21120.9204 Client Specific SARS-CoV-2 RT-PCR Performance

Copy of version 9.0 (approved and current)

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Comments for version 9.0
Add in reagent section a sentence to check lot numbers and expiration dates of all reagents. In reponse to CA-00315

Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
Approval	(b) (6)	05-Oct-2020 20:29	9.0	(b) (6) (b) (6)	
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Version History

Version	Status	Type	Date Added	Date Effective	Date Retired
9.0	Approved and Current	Major revision	05-Oct-2020	05-Oct-2020	Indefinite
8.0	Retired	Major revision	01-Sep-2020	07-Sep-2020	05-Oct-2020
7.0	Retired	Major revision	05-Aug-2020	17-Aug-2020	07-Sep-2020
6.0	Retired	Major revision	26-Jul-2020	03-Aug-2020	17-Aug-2020
5.2	Retired	Minor revision	20-Jul-2020	20-Jul-2020	03-Aug-2020
5.1	Retired	Minor revision	20-Jul-2020	20-Jul-2020	20-Jul-2020
5.0	Retired	Major revision	01-Jul-2020	06-Jul-2020	20-Jul-2020
4.0	Retired	Major revision	11-Jun-2020	15-Jun-2020	06-Jul-2020
3.0	Retired	Major revision	04-Jun-2020	04-Jun-2020	15-Jun-2020
2.0	Retired	Major revision	03-Jun-2020	03-Jun-2020	04-Jun-2020
1.0	Retired	Initial version	22-May-2020	25-May-2020	03-Jun-2020

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INTENDED USE

The Viracor SARS-CoV-2 assay is a real-time RT-PCR test intended for the qualitative detection of SARS-CoV-2 viral RNA in nasopharyngeal swabs, nasal swab, nasopharyngeal wash, nasal wash, oropharyngeal swab and bronchoalveolar lavage and for the quantitative detection of SARS-CoV-2 viral RNA in nasopharyngeal swabs , serum, plasma and saliva from individuals suspected of COVID-19. Testing is limited to Viracor Eurofins Clinical Diagnostics which is a Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a certified high-complexity laboratory.

Results are for the detection and identification of SARS-CoV-2 viral RNA. SARS-CoV-2 RNA is generally detectable in respiratory specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA. Clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

The qualitative assay is intended for use under the Food and Drug Administration's Emergency Use Authorization.

TEST INFORMATION

Test Available: Qualitative: 13 Mar 2020, Quantitative: 26 May 2020

TAT: (b) (4)

The qualitative Coronavirus SARS-CoV-2 RT-PCR assay is a laboratory developed test involving nucleic acid extraction from respiratory (BAL, Nasal Wash, Nasal Swab, NP Swab, NP Wash, OP Swab) followed by real-time PCR amplification for the detection and quantification of SARS-CoV-2 genomic RNA. The quantitative Coronavirus SARS-CoV-2 RT-PCR assay is a laboratory developed test involving nucleic acid extraction from saliva, NP swab, serum and plasma.

Department: Infectious Disease - Biopharma

Test Code	Test Name	Specimen Type
8398003A	Coronavirus SARS-CoV-2 RT-PCR (Study Quantitative)	Nasal Swab, NP Swab, Saliva
8398006A	NR-Coronavirus SARS-CoV-2 RT-qPCR Study Quantitative	
8398001A	Coronavirus SARS-CoV-2 RT-PCR (Study Qual with Ct analyte)	Nasal Swab, NP Swab
8398002A	Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative)	
8398004A	STAT Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative)	
8398005A	AFTER HOURS Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative)	
8398007A	Coronavirus SARS-CoV-2 RT-PCR Saliva (Study Qualitative)	Saliva
8398009A	Coronavirus SARS-CoV-2 RT-PCR Serum (Study Quantitative)	Serum
8398008A	Coronavirus SARS-CoV-2 RT-PCR Plasma (Study Quantitative)	Plasma

Instrument Platforms:

- Extraction:

  21120.705 *NucliSENS easyMAG* (b) (4) *Total Nucleic Acid Extraction*

  - NucliSENS easyMAG or (b) (4) utilizing (b) (4) protocol – Respiratory

  21120.9152 (b) (4) Viral Pathogen Nucleic Acid Isolation

  - ThermoFisher KingFisher utilizing (b) (4) protocol – Respiratory

- Amplification:

  21120.461 *Real-Time PCR and RT-qPCR Using* (b) (4) *Instruments*

  - (b) (4) utilizing (b) (4) (as listed in SOP 21120.696 *PCR and RT-qPCR assay templates*) for use with NucliSENS extraction
  - (b) (4) utilizing (b) (4) (current template date)" (as listed in SOP 21120.696 *PCR and RT-qPCR assay templates*) for use with KingFisher extraction

METHOD PRINCIPLE

For all RT-PCR reactions using this procedure, nucleic acid extractions are performed using a bioMérieux NucliSENS easyMAG or (b) (4) instrument with (b) (4) or ThermoFisher KingFisher instrument with (b) (4) Viral/ Pathogen nucleic acid extraction reagents. The SARS-CoV-2 nucleic acid amplification assay is a real-time (b) (4) reverse-transcription polymerase chain reaction (RT-PCR) assay for detection and quantification of SARS-CoV-2 genomic RNA. Oligonucleotide primers are present which hybridize to the ssRNA genome and allow RNA amplification of a short region in the presence of thermostable DNA polymerase (Taq) enzyme and deoxy nucleotide triphosphates (dNTPs). A dual-labeled oligonucleotide probe that is complementary to an internal sequence of the amplification product is also present in the RT-PCR reaction mixture. The 5' exonucleolytic activity of Taq cleaves the fluorescent molecule (FAM) at the 5´ end of the dual-labeled probe, thus releasing it from the effects of a fluorescence-quenching molecule (e.g. Black Hole Quencher 1) at the 3´ end of the probe.

Additionally, oligonucleotide primers and a TaqMan probe for PCR detection of an internal extraction/ amplification control are also present in the SARS-CoV-2 RT-PCR reaction mix for the simultaneous detection of internal extraction/amplification control DNA in a multiplex reaction for each sample. Fluorescence intensity for both SARS-CoV-2 amplification and internal control amplification is measured in individual wells during each of the (b) (4) amplification cycles and a sample is considered positive when the signal intensity exceeds a predetermined baseline threshold value, which is used to establish a copies/mL value. The cycle number at which this occurs is referred to as the cycle threshold (C_T). Detection of SARS-CoV-2 RNA in a sample is determined by the C_T.

SPECIMEN REQUIREMENTS

Patient Preparation

No special patient preparation is required for this assay.

Specimen Collection and Transport

The performance of the quantitative*SARS-CoV-2* assay was established using plasma, serum, saliva and nasopharyngeal swabs. (b) (4) are also considered acceptable specimen types for use with the *SARS-CoV-2* assay but performance has not been established. See SOP 21120.435 *Specimen Collection and Transport* for procedures for collecting the proper specimens and how to prepare the specimens for transportation to the laboratory.

Specimen Type and Handling

See SOP 21120.595 *Specimen Processing Guide* for specimen types accepted and specimen conditions required for each assay on Viracor Eurofins test menu. This includes clinical laboratory procedures involved in determining specimen acceptability for samples received for testing in the Clinical Laboratory.

See SOP 21120.596 *Clinical Laboratory Processing Guide* for procedure on accessing the electronic Specimen Processing Guide that details appropriate collection and transport containers, volume requirements, and responses for suboptimal specimen.

See SOP 21120.586 *Specimen Receipt and Accessioning* for procedures performed upon receipt of specimen. If the specimen is not going to be tested immediately then it should be stored according to temperatures listed in SOP 21120.600 *Pre-processing Procedures for ID tests and Pre-processing Temperature Requirements for ID and AI*.

Specimen Type	(b) (4)
Respiratory	
Respiratory or Saliva	
Serum	
Plasma	

REAGENTS AND MATERIALS

Check all reagent lot numbers and expiration dates prior to use. Lot numbers are tracked in accordance with SOP 21120.572 *Verification and Qualification of Critical Laboratory Materials*. Lots are used within kits only. Lot numbers are not used interchangeably without prior approval from vendor.

Extraction reagents can be found in the following SOPs:

- 21120.705 *NucliSENS easyMAG* (b) (4) *Total Nucleic Acid Extraction*
- 21120.9152 (b) (4) *Viral Pathogen Nucleic Acid Isolation*

Amplification reagents are as follows:

Description	Source	Part / Cat Number	Storage / Expiration*	Critical Material
(b) (4)				YES
				YES
RNAse Free H2O	(b) (4)			NO

*: See SOP 21120.380 *Expiration Dating of Laboratory Materials* for proper expiration dating assignment.

Reagent Handling

Store reagents at temperature conditions listed above when not in use.

Reagent Preparation

Assay specific primers and probes are prepared following SOP 21120.764 *Oligonucleotide Mix Preparation and Quality Control Procedure.*

(b) (4) AND STANDARDS

Refer to SOP 21120.369 *Analytical Quality Control: Assay* (b) (4) *Verification* for instructions and guidelines for maintaining the analytical accuracy of laboratory test methods through regular calibration and calibration verification procedures.

(b) (4)

Description	Source	Part/Cat No	Storage / Expiration*
(b) (4) indicated in document SOP 21120.556 *Acceptable Assay Standard Values*	(b) (4)		

* See SOP 21120.380 *Expiration Dating of Laboratory Materials* for proper expiration dating assignment.

Standards:

Description	Source	Part/Cat No	Storage / Expiration*
(b) (4) indicated in document *25 800xx_____ Molecular RNA Standard Set.*	(b) (4)		

* See SOP 21120.380 *Expiration Dating of Laboratory Materials* for proper expiration dating assignment.

(b) (4) and Standard Curve Preparation

Information regarding (b) (4) and Standard Curve Preparation can be found in SOP 21120.461 *Real-Time PCR and RT-qPCR Using* (b) (4) *Instruments*.

QUALITY CONTROL

The quality control program for this test is established in accordance with SOP 21120.517 *Analytical Quality Control: Quality Control Procedures*.

Quality control samples are prepared and control ranges are established and maintained in accordance with SOP 21120.517 *Analytical Quality Control: Quality Control Procedures*.

Extraction Controls

Specimen Matrix	Description	Source	Part/Cat No.	Storage / Expiration*
All	MS2 Bacteriophage (Internal control)	(b) (4)		

(b) (4)

* See SOP 21120.380 *Expiration Dating of Laboratory Materials* for proper expiration dating assignment.

Amplification Controls

Specimen Matrix	Description	Source	Part/Cat No.	Storage / Expiration*
(b) (4)				

* See SOP 21120.380 *Expiration Dating of Laboratory Materials* for proper expiration dating assignment.

Control Procedure

(b) (4)

(b) (4) indicated in SOP 21120.556 *Acceptable Assay Standard Values)* are included (b) (4) COV2 RT-PCR (b) (4) (b) (4)

(b) (4)

Quality Control Acceptance Criteria/Repeat Criteria

Refer to SOP 21120.578 *PCR and RT PCR Acceptance and Retest Criteria* for acceptance criteria and corrective actions for (b) (4) (b) (4)

Acceptance Criteria/Repeat Criteria

Negative Controls

Conditions	Action
(b) (4)	

(b) (4)

Internal Control
MS2 (b) (4)
Acceptable Ct (b) (4)

Conditions	Action
(b) (4)	

Proficiency Testing
These tests shall be challenged by in-house and/or external proficiency testing (b) (4)

EQUIPMENT AND SUPPLIES

Equipment and Supplies required to perform this assay can be found in the following SOPs:

- 21120.705 *NucliSENS easyMAG* (b) (4) *Total Nucleic Acid Extraction*
- 21120.9152 (b) (4) *Viral Pathogen Nucleic Acid Isolation*
- 21120.461 *Real-Time PCR and RT-qPCR Using* (b) (4) *Instruments*

The following SOPs may be used to perform this assay:

- 21120.7445 (b) (4) *Plate Sealer Operation Maintenance and Calibration*

Preventative Maintenance

Follow maintenance procedures for equipment as included in the following SOPs:

- 21120.812 *Operation, Qualification and Maintenance of the NucliSENS easyMAG*
- 21120.6763 *Operation Qualification and Maintenance of the* (b) (4)
- 21120.9034 *KingFisher Flex System Operation, Maintenance, and Calibration*
- 21120.785 (b) (4) *Operation, Maintenance, and Calibration*

Environmental Conditions

See instrument manuals for environmental conditions required for operation of equipment.

PROCEDURE

The essential steps to perform the Coronavirus SARS-CoV-2 RT-PCR assay on clinical respiratory include:

Preprocessing for saliva samples ONLY:

(b) (4)

Pre-Analytical

General sample handling and workflow is described in SOP 21120.765 *Clinical Laboratory Workflow Requirements for Infectious Disease, Isotope, and Molecular Testing*.

Safety Note: Samples should incubate in lysis buffer in the BSC for (b) (4) **prior to loading on the easyMAG,** (b) (4) **or KingFisher.**

Analytical

Nucleic Acid Extractions are performed using the one of the following SOPs:

- 21120.705 *NucliSENS easyMAG* (b) (4) *Total Nucleic Acid Extraction*
- 21120.9152 (b) (4) *Viral Pathogen Nucleic Acid Isolation*

For Qualitative testing (CVID 8639, 8734, 8640 & 8642)

Prepare Extraction Run Map in (b) (4)

(b) (4)

For CVID 8639, 8734, 8640, 8642 **ONLY** use the (b) (4)

(b) (4)

For Quantitative testing (CVID 8638, 8505, 8645, 8644, 8646, 8726, 9256)

Prepare Extraction Run Map in (b) (4)

(b) (4)

For Quantitative testing (Serum & Plasma only)

Prepare Extraction Run Map in (b) (4)

(b) (4)

(b) (4)

Nucleic Acid Amplification is performed according to SOP 21120.461 *Real-Time PCR and RT-qPCR Using* (b) (4) (b) (4) *Instruments*. The following apply specifically to the SARS-CoV-2 RT-PCR assay:

For Qualitative testing (CVID 8639, 8734, 8640, & 8642)

Prepare Extraction Map

Log into (b) (4)

(b) (4)

FOR CVID 8639, 8640, 8642 and 8734 ONLY use the clinical laboratory PCR procedure including standards, primer/probe and controls.

For Qualitative testing (CVID 8640, 8642, 8639 & 8734)

Prepare Amplification Map Using (b) (4)

Log into (b) (4)

(b) (4)

For Quantitative testing (CVID 8638, 8505, 8645, 8644, 8646, 8726)

Prepare Amplification Map in (b) (4)

Log into (b) (4)

(b) (4)

For Quantitative testing (Plasma and Serum ONLY)

Prepare Amplification Map in (b) (4)

Log into (b) (4)

(b) (4)

Nucleic acid from the easyMAG (b) (4) extraction protocol will be amplified using the (b) (4) is used for the (b) (4) amplification and analysis. Settings are as follows:

(b) (4)

(b) (4)

- Nucleic acid from the (b) (4) extraction protocol will be amplified using the (b) (4) is used for the (b) (4) Fast amplification and analysis. Settings are as follows:

(b) (4)

Post-Analytical

Analysis is performed according to SOP 21120.461 *Real-Time PCR and RT-qPCR Using* (b) (4) *Instruments* and SOP 21120.575 *Reporting Results for ID.* The following apply specifically to the SARS-CoV-2 RT-PCR assay:

- (b) (4)

CALCULATIONS

Manual Calculations:

(b) (4)

RESULT REPORTING AND REPEAT CRITERIA

Resulting Procedure

Refer to SOP 21120.578 *PCR and RT-qPCR Acceptance and Retest Criteria* for details regarding acceptability and corrective action for sample results. Refer to SOP 21120.575 *Reporting Results for ID* for procedures for result exporting and reporting.

Resulting Procedure (CVID 8644, 8646, 8730, 8726,8645, 9256)

(b) (4)

Analysis of Results for CVID (8644, 8646, 8730, 8726, 8645, 9256)

A. Analyzing results

(b) (4)

(b) (4)

For CVID 8505, 8646, 8644, 8646, 8730, 8726, 9256 only

(b) (4)

Analysis of Results for CVID (8734, 8639, 9734, 8640, &8642)

(b) (4)

(b) (4)

Analysis of Results Plasma and Serum:

(b) (4)

(b) (4)

Resulting is performed automatically during export according to rules described in SOP 21120.1212 *Real Time PCR and RT-qPCR Result Calculation and Rounding*. The following apply specifically to the SARS-CoV-2 RT-PCR assay:

(b) (4)

Units of Measure:

Quantitative: Copies/mL

(b) (4)

LOD= Limit of Detection

(b) (4)

Nasopharyngeal swab – Qual EUA	Copies/mL
LOD	73 copies/mL

(b) (4)

Nasopharyngeal swab – Quant LDT	Copies/mL

(b) (4)

Saliva- Quant/Qual LDT	Copies/mL

(b) (4)

Serum- Quant	Copies/mL

(b) (4)

Plasma-Quant	Copies/mL

(b) (4)

Clinically Reportable Range:

Reportable ranges for the assay are listed in SOP 21120.577 *Rounding and Reporting Rules for qPCR and RT-qPCR Assays*.

Test Code	Test Name	Reportable Range
8398002A 8398004A 8398005A	Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative)	(b) (4)
8398003A and 8398006A, 8398009A, 8398008A	Coronavirus SARS-CoV-2 RT-PCR (Study Quantitative)	
8398001A 8398007A	Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative) Coronavirus SARS Cov2 Saliva Study Qualitative	

Comments:

In order to be accurate with Saliva reporting in collection devices, the following comments will need to be added

(b) (4)

(b) (4) When resulting please follow these steps:

(b) (4)

(b) (4)

Comment for CVID 8644, 8646, 8730, 8726 only:

(b) (4)

EXPECTED VALUES AND REFERENCE RANGES

Expected Values: Not Detected

Alert Values and Critical Values: There are no Alert or Critical values currently associated with this assay.

CLINICAL SIGNIFICANCE

Coronavirus SARS-CoV-2 RT-PCR test is intended for the qualitative detection of SARS-CoV-2.

The qualitative LOD of Viracor's SARS-CoV-2 RT-PCR EUA qualitative assay is 73 copies/mL for nasal wash, nasopharyngeal swab and BAL specimen types. The (b) (4) of Viracor's SARS-CoV-2 RT-qPCR LDT quantitative/qualitative assay is (b) (4) for nasopharyngeal swab saliva specimen types. The assay

(b) (4) has demonstrated that 100% of known SARS-CoV-2 strains will be accurately detected with this assay.

(b) (4)

At the end of 2019, an outbreak of the virus initially referred to as 2019 novel Coronavirus, later identified as SARS-CoV-2, occurred in Wuhan, Hubei Province, China. A betacoronavirus, like MERS-CoV and SARS-CoV, the virus originates from bats. As of January 30, 2020, the International Health Regulations Emergency Committee of the World Health Organization declared a “public health emergency of international concern.”

The disease caused by SARS-CoV-2 has been named coronavirus disease 2019, abbreviated as COVID-19. Main symptoms of the disease include fever, cough and shortness of breath. The CDC recommends reaching out to a physician if you develop symptoms and have been in close contact with a person known to have COVID-19; or if you have recently traveled from an area with widespread or ongoing community spread of COVID-19. The virus is spread via person-to-person contact through respiratory droplets produced when a person coughs or sneezes. The best preventative measures are to avoid close contact with people who are sick; avoid touching nose, eyes and mouth; cover a cough or sneeze with a tissue and discard immediately; and clean and disinfect frequently touched objects and surfaces using a household cleaning spray or wipe. Washing your hands with soap and water for at least 20 seconds frequently is one of the best preventative measures and hand sanitizer can be used when soap and water are not available.

PROCEDURE NOTES

Testing System Unavailable

Viracor Eurofins takes precautions to ensure that testing systems do not have prolonged outages by ensuring that we have redundant equipment for all of our testing platforms. Therefore, our backup plan for a system outage is always to run patient specimens on the redundant system for the impacted assay(s). In rare instances, both the primary and secondary platforms can be out of service. In these cases, we store specimens according to their individual storage requirements until such time as the testing system is back to operational status and testing may resume again. In extreme cases whereby an entire testing system is going to be completely down for an extended period of time of (b) (4) clients will be notified and alternative testing options, potentially at other facilities will be communicated to them where possible and at their discretion.

LIMITATIONS OF THE METHOD

RNA purified from clinical specimens may contain endogenous inhibitors of the PCR reaction that, if undetected, could lead to false negative results. To allow definitive identification of RNA samples containing PCR inhibitors, an internal control bacteriophage is added to each sample prior to RNA extraction. Real-time PCR amplification of the internal control target is performed in a multiplex reaction along with the Coronavirus SARS-CoV-2 RT-PCR dual gene target reaction. If inhibition is detected (CT>(b) (4) the clinical samples are re-extracted and retested. If inhibition is detected after re-extraction and retesting, the result is reported as “See Comment**” with a comment stating “Endogenous inhibition of PCR was detected in this sample; therefore the results for this test were not conclusive. Additional testing with a new sample is recommended. Other PCR tests ordered on this specimen may be partially inhibited. Interpret results with caution.” RNA purified from clinical specimens may also have residual nuclease activity which could result in target RNA degradation and false negative results. Inclusion of the internal bacteriophage lambda control allows rapid, definitive identification of any samples with residual nuclease activity.

Pathogen genomic sequence mutations or polymorphisms could lead to false negative results if the base changes occurred at the critical 3' ends of the oligonucleotide primers or the 5' end of the TaqMan dual-labeled probe. The genomic target for the Coronavirus SARS-CoV-2 RT-PCR assay was specifically selected due to the (b) (4) (b) (4) (b) (4) Amplification curves of all PCR results are monitored by a laboratory scientist for (b) (4) which is an indication of (b) (4) (b) (4)

PERFORMANCE SPECIFICATIONS

Refer to the following documents for performance specifications for the Coronavirus SARS-CoV-2 RT-PCR assay:

- 21120.8918 *SARS-CoV-2 (COVID-19) RT-qPCR Validation Report*
- 21120.9142 *SARS CoV 2 RT qPCR Validation Report Alt Ext & Amp methods*
- 21120.9249 *SARS CoV 2 RT qPCR Swab and* (b) (4) *Saliva Validation Report*

SAFETY

The following personal protective equipment will be applied as directed in currently effective Safety SOPs, including but not limited to, gloves, masks, lab coats, face shields and eye protection.

Personnel executing these procedures must be trained on effective Safety SOPs as listed in 21120.265 *Safety Program*.

See Material Safety Data Sheet (MSDS) manual for further details regarding all agents in the kit.

RELATED DOCUMENTS

21120.265 *Safety Program*
21120.369 *Analytical Quality Control: Assay Calibration and Calibration Verification*
21120.380 *Expiration Dating of Laboratory Materials*
21120.435 *Specimen Collection and Transport*
21120.461 *Real-Time PCR and RT-qPCR Using* (b) (4) *Instruments*
21120.517 *Analytical Quality Control: Quality Control Procedures*
21120.551 *Quality Control Testing of the* (b) (4) *for Clinical Testing*
21120.554 *Real Time PCR and RT-qPCR Result Calculation and Rounding*
21120.556 *Acceptable Assay Standard Values*
21120.572 *Verification and Qualification of Critical Laboratory Materials*
21120.575 *Reporting Results for ID*
21120.577 *Rounding and Reporting Rules for qPCR and RT-qPCR Assays*
21120.578 *PCR and RT PCR Acceptance and Retest Criteria*
21120.580 (b) (4) *User Procedures*
21120.595 *Specimen Processing Guide*
21120.596 *Clinical Laboratory Processing Guide*
21120.600 *Pre-processing Procedures for ID tests and Pre-processing Temperature Requirements for ID and AI*
21120.640 (b) (4) *Processing Procedure*
21120.696 *PCR and RT-qPCR assay templates*
21120.705 *NucliSENS easyMAG* (b) (4) *Total Nucleic Acid Extraction*
21120.764 *Oligonucleotide Mix Preparation and Quality Control Procedure*
21120.765 *Clinical Laboratory Workflow Requirements for Infectious Disease, Isotope, and Molecular Testing*
21120.785 (b) (4) *Operation, Maintenance, and Calibration*
21120.812 *Operation, Qualification and Maintenance of the NucliSENS easyMAG*

21120.873 *Operation, Maintenance, and Calibration of* (b) (4)
21120.3629 (b) (4) *RT-qPCR Master Mix Calculation Sheet*
21120.6763 *Operation Qualification and Maintenance of the* (b) (4)
21120.7445 (b) (4) *Plate Sealer Operation Maintenance and Calibration*
21120.9034 *KingFisher Flex System Operation, Maintenance, and Calibration*
21120.9152 (b) (4) (b) (4) *Viral Pathogen Nucleic Acid Isolation*
21120.9166 (b) (4) *COV2 Fast Master Mix Calculation Sheet*
25 800xx_____ *Molecular RNA Standard Set*
21120.8918 *SARS-CoV-2 (COVID-19) RT-qPCR Validation Report. Original EUA assay (a qualitative assay).*
21120.9109 SARS CoV 2 RT qPCR NW NP SWAB BAL and SERUM (using easyMAG 0-5 mL input) Validation Report. Original EUA validation data analyzed and reported quantitatively.
21120.9142 *SARS CoV 2 RT qPCR Validation Report Alt Ext & Amp methods*. (Bridged to the original EUA new methods: (b) (4)
(b) (4)
21120.9451 *Qualification Protocol to Verify the Limit of Detection,* (b) (4) *with regards to the SARS Coronavirus 2 (SARS-CoV-2) Reverse Transcription Qualitative Real Time PCR assay in Saline and VTM Specimens*

REFERENCES

None

ATTACHMENTS

None