIS (320)	07/14/1998
ENDOCRINOLOGY (330)	03/29/2003
TOXICOLOGY (340)	09/04/2008
HEMATOLOGY (400)	07/14/1998
ANTIBODY NON-TRANSFUSION (530)	05/19/2017
HISTOPATHOLOGY (510)	07/06/2015

LAB CERTIFICATION (CODE)	EFFECTIVE DATE
CYTOLOGY (630)	02/14/2018
CYTOGENETICS (900)	02/13/2019

FOR MORE INFORMATION ABOUT CLIA, VISIT OUR WEBSITE AT WWW.CMS.GOV/CLIA
OR CONTACT YOUR LOCAL STATE AGENCY. PLEASE SEE THE REVERSE FOR
YOUR STATE AGENCY'S ADDRESS AND PHONE NUMBER.
PLEASE CONTACT YOUR STATE AGENCY FOR ANY CHANGES TO YOUR CURRENT CERTIFICATE.

2. CAP Certification – PPD Laboratories US



COLLEGE of AMERICAN PATHOLOGISTS

CAP ACCREDITED
COLLEGE of AMERICAN PATHOLOGISTS

The College of American Pathologists
certifies that the laboratory named below

PPD Global Central Labs LLC
Research Laboratory
Highland Heights, Kentucky
Basel Kashlan, MD

CAP Number: 3171901
AU-ID: 1189732
CLIA Number: 36D0346528

has met all applicable standards for accreditation and is hereby accredited by the College of American Pathologists' Laboratory Accreditation Program. Reinspection should occur prior to February 16, 2021 to maintain accreditation.

Accreditation does not automatically survive a change in director, ownership, or location and assumes that all interim requirements are met.

Chair, Accreditation Committee

President, College of American Pathologists

Sponsor:	**Moderna**
Protocol #:	**mRNA-1273-P301**
PPD Study Code:	**MDRN0024**

Version 7.0
11-Mar-2021

COLLECTION FLOW CHART

(Collect blood tubes in order listed below-top to bottom)

Visit / Time point	Visit 01 Baseline Month 0	Visit 02 Month 1	Visit 03 Month 2	Visit 04 Month 7	Visit 05 Month 13	Visit 06 End of Study	Illness D1	Illness D3 - D21	Illness D28	OL-1 Month 0	OL-2 Month 1	OL-3 Month 2	Unscheduled	Draw Tube Cap Color *Shade may vary per region	Blood Volume of Draw Tube (mL)	Invert	Time Elapsed (minutes) Post Collection / Prior to Centrifugation (minutes)	Centrifugation Speed and Time	Transfer Device	Ship to PPD Central Labs		Storage Condition at Site	Shipping Condition	Shipping Frequency	Special Instructions
Test																									
Immuno 1-8 Coll	8	8	8	8	8	8							8		8 x 6mL Red Top	5x	Clot for at least 60 minutes up to a maximum of 4 hours. Centrifuge and aliquot immediately.	1100-1300 x g for 10 min	OR	1 X (5mL) 23 X (2mL)	~1 mL serum into each vial (cryovial/ transfer vial). Aliquot in order tubes are labeled, 1-24		Frozen at -70°C	Frozen On dry ice	2 x per Week (Mon - Thurs)	Please ship Aliquots 1-10 in first shipment and 11-24 in next shipment. Do not ship the two shipments on the same day
OL Immuno 1-2										2	2	2			2 x 10mL Red Top	5x	Clot for at least 60 minutes up to a maximum of 4 hours. Centrifuge and aliquot immediately.	1100-1300 x g for 10 min	OR	1 X (3.6mL) 9 X (2mL)	~1 mL serum into each vial (cryovial/ transfer vial). Aliquot in order tubes are labeled, 1-10		Frozen at -70°C	Frozen On dry ice	2 x per Week (Mon - Thurs)	Please ship Aliquots 1-5 in first shipment and 6-10 in next shipment. Do not ship the two shipments on the same day
SARS CoV2 Blood							4		4				4		4 x 4 ml Red Top	5x	Clot for at least 60 minutes up to a maximum of 4 hours. Centrifuge and aliquot immediately.	1100-1300 x g for 10 min	OR	8 X	~1 mL serum into each 2 mL Cryovial Aliquot in order tubes are labeled, 1-8		Frozen at -70°C	Frozen On dry ice	Daily	Ship aliquots 1-4 in first shipment and aliquots 5-8 in second shipment.
COVID PCR Swab	X	X					X						X	N/A	Nasopharyngeal Swab and VTM	Please refer to Lab Manual							Frozen at -70°C	Frozen On dry ice	Daily	Ship directly to Viracor. Print out E-Req Form (instead of paper in kit) to include in the box with samples.
OL COVID PCR Swab										X					Nasopharyngeal Swab and VTM	Please refer to Lab Manual							Frozen at -70°C	Frozen On dry ice	Daily	
COVID PCR Saliva								(6) Day 3 Day 5 Day 7 Day 9 Day 14 Day 21	X				X	N/A	GeneFix Saliva Collection Tube	Please refer to Lab Manual							Frozen at -70°C	Frozen On dry ice	All Visist to be Batch Shipped Weekly on Mondays, except for the Unscheduled which should be Shipped Daily	
Biofire RPS							X						X	N/A	Nasopharyngeal Swab and VTM	Please refer to Lab Manual							Frozen at -70°C	Frozen On dry ice	Daily	
Blood Volume (mL)	48	48	48	48	48	48	16	N/A	16	N/A	N/A	N/A	N/A													
Collection Kits	A	A	B	B	B	B	C	D	E	F	G	G	UV (Baggie for Saliva Day 1)													

Estimated Total Blood Volume (mL) = 288
Does not include OL, Illness, and Unscheduled visits.

Micropipette is the preferred transfer device for the immunogenicity aliquots, if unavailable please use the pipette provided in the kit.

Site to provide Illness Visit Bag (containing Kit D- Site fills out subject ID on all labels) to Subject on Illness Visit Day 1.
Illness Visit Day 1 may be at Clinic or a Home Visit

If subject doesn't allow for site home visit, then site drops off Baggy with Saliva Collection supplies from the unscheduled kit and Illness Visit Bag (containing Kit D) at subjects home.
Neither NP swab will be collected.

Visit OL-2 is only for subjects who have received a single vaccine dose and received a 2nd dose at Visit OL-1.

Once subject collects any saliva sample they notify the site to pick up saliva sample day of collection in syrofoam shipper. Please ensure the Requisition Form is also picked up with the collection date entered. Please enter the information from the paper requision form into e-Requisition in Preclarus.

For ALL samples, please fill out e-Requisition in Preclarus – Paper Requisition included in kits are for EMERGENCY USE ONLY

Print out E-Req Form (instead of the paper requisitions provided in the kit) to include in shipment to Viracor.

Odd Number Sites to ship Monday/Wednesday. Even Number Sites to Tuesday/Thursday.

Swab can be stored at -20 until shipped same day if -70°C is not available. Saliva and Serum can be stored at -20 until shipped weekly if -70°C is not available.

The 2mL Immuno transfer vials provided in the UV kit will not contain any orange cap 2mL vials, but instead will include 23 of the 2mL w/ Cap O Ring Conical Bottom Skirted cryovials.

Illness Day 3, 5, 7, 9, 14, 21, 28 Saliva Collection Guidance
NOTE:
- **COVID positive result at Day 1 will require all saliva sample collections Day 3, 5, 7, 9, 14, 21, 28**
- **COVID negative result at Day 1; instruct subject to stop collecting saliva samples; any previously collected samples should be shipped to Viracor.**

Site to fill out subject ID on all 6 labels and on all 6 copies of the Sample Requision Form in Kit
1. **Subject collects saliva sample and fills out collection date on Sample Requision Form**
2. **Subject places saliva sample and sample req form in provided Biohazardous bag at Room Temperature- DO NOT REFRIGERATE**
3. **Site picks up saliva sample at subject's home on day of collection and transports back to site in syrofoam shipper at Room Temperature - DO NOT REFRIGERATE**
4. **Site freezes sample at -80C**
5. **Batch ship all saliva samples weekly.**

Central Labs @ PPD US: 1-800-323-2996 or 1-859-781-8877; siteservices.us@ppdi.com

Sponsor:	**Moderna**
Protocol #:	**mRNA-1273-P301**
PPD Study Code:	**MDRN0024**

Version 6.0B
5-Jan-2021

COLLECTION FLOW CHART

(Collect blood tubes in order listed below-top to bottom)

Visit / Time point	Visit 01 Baseline Month 0	Visit 02 Month 1	Visit 03 Month 2	Visit 04 Month 7	Visit 05 Month 13	Visit 06 End of Study	Illness D1	Illness D3 - D21	Illness D28	OL-1 Month 0	OL-2 Month 1	OL-3 Month 2	Unscheduled	Draw Tube Cap Color *Shade may vary per region	Blood Volume of Draw Tube (mL)	Invert	Time Elapsed (minutes) Post Collection / Prior to Centrifugation (minutes)	Centrifugation Speed and Time	Transfer Device	Ship to PPD Central Labs		Storage Condition at Site	Shipping Condition	Shipping Frequency	Special Instructions
Test																									
Immuno 1-8 Coll	8	8	8	8	8	8							8		8 x 6mL Red Top	5x	Clot for at least 60 minutes up to a maximum of 4 hours. Centrifuge and aliquot immediately.	1100-1300 x g for 10 min	OR	1 X (5mL) 23 X (2mL)	~1 mL serum into each vial (cryovial/ transfer vial). Aliquot in order tubes are labeled, 1-24		Frozen at -70°C	Frozen On dry ice	2 x per Week (Mon - Thurs)	Please ship Aliquots 1-10 in first shipment and 11-24 in next shipment. Do not ship the two shipments on the same day
OL Immuno 1-2										2	2	2			2 x 10mL Red Top	5x	Clot for at least 60 minutes up to a maximum of 4 hours. Centrifuge and aliquot immediately.	1100-1300 x g for 10 min	OR	1 X (3.6mL) 9 X (2mL)	~1 mL serum into each vial (cryovial/ transfer vial). Aliquot in order tubes are labeled, 1-10		Frozen at -70°C	Frozen On dry ice	2 x per Week (Mon - Thurs)	Please ship Aliquots 1-5 in first shipment and 6-10 in next shipment. Do not ship the two shipments on the same day
SARS CoV2 Blood							4		4				4		4 x 4 ml Red Top	5x	Clot for at least 60 minutes up to a maximum of 4 hours. Centrifuge and aliquot immediately.	1100-1300 x g for 10 min	OR	8 X	~1 mL serum into each 2 mL Cryovial Aliquot in order tubes are labeled, 1-8		Frozen at -70°C	Frozen On dry ice	Daily	Ship aliquots 1-4 in first shipment and aliquots 5-8 in second shipment.
COVID PCR Swab	X	X					X						X	N/A	Nasopharyngeal Swab and Saline	Please refer to Lab Manual						Frozen at -70°C	Frozen On dry ice	Daily	Ship directly to Viracor. Print out E-Req Form (instead of paper in kit) to include in the box with samples.
OL COVID PCR Swab										X					Nasopharyngeal Swab and VTM	Please refer to Lab Manual						Frozen at -70°C	Frozen On dry ice	Daily	
COVID PCR Saliva								(6) Day 3 Day 5 Day 7 Day 9 Day 14 Day 21	X				X	N/A	GeneFix Saliva Collection Tube	Please refer to Lab Manual						Frozen at -70°C	Frozen On dry ice	All Visist to be Batch Shipped Weekly on Mondays, except for the Unscheduled which should be Shipped Daily	
Biofire RPS							X						X	N/A	Nasopharyngeal Swab and VTM	Please refer to Lab Manual						Frozen at -70°C	Frozen On dry ice	Daily	
Blood Volume (mL)	48	48	48	48	48	48	16	N/A	16	N/A	N/A	N/A	N/A												
Collection Kits	A	A	B	B	B	B	C	D	E	F	G	G	UV (Baggie for Saliva Day 1)												

Estimated Total Blood Volume (mL) = 288
Does not include OL, Illness, and Unscheduled visits.

Micropipette is the preferred transfer device for the immunogenicity aliquots, if unavailable please use the pipette provided in the kit.

Site to provide Illness Visit Bag (containing Kit D- Site fills out subject ID on all labels) to Subject on Illness Visit Day 1.
Illness Visit Day 1 may be at Clinic or a Home Visit

If subject doesn't allow for site home visit, then site drops off Baggy with Saliva Collection supplies from the unscheduled kit and Illness Visit Bag (containing Kit D) at subjects home.
Neither NP swab will be collected.

Visit OL-2 is only for subjects who have received a single vaccine dose and received a 2nd dose at Visit OL-1.

Once subject collects any saliva sample they notify the site to pick up saliva sample day of collection in syrofoam shipper. Please ensure the Requisition Form is also picked up with the collection date entered. Please enter the information from the paper requision form into e-Requisition in Preclarus.

For ALL samples, please fill out e-Requisition in Preclarus – Paper Requisition included in kits are for EMERGENCY USE ONLY

Print out E-Req Form (instead of the paper requisitions provided in the kit) to include in shipment to Viracor.

Odd Number Sites to ship Monday/Wednesday. Even Number Sites to Tuesday/Thursday.

Swab can be stored at -20 until shipped same day if -70°C is not available. Saliva and Serum can be stored at -20 until shipped weekly if -70°C is not available.

The 2mL Immuno transfer vials provided in the UV kit will not contain any orange cap 2mL vials, but instead will include 23 of the 2mL w/ Cap O Ring Conical Bottom Skirted cryovials.

Illness Day 3, 5, 7, 9, 14, 21, 28 Saliva Collection Guidance
NOTE:
- **COVID positive result at Day 1 will require all saliva sample collections Day 3, 5, 7, 9, 14, 21, 28**
- **COVID negative result at Day 1; instruct subject to stop collecting saliva samples; any previously collected samples should be shipped to Viracor.**

Site to fill out subject ID on all 6 labels and on all 6 copies of the Sample Requision Form in Kit
1. **Subject collects saliva sample and fills out collection date on Sample Requision Form**
2. **Subject places saliva sample and sample req form in provided Biohazardous bag at Room Temperature- DO NOT REFRIGERATE**
3. **Site picks up saliva sample at subject's home on day of collection and transports back to site in syrofoam shipper at Room Temperature - DO NOT REFRIGERATE**
4. **Site freezes sample at -80C**
5. **Batch ship all saliva samples weekly.**

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