TRAINING UPDATE

Lab Location:	SGMC & WOMC	**Date Distributed:**	5/20/2020
Department:	Core Lab	**Due Date:**	6/15/2020
		Implementation:	**5/20/2020**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

SARS-CoV-2 PCR using Cepheid GeneXpert®
SGMC.M1011 v4

Cepheid SARS-CoV-2 PCR Quality Control Log AG.F509.2

Description of change(s):

SOP

Section	Reason
6.3	Changed external QC frequency per IQCP (*deleted day of testing QC*)
16	Added IQCP info

FORM – removed requirement to perform external QC each day of testing

This revised SOP and FORM was implemented on May 20, 2020

Document your compliance with this training update by taking the quiz in the MTS system.

Technical SOP

Title	**SARS-CoV-2 PCR using Cepheid GeneXpert®**
Prepared by	Ron Master Date: 03/23/2020
Owner	Ron Master Date: 03/23/2020

Laboratory Approval	**Local Effective Date:**	
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		

TABLE OF CONTENTS

1. TEST INFORMATION

Assay	Method/Instrument	Test Code
Cepheid Xpert® Xpress SARS-CoV-2 Test	Real-time Polymerase Chain Reaction (PCR) Assay / GeneXpert System	COVID

Synonyms/Abbreviations
SARSCoV2, COVID19

Department
Core Lab

2. ANALYTICAL PRINCIPLE

The Xpert Xpress SARS-CoV-2 test is a molecular in vitro diagnostic test that aids in the detection and diagnosis SARS-CoV-2 and is based on widely used nucleic acid amplification technology. The Xpert Xpress SARS-CoV-2 test contains primers and probes and internal controls used in RT-PCR for the in vitro qualitative detection of SARS-CoV-2 RNA in nasopharyngeal swab specimens. The Xpert Xpress SARS-CoV-2 test is performed on GeneXpert Instrument Systems.

The GeneXpert Instrument Systems automate and integrate sample preparation, nucleic acid extraction and amplification, and detection of the target sequences in simple or complex samples using real-time PCR assays. The systems consist of an instrument, computer, and preloaded software for running tests and viewing the results. The systems require the use of single-use disposable cartridges that hold the RT-PCR reagents and host the RT-PCR process. Because the cartridges are self-contained, cross-contamination between samples is minimized. For a full description of the systems, see the GeneXpert Dx System Operator Manual.

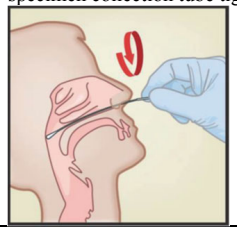
The Xpert Xpress SARS-CoV-2 test includes reagents for the detection of RNA from SARS-CoV-2 in nasopharyngeal swab specimens. A Sample Processing Control (SPC) and a Probe Check Control (PCC) are also included in the cartridge utilized by the GeneXpert instrument. The SPC is present to control for adequate processing of the sample and to monitor for the presence of potential inhibitor(s) in the RT-PCR reaction. The SPC also ensures that the RT-PCR reaction conditions (temperature and time) are appropriate for the amplification reaction and that the RT-PCR reagents are functional. The PCC verifies reagent rehydration, PCR tube filling, and confirms that all reaction components are present in the cartridge including monitoring for probe integrity and dye stability.

The nasopharyngeal swab specimen is collected and placed into a viral transport tube containing 3 mL transport medium. The specimen is briefly mixed by rapidly inverting the collection tube 5 times. Using the supplied transfer pipette, the sample is transferred to the sample chamber of the Xpert Xpress SARS-CoV-2 cartridge. The GeneXpert cartridge is loaded onto the

GeneXpert Instrument System platform, which performs hands-off, automated sample processing, and real-time RT-PCR for detection of viral RNA.

3. SPECIMEN REQUIREMENTS

3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	None
Specimen Collection and/or Timing	In order to obtain an adequate specimen, the procedure for specimen collection must be followed closely **Collect nasopharyngeal specimens according to the following procedure using the recommended swab:** For collection and transport of nasopharyngeal swab specimens, use the Xpert Nasopharyngeal Sample Collection Kit for Viruses Cepheid Catalog number: SWAB/B-100 (Copan UTM P/N 330C and Copan nylon swab P/N 503CS01) or Quest 3-mL VCM/NP or urethral swab set. Insert the swab into either nostril, passing it into the posterior nasopharynx (see Figure 1). Rotate swab by firmly brushing against the nasopharynx several times. Remove and place the swab into a viral transport tube (3 mL). Break swab at the indicated break line and cap the specimen collection tube tightly. 
Special Collection Procedures	See above
Other	None

3.2 Specimen Type & Handling

Criteria	
Type -Preferred	Nasopharyngeal swab in viral transport medium
-Other Acceptable	None

Criteria	
Collection Container	Swab in UTM or VCM transport medium
Volume - Optimum	NP swab in viral transport medium
- Minimum	N/A
Transport Container & Temperature	Xpert Nasopharyngeal Sample Collection Kit for Viruses Cepheid Catalog number: SWAB/B-100 or Quest 3-mL VCM/NP or urethral swab set 8 hours at 15-30°C
Stability & Storage Requirements	Room Temperature (15-30°C): 8 hours
	Refrigerated (2-8°C): 7 days
	Frozen: Not acceptable
Timing Considerations	Not applicable
Unacceptable Specimens & Actions to Take	• Any specimen, which does not meet the above criteria • Follow specimen rejection process
Compromising Physical Characteristics	Not applicable
Other Considerations	None

NOTE: Labeling requirements for all reagents, calibrators and controls include: (1) Open date, (2) Substance name, (3) Lot number, (4) Date of preparation, (5) Expiration date, (6) Initials of tech, and (7) Any special storage instructions. Check all for visible signs of degradation.

4. REAGENTS

The package insert for a new lot of kits or reagents must be reviewed for any changes before the kit is used.

4.1 Reagent Summary

Reagents / Kits	Supplier & Catalog Number
Xpert Xpress SARS-CoV-2 Assay kit	Cepheid XPRSARS-COV2-10 contains sufficient reagents to process 10 samples

4.2 Reagent Preparation and Storage

Assay Kit - Xpert® SARS-CoV-2- XPRSARS-COV2-10	
Xpert Xpress SARS-CoV-2 test Cartridges with integrated reaction tubes	Cartridge: • Bead 1 (freeze-dried) 1 of each per cartridge • Bead 2 (freeze-dried) 1 of each per cartridge • Bead 3 (freeze-dried) 1 of each per cartridge • Lysis Reagent (Guanidinium thiocyanate) – 1.5 mL per cartridge • Binding Reagent – 1.5 mL per cartridge • Elution Reagent – 3.0 mL per cartridge Disposable transfer pipettes – 12 per kit

Storage/ Stability	Store the Xpert Xpress SARS-CoV-2 cartridges at 2–28 °C until the expiration date provided on the label. Do not open a cartridge lid until you are ready to perform testing. Do not use a cartridge that has leaked
Preparation	None required

5. CALIBRATORS/STANDARDS

Not applicable

6. QUALITY CONTROL

6.1 Controls Used

Xpert Xpress SARS-CoV-2	Supplier and Catalog Number
Sample Processing Control (SPC)	Cartridge component
Probe Check Control (PCC)	Cartridge component
Negative External Control	SeraCare AccuPlex™ Reference Material Kit, catalog number 0505-0126 (Order Code CEPHEID)
Positive External Control	SeraCare AccuPlex™ Reference Material Kit, catalog number 0505-0126 (Order Code CEPHEID)

6.2 Control Preparation and Storage

Sample processing control (SPC) - Included in the Cartridge	
Storage	Refer to section 4
Stability	Refer to section 4
Preparation	Ready to use

Probe Check Control (PCC) - Included in the Cartridge	
Storage	Refer to section 4
Stability	Refer to section 4
Preparation	Ready to use

External Characterized Positive & Negative Controls	
Storage	Store at 2-8°C
Stability	Stable until manufacturer's expiration date.
Preparation	Ready for use

6.3 Number and Frequency

QC Frequency and Procedure	
1	A Sample Processing Control (SPC) and a Probe Check Control (PCC) (internal controls) are run within each test
2	External Controls are run with each new kit lot number or shipment or every 31 days, whichever is more frequent. External controls must be treated in the same manner as a patient samples.
3	Mix control by rapidly inverting the external control tube 5 times. Open the cap on the external control tube.
4	Open the cartridge lid.
5	Using a clean transfer pipette, transfer one draw of the external control sample into the large opening (Sample Chamber) in the cartridge.
6	Close the cartridge lid and start the test following instructions in Section 8.2, GeneXpert Analysis

6.4 Tolerance Limits and Criteria for Acceptable QC

A. Tolerance Limits

Control Type	Instrument-Reported Assay Result	Interpretation of Result
External Positive Control	See Section 10.1	See Section 10.1
External Negative Control	See Section 10.1	See Section 10.1
SPC	Passes if Meets the Assigned Acceptance Criteria. See Section 10.1	
PCC		

B. Criteria for Acceptable QC

- All controls must yield acceptable result.
- Controls and patient data must be reviewed for acceptability and for atypical or unexpected results or trends prior to reporting patient results.
- DO NOT release results from runs with unacceptable controls or with unusual patterns, trends or distribution in patient values.

C. Corrective Action

- Report problem to supervisor or designee.
- All rejected runs must be effectively addressed and include the following documentation:
  - Control(s) that failed (e.g., positive control with negative result) and/or atypical or unexpected patient results
  - Actions taken
  - Statement of what was done with the patient samples from the affected run/batch,
  - Date and initials of the person recording the information.

- Patient samples in failed analytical runs must be reanalyzed.

NOTE: The laboratory director or designee may override rejection of partial or complete runs. Justification for the override must be documented in detail.

6.5 Documentation

- Record all Quality Control results (failed and successful) manually or electronically.
- Quality control records are reviewed daily at the bench, weekly by the Group Lead or designee, and monthly by the Supervisor/Manager or designee.
- Refer to complete policies and procedures for QC documentation and for record retention requirements in the Laboratory QC Program.
- Refer to Quest Diagnostics Records Management Program for Quality Control record retention requirements.

7. EQUIPMENT and SUPPLIES

7.1 Assay Platform

- Cepheid GeneXpert System

7.2 Equipment

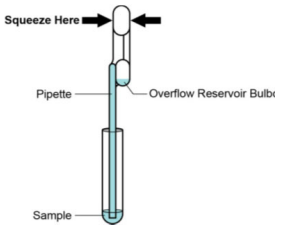
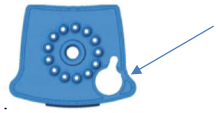
- Computer, monitor, printer, and required application software
- Biological Safety Cabinet
- Timer
- Refrigerator, 2-8°C
- Vortex mixer

7.3 Supplies

- Sterile transfer pipette
- Personal protective equipment (lab coat, powder-free gloves, face shields, and etc.)
- Disposable biohazard waste containers (sharps, etc.)
- 4X4 gauze
- 10% bleach
- 70% ethanol

8. PROCEDURE

NOTE: For all procedures involving specimens, buttoned lab coats, gloves, and face protection are required minimum personal protective equipment. Report all accidents to your supervisor.

8.1	Preparation of Cartridge
Notes: • All work must be performed in an appropriate BSC. • Before testing, clean the work area with a solution of 1:10 dilution of household chlorine bleach and then repeat the cleaning of the work area with 70% ethanol. Wipe work surfaces dry completely before proceeding • Do not open a cartridge until you are ready to perform testing • Start the test within 15 minutes of adding the sample to the cartridge. • Do not touch the integrated reaction tube that is attached to the cartridge.	
1.	Remove the cartridge from the package.
2.	Check that the specimen transport tube is closed.
3.	Mix specimen by rapidly inverting the specimen transport tube five (5) times. Open the cap on the specimen transport tube.
4.	Open the cartridge lid.
5.	Remove the transfer pipette from the wrapper.
6.	Squeeze the top bulb of the transfer pipette completely and then place the pipette tip in the specimen transport tube. 
7.	Release the top bulb of the pipette to fill the pipette before removing from the tube. After filling pipette, excess sample will be seen in the overflow reservoir bulb of the pipette. Check that the pipette does not contain bubbles.
8.	To transfer the sample to the cartridge, squeeze the top bulb of the transfer pipette completely again to empty the contents of the pipette into the large opening (Sample Chamber) in the cartridge. Dispose of the used pipette. 
9.	Close the cartridge lid and proceed to Section 8.2.

8.2	GeneXpert Analysis
1.	Turn on the GeneXpert Instrument System, and then turn on the computer.
2.	On the desktop, double-click the GeneXpert software icon.
3.	Log on to the GeneXpert Instrument System software using user name and password.
4.	In the GeneXpert Dx Systems window, click **Create Test**.
5.	In the Sample ID box, scan or type the sample ID. Make sure you type the correct sample ID. The sample ID is associated with the test results and is shown in the View Results window and all the reports.
6.	Scan the barcode on the Xpert Xpress SARS-CoV-2 cartridge. Using the barcode information, the software automatically fills in the boxes for the following fields: Reagent Lot ID, Cartridge SN, and Expiration Date.
7.	In the GeneXpert Dx Systems, click **Start Test**.
8.	Locate the module with the blinking green light, open the instrument module door and load the cartridge.
9.	Close the door. The test starts and the green light stops blinking. When the test is finished, the light turns off and the door will unlock. Remove the cartridge.
10.	Dispose of the used cartridges in biohazard waste container.
11.	A report is printed for each sample at the completion of testing.

NOTE: In the event that the test system becomes inoperable, notify supervision or designee for further direction. Patient specimens must be stored in a manner that maintains the integrity of the specimen.

9. CALCULATIONS

Not applicable

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Data

The results are interpreted automatically by the GeneXpert System and are clearly shown in the View Results window. The Xpert Xpress SARS-CoV-2 test provides test results based on the detection of two gene targets according to the algorithms shown in Table 1.

Table 1. Xpert Xpress SARS-CoV-2 Possible Results

Result text	N2	E	SPC
SARS-CoV-2 POSITIVE	+	+	+/-
SARS-CoV-2 POSITIVE	+	-	+/-
SARS-CoV-2 PRESUMPTIVE POSITIVE	-	+	+/-
SARS-CoV-2 NEGATIVE	-	-	+
INVALID	-	-	-

Xpert Xpress SARS-CoV-2 Results and Interpretation

Assay Result Reported	Interpretation of Result
SARS-CoV-2 POSITIVE	The 2019 novel coronavirus (SARS-CoV-2) target nucleic acids are detected. • The SARS-CoV-2 signal for the N2 nucleic acid target or signals for both nucleic acid targets (N2 and E) have a Ct within the valid range and endpoint above the minimum setting • SPC: NA; SPC is ignored because coronavirus target amplification occurred • Probe Check: PASS; all probe check results pass
SARS-CoV-2 PRESUMPTIVE POSITIVE	The 2019 novel coronavirus (SARS-CoV-2) nucleic acids may be present. **Sample should be retested. Repeat test according to the Retest Procedure in Section 10.6.** For samples with a repeat Presumptive Positive result, Report result as DETECTED. • The SARS-CoV-2 signal for only the E nucleic acid target has a Ct within the valid range and endpoint above the minimum setting • SPC: NA; SPC is ignored because a target amplification has occurred. • Probe Check: PASS; all probe check results pass
SARS-CoV-2 NEGATIVE	The 2019 novel coronavirus (SARS-CoV-2) target nucleic acids are not detected. • The SARS-CoV-2 signals for two nucleic acid targets (N2 and E) do not have a Ct within the valid range and endpoint above the minimum setting • SPC: PASS; SPC has a Ct within the valid range and endpoint above the minimum setting • Probe Check: PASS; all probe check results pass
INVALID	SPC does not meet acceptance criteria. Presence or absence of the 2019 novel coronavirus (SARS-CoV-2) nucleic acids cannot be determined. **Repeat test according to the Retest Procedure in Section 10.6.** • SPC: FAIL; SPC and SARS-CoV-2 signals do not have a Ct within valid range and endpoint below minimum setting • Probe Check – PASS; all probe check results pass Repeat test according to the instructions in Section 10.6, Retest Procedure

Assay Result Reported	Interpretation of Result
ERROR	Presence or absence of the 2019 novel coronavirus (SARS-CoV-2) nucleic acids cannot be determined. **Repeat test according to the Retest Procedure in Section 10.6.** • SARS-CoV-2: NO RESULT • SPC: NO RESULT • Probe Check: FAIL[1]; all or one of the probe check results fail [1] If the probe check passes, the error is caused by the maximum pressure limit exceeding the acceptable range or by a system component failure.
NO RESULT	Presence or absence of the 2019 novel coronavirus (SARS-CoV-2) nucleic acids cannot be determined. **Repeat test according to the Retest Procedure in Section 10.6**. A NO RESULT indicates that insufficient data were collected. For example, the operator stopped a test that was in progress. • SARS-CoV-2: NO RESULT • SPC: NO RESULT • Probe Check: NA (not applicable)

10.2 Rounding

Not applicable

10.3 Units of Measure

Not applicable

10.4 Analytical Measurement Range (AMR)

Not applicable

10.5 Review Patient Data

- Review patient results for unusual patterns, trends or distribution.
- Report atypical or unexpected results or trends for this test to appropriate supervisory personnel, prior to releasing results.

10.6 Repeat Criteria and Resulting

If any of the test results mentioned below occur, repeat the test once according to instructions in Retest Procedure below.

- A PRESUMPTIVE POSITIVE indicates the 2019 novel coronavirus (SARS-CoV-2) nucleic acids may be present.

- An INVALID result indicates that the control SPC failed. The sample was not properly processed, PCR is inhibited, or the sample was not properly collected.
- An ERROR result could be due to, but not limited to, Probe Check Control failure, system component failure, or the maximum pressure limits were exceeded.
- A NO RESULT indicates that insufficient data were collected. For example, cartridge failed integrity test, the operator stopped a test that was in progress, or a power failure occurred.

If an External Control fails to perform as expected, repeat external control test and/or contact Cepheid for assistance.

Retest Procedure	
To retest a non-determinate result (INVALID, NO RESULT, or ERROR), use a new cartridge. Use the leftover sample from the original specimen transport medium tube or new external control tube.	
1.	Put on a clean pair of gloves. Obtain a new Xpert Xpress SARS-CoV-2 cartridge and a new transfer pipette.
2.	Check the specimen transport tube or external control tube is closed.
3.	Mix the sample by rapidly inverting the specimen transport medium tube or external control tube 5 times. Open the cap on the specimen transport tube or external control tube.
3.	Open the cartridge lid.
4.	Using a clean transfer pipette (supplied), transfer sample (one draw) to the sample chamber with the large opening in the cartridge.
5.	Close the cartridge lid.
6.	Follow the procedure in Section 8.2, Starting the Test.

Repeat Criteria	
IF the PCR result is …	**THEN…**
Error/No Result/ Invalid result upon repeat testing	Report as INVLD; Add comment MPSP
Positive	Report as “Detected”
Negative	Report as “Not Detected”

Message	**Code**
Detected	DET
Not Detected	NTD
Non-amplification of the internal control suggests presence of PCR inhibitors in the patient sample. Additional sample should be submitted for testing if clinically warranted.	MPSP

If manually entering in results, use function **MEM** to enter results.

Enter Shift (1, 2, or 3), Press Enter to default in current shift

Worksheet: Use WIM2 for WOMC or SIM2 for SGMC.
Test: <Enter>
Enter "A" (Accept)
Enter Accession number
Press <Enter> until Result screen displayed
Key in result using appropriate code from above

If instrument is interfaced with Sunquest, use function **OEM** to view and release results.

Shift: Press Enter
Device: Type in **WOCE** (White Oak) **or SGCE** (Shady Grove)
Refer to addendum A for additional information on interfaced results.

11. EXPECTED VALUES

11.1 Reference Ranges

Not detected

11.2 Critical Values

Detected (inpatients only)

11.3 Standard Required Messages

None established

12. CLINICAL SIGNIFICANCE

An outbreak of respiratory illness of unknown etiology in Wuhan City, Hubei Province, China was initially reported to the World Health Organization (WHO) on December 31, 2019. Chinese authorities identified a novel coronavirus (2019-nCoV), which has resulted in thousands of confirmed human infections in multiple provinces throughout China and exported cases in several Southeast Asian countries and more recently the United States. Cases of severe illness and some deaths have been reported. The International Committee for Taxonomy of Viruses (ICTV) renamed the virus SARS-CoV-2.

13. PROCEDURE NOTES

- **FDA Status: For Use Under an Emergency Use Authorization (EUA) Only**
- Treat all biological specimens, including used cartridges, as if capable of transmitting infectious agents. Because it is often impossible to know which might be infectious, all biological specimens should be treated with standard precautions.
- In the event of contamination of the work area or equipment with samples or controls, thoroughly clean the contaminated area with a solution of 1:10 dilution of household

chlorine bleach and then repeat the cleaning of the work area with 70% ethanol. Wipe work surfaces dry completely before proceeding.

- Do not open the Xpert Xpress SARS-CoV-2 cartridge lid except when adding specimen.
- Do not use a cartridge that has been dropped after removing it from the packaging.
- Do not shake the cartridge. Shaking or dropping the cartridge after opening the cartridge lid may yield non-determinate results.
- Do not place the sample ID label on the cartridge lid or on the barcode label on the cartridge.
- Do not use a cartridge with a damaged barcode label.
- Do not use a cartridge that has a damaged reaction tube.
- Each single-use Xpert Xpress SARS-CoV-2 cartridge is used to process one test. Do not reuse processed cartridges.
- Each single-use disposable pipette is used to transfer one specimen. Do not reuse disposable pipettes.
- Do not use a cartridge if it appears wet or if the lid seal appears to have been broken.
- Wear clean lab coats and gloves. Change gloves between the handling of each specimen.

14. LIMITATIONS OF METHOD

14.1 Precision

Not applicable

14.2 Interfering Substances

N/A

14.3 Clinical Sensitivity/Specificity/Predictive Values

The performance of the Xpert SARS-CoV-2 test was evaluated using contrived clinical nasopharyngeal (NP) swab specimens in viral transport medium obtained from individuals with signs and symptoms of respiratory illness. The samples were prepared by spiking each individual clinical NP swab sample with AccuPlex SARS-CoV-2 (a quantitated reference material – recombinant Sindbis virus particle containing target sequences from the SARS-CoV-2 genome) at concentrations approximate to 2x LoD, 3x LoD and 5x LoD. The NP swab samples were determined to be negative for SARS-CoV-2 prior to spiking the specimens. Negative NP swab samples were also tested in the study.
The Instructions for Use shows the samples with the target concentrations of the AccuPlex SARS-CoV-2, the number of concordant results and total number tested as well as the percent agreement with the 95% confidence interval (95% CI) where appropriate. The results show 100% agreement with the expected results in the AccuPlex SARS-CoV-2 spiked samples and 100% agreement with the expected results in the negative samples.

Studies were performed to determine the analytical limit of detection (LoD) of the Xpert Xpress SARS-CoV-2. The LoD of Xpert Xpress SARS-CoV-2 was established using one lot of reagent and limiting dilutions of AccuPlex SARS-CoV-2 prepared in simulated background matrix and nasopharyngeal swab clinical matrix. Verification of the estimated LoD claim was performed on one reagent lot in replicates of 35 prepared in nasopharyngeal swab clinical matrix. The LoD is

the lowest concentration (reported as copies/µL) of AccuPlex SARS-Cov-2 recombinant viral sequence that can be reproducibly distinguished from negative samples ≥ 95% of the time with 95% confidence. The claimed LoD for the assay is 250 copies/mL.

The inclusivity of Xpert Xpress SARS-CoV-2 was evaluated using in silico analysis of the assay primers and probes in relation to 324 SARS-CoV-2 sequences available in the GISAID gene database for two targets, E and N2.
For the E target, Xpert Xpress SARS-CoV-2 had 100% match to all sequences with the exception of 4 sequences that had a single mismatch. For the N2 target, Xpert Xpress SARS-CoV-2 had 100% match to all sequences with the exception of 2 sequences that had a single mismatch. None of these mismatches found for both targets are predicted to have a negative impact on the performance of the assay, given the location of the mutations in the primer and probe regions respectively for the two variants. These mutations are not predicted to adversely affect the probe and primer binding to the sequences or reduce assay efficiency.

An in silico analysis for possible cross-reactions with all the organisms listed in Table 5 was conducted by mapping primers and probes in the Xpert Xpress SARS-CoV-2 test individually to the sequences downloaded from the GISAID database. E primers and probes are not specific for SARS-CoV-2 and will detect Human and Bat SARS-coronavirus. No potential unintended cross reactivity with other organisms listed in Instructions for Use is expected based on the in silico analysis.

Xpert Xpress SARS-CoV-2 Analytical Specificity Microorganisms
Microorganisms from the Same Genetic Family
Human coronavirus 229E
Human coronavirus NL63
SARS-coronavirus
MERS-coronavirus
Bat coronavirus

High Priority Organisms
Adenovirus (e.g. C1 Ad. 71)
Human coronavirus OC43
Human Metapneumovirus (hMPV)
Human coronavirus HKU1
Parainfluenza virus 1-4
Influenza A
Influenza B
Influenza C
Enterovirus (e.g. EV68)
Respiratory syncytial virus
Rhinovirus
Chlamydia pneumoniae
Haemophilus influenzae
Legionella pneumophila
Mycobacterium tuberculosis
Streptococcus pneumoniae
Streptococcus pyogenes

Bordetella pertussis
Mycoplasma pneumoniae
Pneumocystis jirovecii (PJP)
Parechovirus
Candida albicans
Corynebacterium diphtheriae
Legionella non-pneumophila
Bacillus anthracis (Anthrax)
Moraxella catarrhalis
Neisseria elongate and meningitidis
Pseudomonas aeruginosa
Staphylococcus epidermidis
Staphylococcus salivarius
Leptospira
Chlamydia psittaci
Coxiella burnetii (Q-Fever)
Staphylococcus aureus

- Performance of the Xpert Xpress SARS-CoV-2 has only been established in nasopharyngeal swab specimens. Specimen types other than nasopharyngeal swab may give inaccurate results.
- A false negative result may occur if a specimen is improperly collected, transported or handled. False negative results may also occur if inadequate numbers of organisms are present in the specimen.
- As with any molecular test, mutations within the target regions of Xpert Xpress SARS-CoV-2 could affect primer and/or probe binding resulting in failure to detect the presence of virus.
- This test cannot rule out diseases caused by other bacterial or viral pathogens. Erroneous test results might occur from improper specimen collection; failure to follow the recommended sample collection, handling, and storage procedures; technical error; sample mix-up; or because the number of organisms in the specimen is too low to be detected by the test. Careful compliance with the instructions in this insert is necessary to avoid erroneous results.

15. SAFETY

Refer to your local and corporate safety manuals and Safety Data Sheet (SDS) for detailed information on safety practices and procedures and a complete description of hazards.

16. RELATED DOCUMENTS

- Biological Safety Cabinet, Micro procedure
- Laboratory Quality Control Program
- Laboratory Safety Manual
- Safety Data Sheets (SDS)

- Quest Diagnostics Incorporated Records Management Program for Record Retention Requirements SOP.
- GeneXpert Dx System Operator Manual
- Cepheid GeneXpert® Dx System Maintenance, Micro procedure
- Cepheid SARS-CoV-2 PCR Quality Control Log (AG.F509)
- Cepheid Xpert® Xpress SARS-CoV-2 package insert 302-3562, Rev A May 2020
- Cepheid GeneXpert® Xpert Xpress SARS-CoV-2 PCR Assay Individual Quality Control Plans (VC 665, VC 666)

17. REFERENCES

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4. Clinical and Laboratory Standards Institute. Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline. Document M29 (refer to latest edition).
5. REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on the classification labeling and packaging of substances and mixtures amending and repealing, List of Precautionary Statements, Directives 67/548/EEC and 1999/45/EC (amending Regulation (EC) No 1907/2007).
6. Occupational Safety and Health Standards, Hazard Communication, Toxic and Hazard Substances (March 26, 2012) (29 C.F.R., pt. 1910, subpt. Z).

18. DOCUMENT HISTORY

Version	Date	Section	Revision	Revised By	Approved By
1	4/17/20	3.2	Added Quest 3-mL VCM/swab set as acceptable collection and transport medium	R Master	R Master
2	5/7/20	11.2, Add A	Specify only applies to inpatients	L Barrett	R Master
3	5/18/20	6.3	Changed external QC frequency per IQCP	L Barrett	R Master
		16	Added IQCP info		

19. ADDENDA

A. Cepheid Testing and Running via Sunquest Interface

Addendum A

Cepheid Testing and Running via Sunquest Interface

A. General Information:

1. This interface does NOT go through DI-Instrument Manager. Cepheid is interfaced directly to Sunquest. The Sunquest interface is set up for Autoverification.
2. All tests will auto-file with the following exceptions:
   - Positive *C. difficile* results
   - Positive MRSA results
   - Positive SARS-CoV-2 results (on inpatients only)
3. If the test is one of the above exceptions, then the results will be held in Sunquest. These results must be called and documented per routine process.
4. Use function OEM on Sunquest SmarTerm to review results.
   a. Access OEM
      - At DEVICE: prompt, type in Method code **WOCE** (WOMC) or **SGCE** (SGMC).
      - Results will display cup by cup.
        - Those that were auto-filed require no action, proceed to next cup.
        - For positive results that were held, continue with steps b and c below.
      - Refer to *OEM - On Line Result Entry Method* procedure (LIS SOP) for additional information about review and release of results.

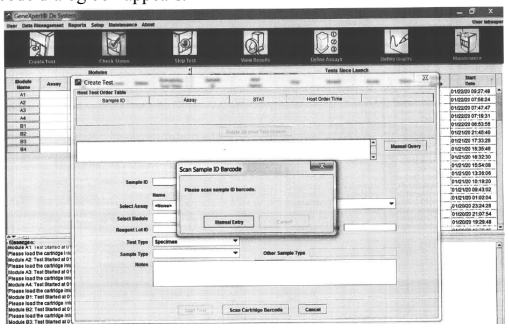
   b. Call results. Append CBACK documentation to results including who you called, date, time and tech code. Required format is:

      -CBACK-;full name of person called DATE TIME Tech code
      Example -CBACK-;Sue Smith 032420 1420 4568

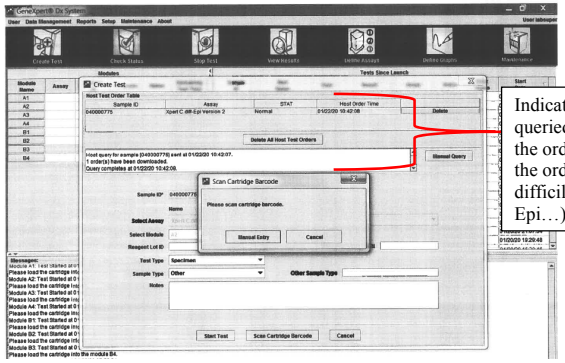
   c. Click on Accept to release results.
5. Perform an OFC (Online File Cleanup) at least once per shift. This process cleans up the online data that was sent to Sunquest.
   a. In Sunquest (SmarTerm) access function OFC
   b. Type in the method code (WOCE or SGCE).
   c. At the Start at Cup Number prompt, type in 1 and then press ENTER.
   d. At the Stop at Cup Number prompt, press ENTER.

B. Running Tests on Cepheid:

1. Create Test
   a. In the GeneXpert Dx System window, click **Create Test** on the menu bar. The Scan Sample ID Barcode dialog box appears.



   b. Scan the Sunquest barcode label.



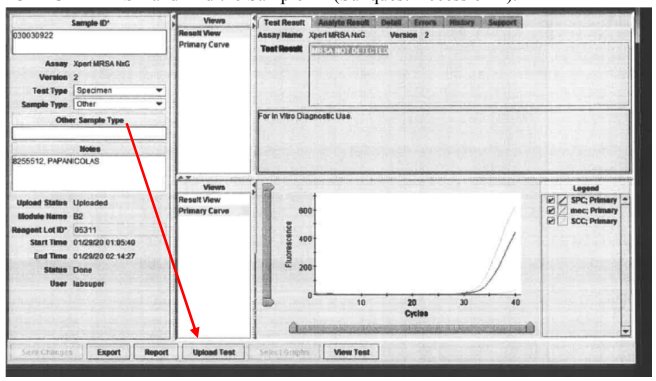
Indicates the Cepheid queried Sunquest and found the order. In this example the order was for a C difficile PCR (Xpert C diff-Epi…)

   c. Scan the cartridge barcode.

2. Click **OK**
3. Click **Create Test**
4. Load cartridge
5. Verify that the test has started before walking away
6. When testing is completed results will print to Cepheid printer.

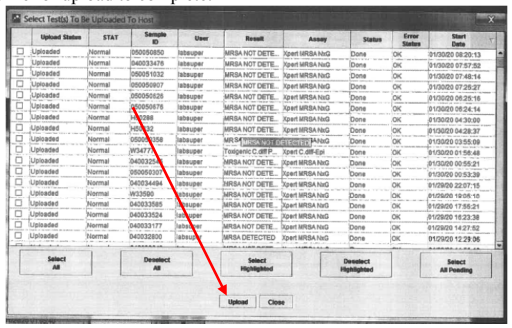
C. Manually uploading results to Sunquest (Example Sunquest downtime)

1. From the Cepheid, go to VIEW RESULTS
   a. Click on **UPLOAD TEST** and find the Sample ID (Sunquest Accession #).



   b. Check off the one that you want to upload (located to the left of the Update Status column). Note: You can check off one or more accession numbers at the same time.

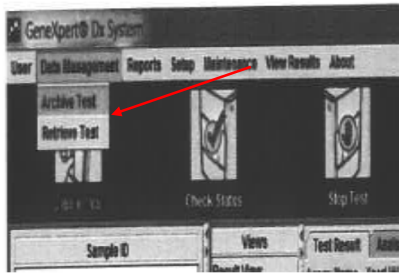
   c. Click on **UPLOAD** to resend to Sunquest. Results will now upload into Sunquest. It make take a little time for upload to complete.



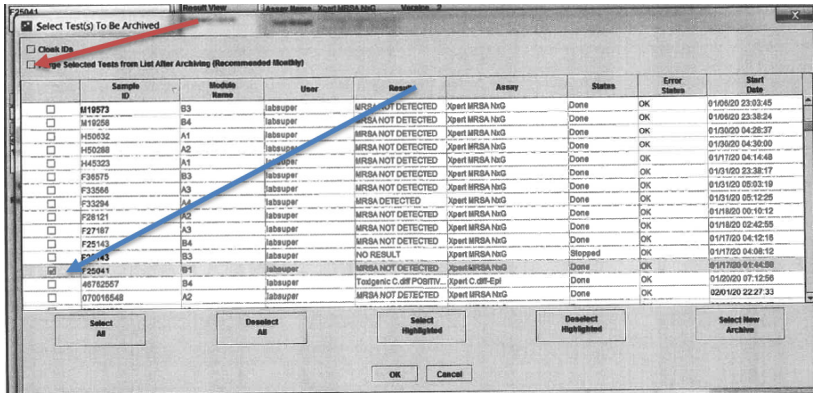
   d. Review in Sunquest OEM to document any positive result call notification.

D. Editing Sample ID (SQ Accession #)

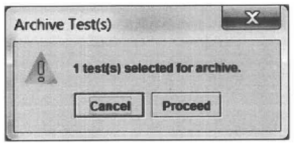
1. From the main screen -→Data Management-→ Click on Archive Test



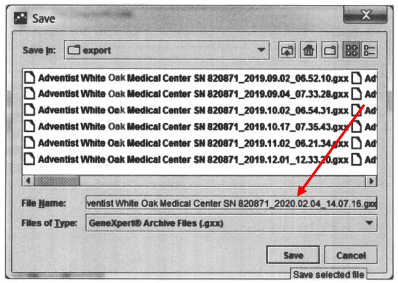
2. In the upper left corner click on **Purge Selected Tests from the LIS after Archiving** (red arrow). Then locate the Sample ID (SQ Accession#) that you want and select it by clicking on box to the left of the Sample ID (blue arrow). Then click on OK.



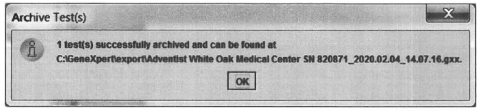
3. At the Archive Test prompt, click on **Proceed**.



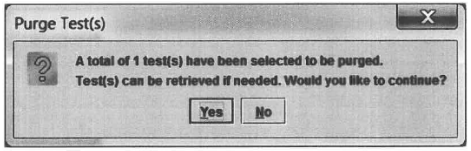
4. Archive file is generated (File name is system generated) and click on **SAVE**. Note that the File Name has the date and time as part of the file name. In the example below "2020.02.04_1407" is the date of 2/4/20 and time of 1407.



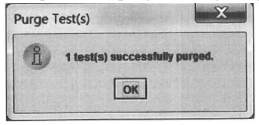
5. Archive message displays, click on **OK**



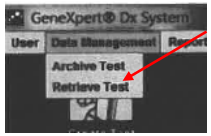
6. Purge message displays, click on **OK**



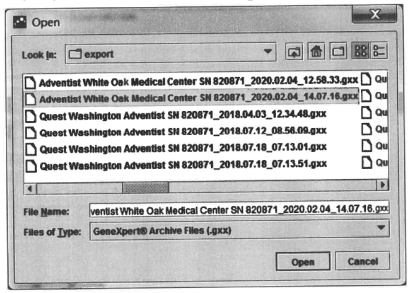
7. Completion of purge message displays



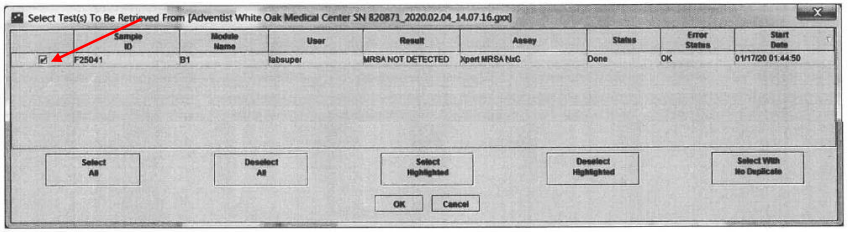
8. Retrieve test by going to Main screen -→ Data Management-→ Retrieve Test



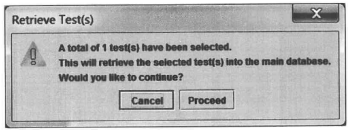
9. Locate file that you exported (Note, part of the file name consists of the date and time file was created.). Highlight the file and click on Open.

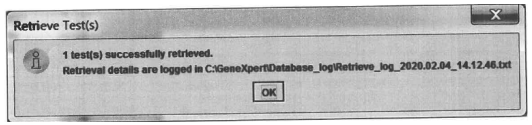


10. To the left of the Sample ID, check off the Sample ID (SQ acc #) that you want to retrieve to edit. Then click on OK.

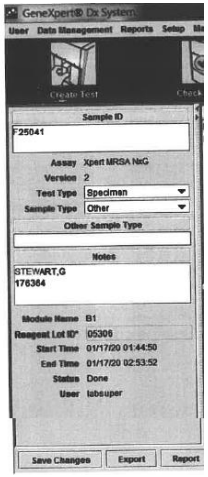


11. Retrieve prompt displays. Click on **Proceed**. Retrieve Test(s) confirm displays. Click on **OK**.

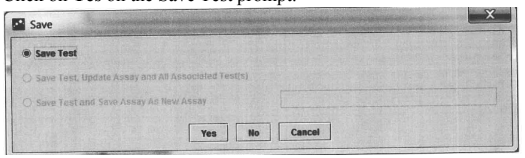




12. Proceed to edit Sample ID (SQ Accession #). Click on Save when you are done.



13. Click on **Yes** on the Save Test prompt.



14. Follow the steps in part C above to upload the results to Sunquest.

Adventist HealthCare

Cepheid SARS-CoV-2 PCR QC LOG

☐ Shady Grove Medical Center
☐ White Oak Medical Center

Last external QC performed (date): _____ **Next external QC is due =** ***Month*** _____ ***Circle day below***

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31

1. **External Positive and Negative Controls** are tested and documented with each new kit lot number or shipment or every 31 days, whichever is more frequent.
2. **Internal controls** must be documented each time the test is performed.
3. If QC results are not acceptable, document corrective action. Do not accept patient results before reviewing QC results for proper reactions.

Date	Patient Name / MR#	Patient Result	Kit	Internal Controls	External Pos Control (+) = Positive		External Neg Control (-) = Negative		Tech Code
		DET/ NTD / INVLD	Lot # / Expire	Pass / Fail	Lot # / Expire	Result	Lot # / Expire	Result	

Weekly review:	Weekly review:	Weekly review:
Weekly review:	Weekly review:	Monthly review: