TRAINING UPDATE

Lab Location:	SGMC & WOMC	**Date Distributed:**	5/5/2020
Department:	Core Lab	**Due Date:**	5/31/2020
		Implementation:	**5/5/2020**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Methicillin-resistant S. aureus (MRSA) PCR using Cepheid GeneXpert® SGAH.M995 v2

Description of change(s):

Section	Reason
7	Clarify supply list
10.6	Added interfaced reporting & calling
11.2	Deleted critical value
19	Added addendum A – Cepheid Interface info

This revised SOP was implemented on May 5, 2020

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

Technical SOP

Title	**Methicillin-resistant *S. aureus* (MRSA) PCR using Cepheid GeneXpert®**
Prepared by	Ron Master Date: 4/16/2018
Owner	Ron Master Date: 4/16/2018

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	Local Code
Methicillin Resistant *Staphylococcus aureus*, PCR Cepheid Xpert® MRSA NxG	Real-time Polymerase Chain Reaction (PCR) Assay / GeneXpert System	MRSPR

Synonyms/Abbreviations
MRSA PCR, Xpert MRSA

Department
Core Lab

2. ANALYTICAL PRINCIPLE

The Xpert MRSA NxG Assay is performed on the GeneXpert Instrument Systems. The GeneXpert Instrument Systems automate and integrate sample preparation, nucleic acid extraction and amplification, and detection of the target sequence 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 PCR reagents and host the 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 or the GeneXpert Infinity System Operator Manual.

The Xpert MRSA NxG Assay includes reagents for the detection of MRSA. A Sample Processing Control (SPC) and a Probe Check Control (PCC) are also included in the cartridge. The SPC is present to control for adequate processing of the sample and to monitor the presence of inhibitors in the PCR reaction. The PCC verifies reagent rehydration, PCR tube filling in the cartridge, probe integrity, and dye stability.

The primers and probes in the Xpert MRSA NxG Assay detect proprietary sequences for methicillin/oxacillin resistance (*mecA* and *mecC* genes), and *SCCmec*, which is inserted into the SA chromosome at the *attB* site.

An Early Assay Termination function provides positive results if target DNA reaches a predetermined threshold before the full 40 PCR cycles have been completed. When MRSA target levels (*mecA*/*mecC* and *SCCmec*) are high enough to generate very early Cts, the SPC amplification curve will be not seen and its results will not be reported.

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 nasal specimens according to the following procedure using the recommended swab** (refer to section 3.2: Preferred specimen type): • Open the collection device by peeling back the outer packaging • Keep both swabs attached to the red cap at all times. • Holding the swab cap with both swabs attached, sample each nare one at a time. • Ask the patient to tilt his/her head back. Insert dry swabs approximately 1–2 cm into each nostril • Rotate the swabs against the inside of the nostril for 3 seconds and apply slight pressure with a finger on the outside of the nose to help assure good contact between the swab and the inside of the nose • Using the same swabs, repeat for the second nostril, trying not to touch anything but the inside of the nose • Place the dual swab specimens into the transport tube containing the Liquid Stuart Medium • Make sure the red cap is on tightly • Label the transport tube • Ship the swabs to the laboratory according to standard specimen packing and shipping procedures
Special Collection Procedures	See above
Other	None

3.2 Specimen Type & Handling

Criteria	
Type -Preferred **-Other Acceptable**	2 Nasal swabs None
Collection Container	Swab in transport tube
Volume - Optimum **- Minimum**	2 swabs in transport tube 1 swab in transport tube

Criteria	
Transport Container & Temperature	Cepheid Sample Collection Device (Part No. 900-0370 Dual Rayon Swab in Liquid Stuart Medium) or the Copan Dual Rayon Swab and Transport Systems (139C LQ STUART). Store and transport the specimen at room temperature or refrigerated at 2–8° C
Stability & Storage Requirements	Room Temperature: 24 hours
	Refrigerated: 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 • Do not accept any sources other than nasal swabs • Do not accept nasopharyngeal specimens
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® MRSA NxG	Xpert MRSA NxG Assay kit (GXMRSA-NXG-10 or GXMRSA-NXG-120) contains sufficient reagents to process 10 or 120 samples or equivalent

4.2 Reagent Preparation and Storage

Assay Kit - Xpert® MRSA, GXMRSA-100N-10 and GXMRSA-120	
Xpert MRSA NxG Assay Cartridges with integrated reaction tubes	Cartridge: • Bead 1 (freeze-dried, 1 per cartridge) – polymerase, dNTPs, and bovine serum albumin (BSA) • Bead 2 (freeze-dried, 1 per cartridge) – primers, probes, and BSA

	• Bead 3 (freeze-dried, 1 per cartridge) – Sample Processing Control (SPC) and ~6000 non-infectious sample preparation control spores. • Reagent 1 (3.0 mL per cartridge) – Tris Buffer, EDTA, salts and surfactants • Reagent 2 (3.5 mL per cartridge) – Sodium Hydroxide
Xpert MRSA NxG Elution Reagent	• Guanidinium thiocyanate GXMRSA-NXG-10 – 10 x 2.0 mL per vial GXMRSA-NXG-120 – 125 x 2.0 mL per vial
Storage/ Stability	2-28°C / Manufacturer's expiration date Do not use a cartridge that has leaked
Preparation	None required

5. CALIBRATORS/STANDARDS

Not applicable

6. QUALITY CONTROL

6.1 Controls Used

GeneXpert® MRSA PCR Assay	Supplier and Catalog Number
Sample Processing Control (SPC)	Cartridge component
Probe Check Control (PCC)	Cartridge component
Negative External Control	Zeptometrix NATtrol Negative Control (NATMSSE-6MC)
Positive External Control	Zeptometrix NATtrol MRSA Positive Control (NATMRSA-6MC)

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. They must be treated in the same manner as patient samples.
3	Vortex the NATtrol control for 5-10 seconds
4	Pipette 100 µL of each the Negative and Positive NATtrol controls into 2 mL of Elution Reagent
5	Use a transfer pipette (not provided) to transfer the entire contents from the Elution Reagent vial into the Sample Chamber of 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
- Pipettor – 100uL

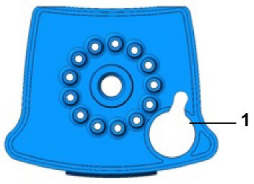
7.3 Supplies

- Sterile transfer pipette
- Pipettor tips (for control preparation)
- Plastic-backed absorbent pads (Blood Bloc or equivalent)
- Personal protective equipment (lab coat, powder-free gloves, face shields, and etc)
- Disposable biohazard waste containers (sharps, etc.)

- 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 and Elution Reagent from the package.
2.	Remove one swab from the specimen transport container and insert the swab into the tube containing the Elution Reagent. Note: Use only one of the swabs. The second swab is required for repeat testing. Insert the swab from the external controls (preparation described in 6.2) into the tubes containing the Elution Reagent.
3.	Hold the swab by the stem near the rim of the vial, lift the swab a few millimeters from the bottom of the tube and push the stem against the edge of the vial to break it. Make sure the swab is short enough to allow the cap to close tightly. Note: Use clean gauze or plastic-backed absorbent pads for each sample when breaking off swab to minimize risks of contamination.
5.	Close the lid and vortex at high speed for 10 seconds.
6.	Open the cartridge lid.
7.	Using a clean transfer pipette, transfer the entire contents of the Elution Reagent to the Sample chamber (large opening, labeled 1 below) of the Xpert assay cartridge. 
8.	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 NxG Assay cartridge.
7.	In the GeneXpert Dx Systems, click Start Test.
8.	Open the instrument module door with the blinking green light 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.
10.	Wait until the system releases the door lock before opening the module door and removing the cartridge. 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 interpolated by the GeneXpert Instrument System from measured fluorescent signals and embedded calculation algorithms and will be shown in the View Results window. Possible results are:

Assay Result Reported	Interpretation of Result
MRSA NOT DETECTED	MRSA target DNA is not detected (presumed not colonized with MRSA), SPC meets acceptance criteria. • mec – NEG / SCC – NEG or mec – NEG / SCC – POS, or mec – POS / SCC – NEG • SPC – PASS • Probe Check – PASS

Assay Result Reported	Interpretation of Result
MRSA DETECTED	MRSA target DNA is detected (presumptive positive for MRSA colonization). • mec – POS • SCC – POS • SPC – NA (not applicable) • Probe check – PASS
INVALID	INVALID Presence or absence of MRSA cannot be determined, repeat test with extra swab. SPC does not meet acceptance criteria, the sample was not properly processed, or PCR is inhabited. • mec – INVALID • SCC – INVALID • SPC – FAIL • Probe Check – PASS
ERROR	Presence or absence of MRSA cannot be determined, repeat test with extra swab. The Probe Check control failed, which is probably due to an improperly filled reaction tube, a probe integrity problem, or because the maximum pressure limits were exceeded. • mec – NO RESULT • SCC – NO RESULT • SPC – NO RESULT • Probe Check – FAIL* * If the probe check passed, the error is caused by a system component failure.
NO RESULT	Presence or absence of MRSA cannot be determined, repeat test with extra swab. Insufficient data were collected to produce a test result (for example, the operator stopped a test that was in progress). • mec – NO RESULT • SCC – 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

Repeat Criteria	
IF the PCR result is …	**THEN…**
Error/No Result/ Invalid result upon repeat testing	Report as INVLD; Add comment MPSP
Error/No Result/ Invalid and no second swab available	Report as INVLD; Add comment MPNP
Positive	Report as "Detected"
Negative	Report as "Not Detected"

Message	**Code**
Detected	DET
Not Detected	NTD
Non-amplification of the internal control suggests the presence of PCR inhibitors in the patient sample. Unable to repeat testing as second swab was not submitted. An additional sample should be submitted for testing if clinically warranted.	MPNP
After repeat analysis, non-amplification of the internal control suggests the presence of PCR inhibitors in the patient sample. An 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.

A result of 'Detected' will be flagged by the LIS to be called as a courtesy to the patient care area. Document the call per standard procedure or refer to addendum A for details.

11. EXPECTED VALUES

11.1 Reference Ranges

Not detected

11.2 Critical Values

~~Detected~~ None established

11.3 Standard Required Messages

None established

12. CLINICAL SIGNIFICANCE

Staphylococcus aureus (SA) is a well-documented human opportunistic pathogen that causes both community and healthcare- associated infections. It is a major healthcare-associated pathogen that can cause a variety of diseases including bacteremia, pneumonia, osteomyelitis, acute endocarditis, toxic shock syndrome, food poisoning, myocarditis, scalded skin syndrome, carbuncles, boils, and abscesses.[1]

In the early 1950s, acquisition and spread of beta-lactamase-encoding plasmids thwarted the effectiveness of penicillin for treating *S. aureus* (SA) infections. In 1959, methicillin, a semi-synthetic penicillin, was introduced. However, by 1960, methicillin-resistant SA (MRSA) strains were identified. Resistance is now known to be conferred when SA acquires a Staphylococcal cassette chromosome (SCC) *mec* gene complex containing either *mecA* or *mecC*. MRSA causes infections in both healthcare and community settings, resulting in significant morbidity and mortality. Attributable mortality of 33% has been reported for MRSA bacteremia. Control strategies and policies to limit the spread of these infections have been developed and implemented in a variety of healthcare settings. Controlling MRSA is a primary focus of most hospital infection prevention programs.[1–5] Currently, the standard method for detecting MRSA is culture, which can require several days to generate a definitive result. A study among patients in Veterans Administration Hospitals in the United States showed a significant impact on reducing healthcare-associated MRSA infections by using universal screening of patients for MRSA nasal colonization on admission as part of a bundle of infection control measures.[6]

13. PROCEDURE NOTES

- **FDA Status: FDA Exempt/Cleared or Approved**
- 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.
- Follow your institution's safety procedures for working with chemicals and handling biological samples.
- 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.
- The Xpert MRSA NxG Assay does not provide susceptibility results. Additional time is required to culture and perform susceptibility testing.
- Do not substitute Xpert NxG MRSA reagents with other reagents.
- Do not open the Xpert NxG MRSA cartridge lid except when adding sample.
- Do not use a cartridge that has been dropped or shaken after you have added the sample.
- Do not use a cartridge that has a damaged reaction tube.
- Each single-use Xpert MRSA NxG cartridge is used to process one test. Do not reuse spent cartridges.

14. LIMITATIONS OF METHOD

14.1 Precision

Not applicable

14.2 Interfering Substances

As indicated in the package insert, potentially interfering substances evaluated include blood, mucus and nasal sprays used to relieve decongestion, nasal dryness or irritation. The presence of these substances did not significantly inhibit PCR and did not give invalid or erroneous results.

14.3 Clinical Sensitivity/Specificity/Predictive Values

As indicated in the Package Insert, the Xpert MRSA NxG assay had overall sensitivity, specificity, positive predicative value, and negative predicative value of 86.3%, 94.9%, 80.5%, and 96.6% respectively when compared to a 2nd FDA-cleared NAAT test and culture. The assay had sensitivity, specificity, positive predicative value, and negative predicative value of 94.3%, 93.2%, 73.0%, and 98.8% respectively when compared to a direct culture.

- The performance of the Xpert MRSA NxG Assay was validated using the procedures provided in this package insert only. Modifications to these procedures may alter the performance of the test. Results from the Xpert NxG MRSA Assay should be

interpreted in conjunction with other laboratory and clinical data available to the clinician.

- Erroneous test results might occur from improper specimen collection, not following the recommended sample collection procedure, handling or storage, technical error, sample mix-up, or because the number of organisms in the specimen is not detected by the test. Careful compliance to the instructions in this insert is necessary to avoid erroneous results.
- Because the detection of MRSA is dependent on the number of organisms present in the sample, reliable results are dependent on proper specimen collection, handling, and storage.
- Rerunning the Xpert MRSA NxG when results are INVALID, ERROR, and NO RESULT should depend on practices and policies within each facility. Alternate procedures (e.g. culture using selective agar plates with or without overnight incubation in a selective enrichment broth) should be available. For culturing, remaining swab specimens should be placed in appropriate transport systems and cultured within 4 days.
- A positive test result does not necessarily indicate the presence of viable organism. It is however, presumptive for the presence of MRSA.
- Testing with Xpert MRSA NxG assay should be used as an adjunct to other methods available.
- Test results might also be affected by concurrent antibiotic therapy. Therefore, therapeutic success or failure cannot be assessed using this test because DNA might persist following antimicrobial therapy.
- Mutations or polymorphisms in primer or probe binding regions may affect detection of new or unknown MRSA variants resulting in a false negative result.

15. SAFETY

- Reagent 2 contains sodium hydroxide (pH > 12.5); (R34 EU Risk) which is corrosive to eyes and skin requiring eye and skin protection.
- 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
- MRSA PCR Quality Control Log (AG.F409)

- Cepheid GeneXpert® MRSA PCR Individual Quality Control Plans (SGAH.VC373, WAH.VC254)

17. REFERENCES

1. Xpert® NxG MRSA Assay current package insert (301-4055, Rev. A December 2016)
2. Mainous AG, Hueston WJ, Everett, CJ, Vanessa A. Diaz VA. Nasal Carriage of *Staphylococcus aureus* and Methicillin-Resistant *S. aureus* in the United States, 2001-2002. An Family Medicine. 2006;4(2):132-137.
3. National Nosocomial Infections Surveillance (NNIS) System Report, data summary from January 1992 through June 2004, issued October 2004. Am J Infect Control 2004;32:470-85.
4. Chaix C, Durand-Zileski I, Alberti C, Buisson B. Control of Endemic Methicillin Resistant *Staphylococcus aureus*. JAMA 1999;282(19):1745-51.
5. Shopsin B, Kreiswirth BN. Molecular Epidemiology of Methicillin-Resistant *Staphylococcus aureus*. Emerging Infectious Diseases 2001;7(2) 323-6.
6. Salgado CD et al. Community-Acquired Methicillin-Resistant *Staphylococcus aureus*: A Meta-analysis of Prevalence and Risk Factors. CID 2003;36:131.
7. Centers for Disease Control and Prevention. Biosafety in microbiological and biomedical laboratories. Richmond JY and McKinney RW (eds) (1993). HHS Publication number (CDC) 93-8395.
8. Clinical and Laboratory Standards Institute (formerly National Committee for Clinical Laboratory Standards). Protection of laboratory workers from occupationally acquired infections; Approved Guideline. Document M29 (refer to latest edition).

18. DOCUMENT HISTORY

Version	Date	Section	Revision	Revised By	Approved By
0	11/20/18	6.3	Changed external frequency	L Barrett	R Master
0	11/20/18	16	Added IQCP info		
1	4/20/20	7	Clarify supply list	L Barrett	R Master
		10.6	Added interfaced reporting & calling		
		11.2	Deleted critical value		
		19	Added addendum A		

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

3. If the test is positive for SARS-CoV-2, *C. difficile* or MRSA, 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:

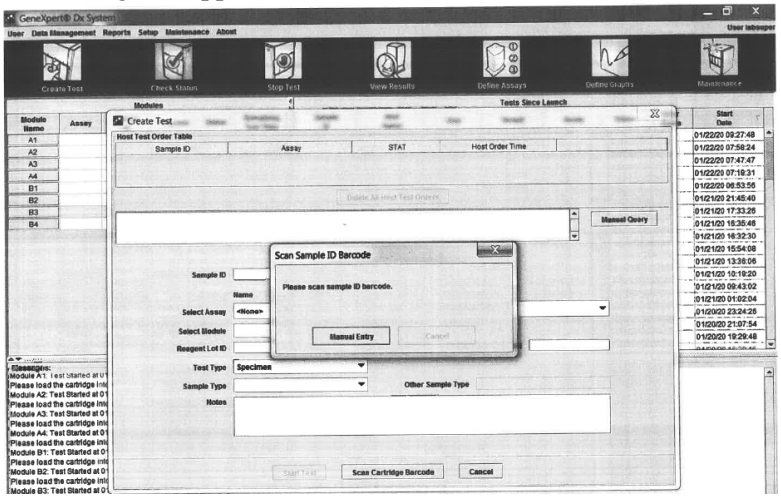
      -CBACK-;full name of person called DATE TIME Tech code
      Example -CBACK-;Sue Smith 032420 1420 4568

   c. Click on Accept to release results.

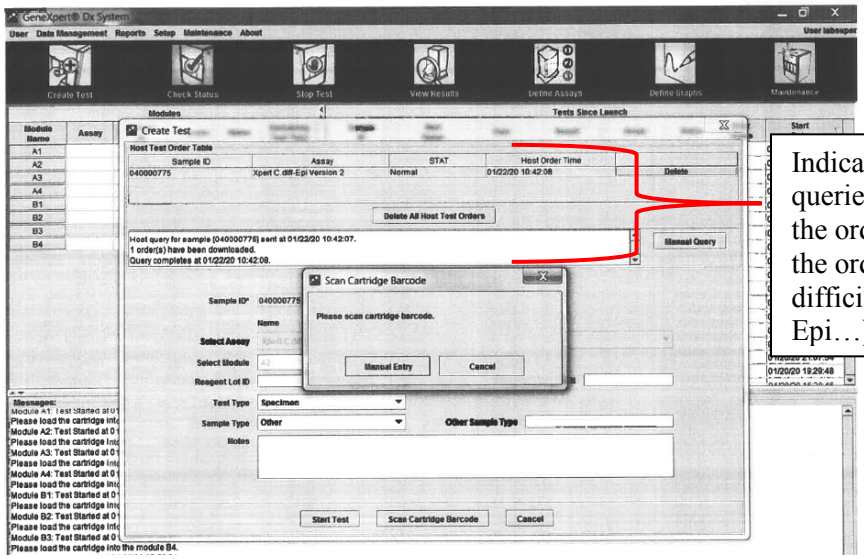
5. Perform an OFC (Online File Cleanup) at least once per shift. This process cleans up the online data that was sent to Sunquest.
   a. In Sunquest (SmarTerm) access function OFC
   b. Type in the method code (WOCE or SGCE).
   c. At the Start at Cup Number prompt, type in 1 and then press ENTER.
 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

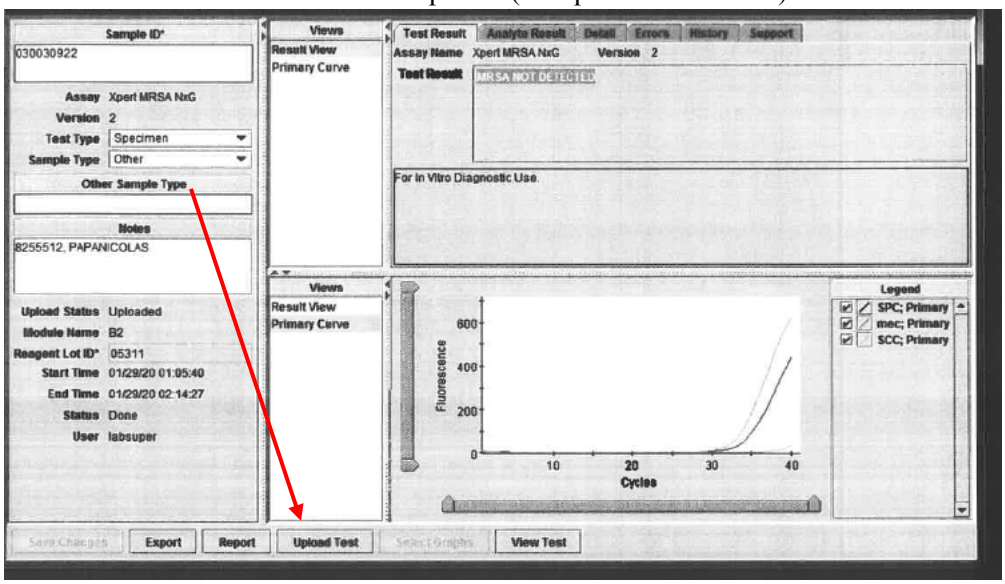
   c. Scan the cartridge barcode.

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)

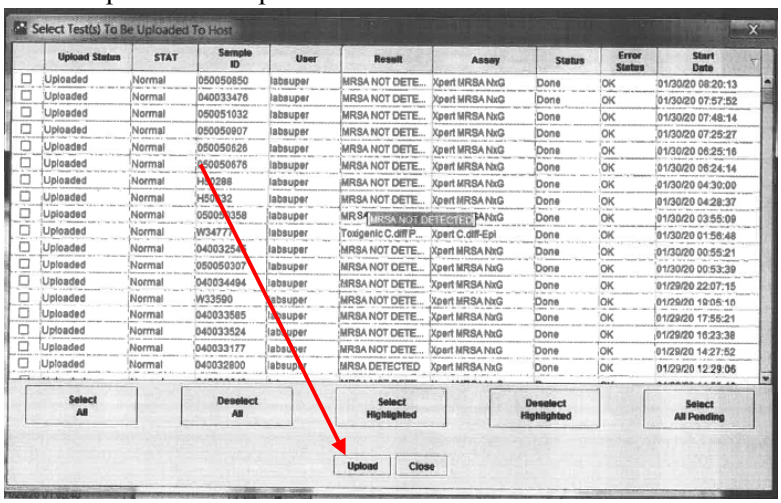
1. From the Cepheid, go to VIEW RESULTS

   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.

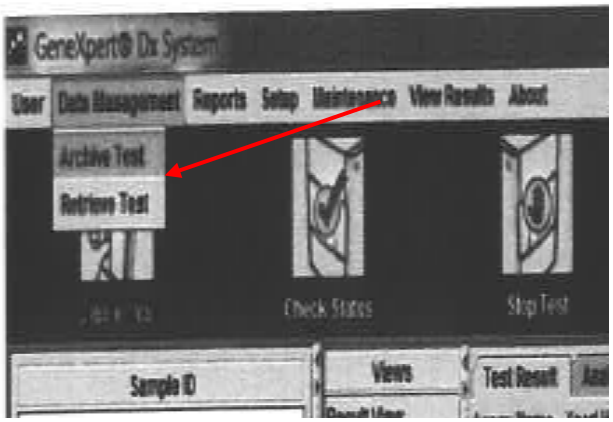
   c. Click on **UPLOAD** to resend to Sunquest. Results will now upload into Sunquest. It make take a little time for upload to complete.



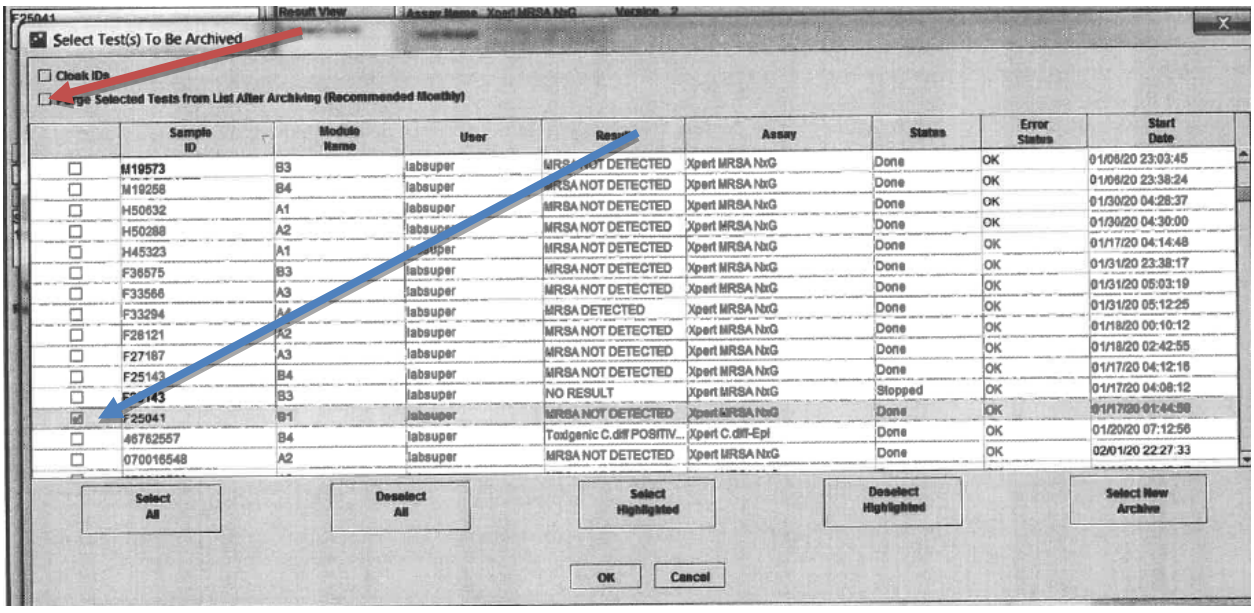
   d. Review in Sunquest OEM to document any positive result call notification.

D. Editing Sample ID (SQ Accession #)

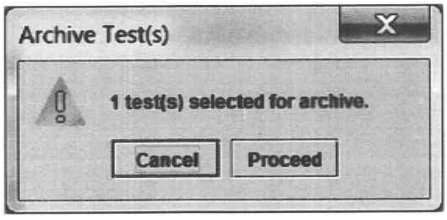
1. From the main screen -→Data Management-→ Click on Archive Test



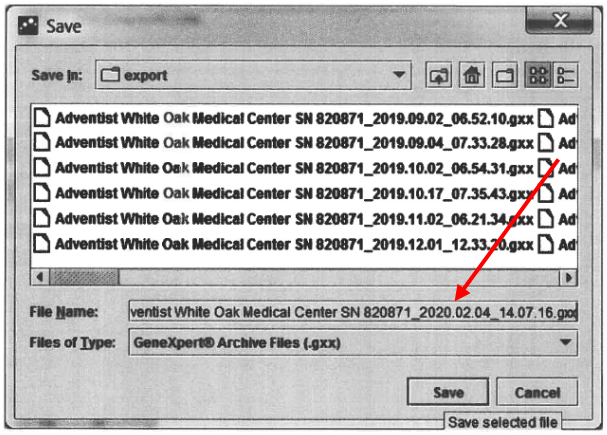
2. In the upper left corner click on **Purge Selected Tests from the LIS after Archiving** (red arrow). Then locate the Sample ID (SQ Accession#) that you want and select it by clicking on box to the left of the Sample ID (blue arrow). Then click on OK.



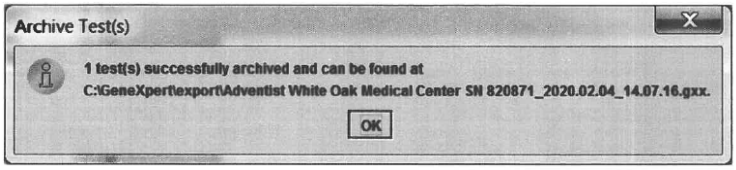
3. At the Archive Test prompt, click on **Proceed**.



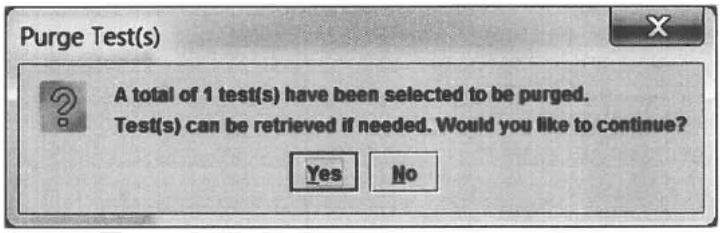
4. Archive file is generated (File name is system generated) and click on **SAVE**. Note that the File Name has the date and time as part of the file name. In the example below "2020.02.04_1407" is the date of 2/4/20 and time of 1407.



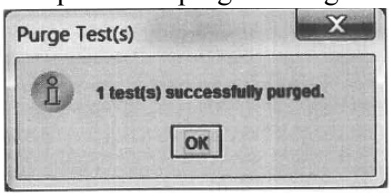
5. Archive message displays, click on **OK**



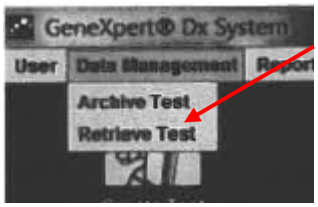
6. Purge message displays, click on **OK**



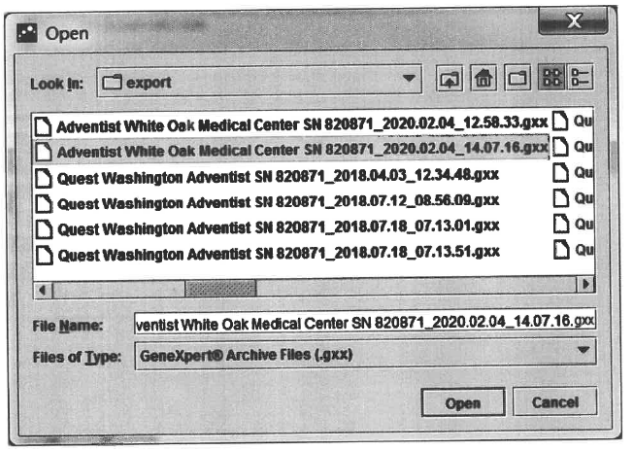
7. Completion of purge message displays



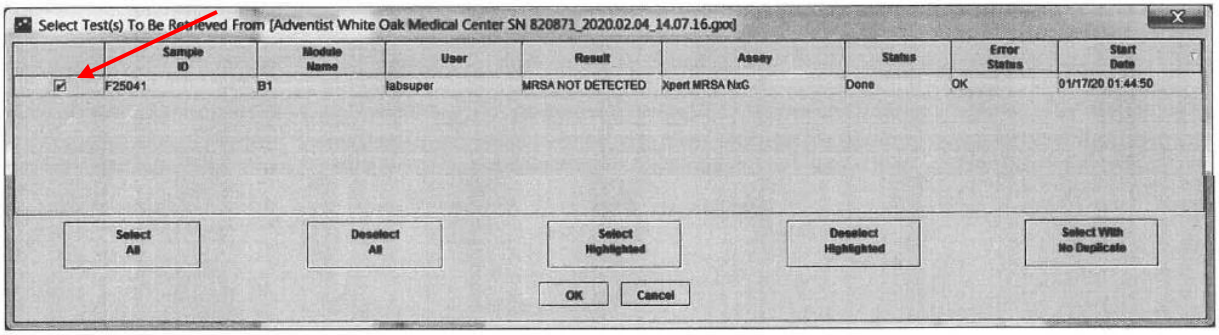
8. Retrieve test by going to Main screen -→ Data Management-→ Retrieve Test



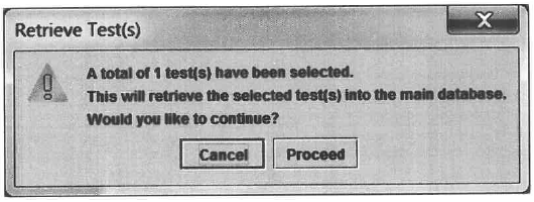
9. Locate file that you exported (Note, part of the file name consists of the date and time file was created.). Highlight the file and click on Open.

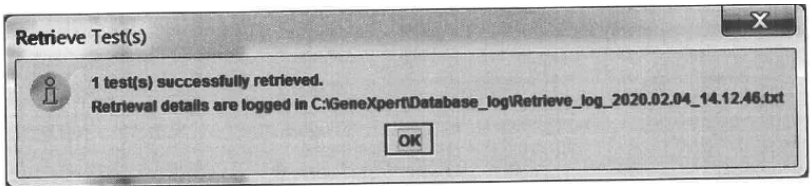


10. To the left of the Sample ID, check off the Sample ID (SQ acc #) that you want to retrieve to edit. Then click on OK.

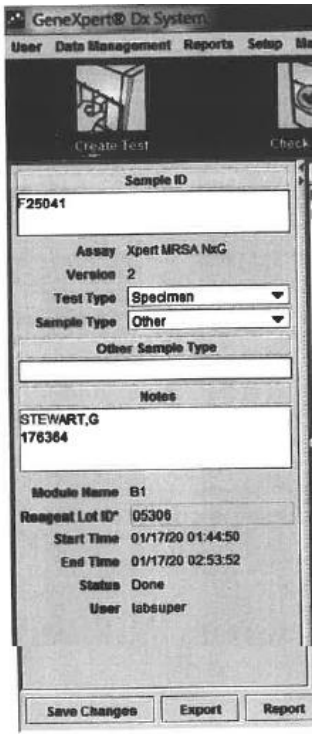


11. Retrieve prompt displays. Click on **Proceed**. Retrieve Test(s) confirm displays. Click on **OK**.

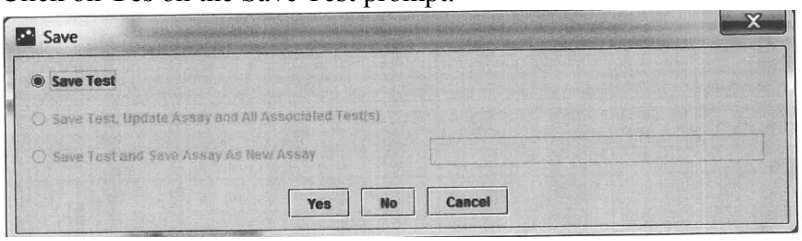




12. Proceed to edit Sample ID (SQ Accession #). Click on Save when you are done.



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



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