TRAINING UPDATE

Lab Location:	GEC and FWMC	**Date Distributed:**	5/18/23
Department:	Core Lab/ Micro	**Due Date:**	6/30/23

DESCRIPTION OF NEW PROCEDURE

Name of procedure:
Title: AHC.E 104 SARS-CoV-2 RNA (COVID-19) by cobas® LIAT
New procedure Read the attached procedure. This new test will be offered in addition to the current SARS CoV-2 and Influenza A and B test. The new "COVID only "test is run very similarly to the current test. Familiarize yourself with any differences (test codes, screens, etc). This New SOP will be implemented June 6, 2023

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

Technical SOP

Title	**SARS-CoV-2 RNA (COVID-19) by cobas® LIAT**	
Prepared by	Demetra Collier	Date: 4/24/23
Owner	Vittal Ponraj	Date: 4/24/23

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
CoV2(COVID-19) Qualitative	Real-time reverse transcriptase polymerase chain reaction (RT-PCR)	LCOVID

Synonyms/Abbreviations
SARS-CoV-2 PCR, SARS CoV-2 RNA (COVID-19) Rapid Qualitative NAAT

Department
Core Lab

2. ANALYTICAL PRINCIPLE

cobas® SARS-CoV-2 assay uses real-time reverse transcriptase polymerase chain reaction (RT-PCR) technology to rapidly (approximately 20 minutes) detect SARS-CoV-2 virus from nasopharyngeal, mid-turbinate and nasal swabs. The automation, small footprint, and easy-to-use interface of the cobas® Liat® System enable performance of this test to occur at the POC or in a clinical laboratory setting.

The **cobas**® SARS-CoV-2 assay is performed on the **cobas**® Liat® Analyzer which automates and integrates sample purification, nucleic acid amplification, and detection of the target sequence in biological samples using real-time RT-PCR assays. The assay targets both the ORF1 a/b non-structural region and structural nucleocapsid protein (N) gene that are unique to SARS-CoV-2. An Internal Process Control (IPC) is also included. The IPC is present to control for adequate processing of the target virus through steps of sample purification, nucleic acid amplification, and to monitor the presence of inhibitors in the RT-PCR processes.

3. SPECIMEN REQUIREMENTS

3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	N/A
Specimen Collection and/or Timing	Follow manufacturer's instructions. Avoid nasal sprays, ointments, gels and antibiotics prior to collection. Avoid use of throat lozenges. 1. Insert the collected swab into a UTM/VTM tube. Place the swab head at least ½ inch below the surface of the media and swirl the swab in the media.

Component	Special Notations
	2. Break the swab shaft and leave the swab in the UTM tube (i.e. sample tube) 3. Attach the cap securely. Store at room temperature (up to 4 hours) or refrigerate (up to 72 hours)
Special Collection	N/A
Other	N/A

3.2 Specimen Type & Handling

Criteria		
Type -Preferred **-Other Acceptable**	Sterile nasopharyngeal swabs, in approved UTM/VTM (Viral Transport media). See list of acceptable swabs/VTM kits below	
Approved Collection Container	**Specimen Collection Kit** Nasopharyngeal Swab Collection Kits Flexible minitip FLOQSwab™ with Universal Transport Medium™ (UTM) from Copan Diagnostics; P/N 305C OR BD Universal Viral Transport (UVT) 3-mL collection kit with a flocked flexible minitip swab; P/N 220531 ThermoFisher Scientific Remel™ MART; R12565, R12566, R12567 ThermoFisher Scientific Remel™ M4; R12550 ThermoFisher Scientific Remel™ M5; R12555 ThermoFisher Scientific Remel™ M6; R12563,R12568,R12569	
Volume - Optimum **- Minimum**	3.0 mL 1.0 mL	
Transport Container & Temperature	Sample collection kit at room temperature	
Stability & Storage Requirements	Room Temperature:	0-4 hours
	Refrigerated (2-8°C)	0-72 hours
	Frozen: (-70°C) or colder	Indefinitely (≥ 72 hours) (and transport on dry ice)
Timing Considerations	N/A	
Unacceptable Specimens & Actions to Take	• Specimens containing calcium alginate swabs, cotton swabs with wooden shaft. • Dry Swabs, Swabs transported without UTM/VTM • Swabs not listed on the Approved Collection List • Specimens exceeding stability • Quantity Not Sufficient • Specimens from leaking, uncapped or broken container	
Compromising Physical Characteristics	None	
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
cobas® SARS-CoV-2, 20 EA/Kits	Roche Supplier #09408592190

4.2 Reagent Preparation and Storage

Reagents in the cobas® SARS-CoV-2 Reagent Tube	
Reagent 1	cobas® Liat® SARS-CoV-2 Master Mix-1
Reagent 2	cobas® Liat® SARS-CoV-2 Master Mix-2
Reagent 3	cobas® Liat® SARS-CoV-2 Master Mix-3
Reagent 4	cobas® Liat® Internal Process Control
Reagent 5	Proteinase K
Reagent 6	cobas® Liat® Magnetic Glass Particles
Reagent 7	cobas® Liat® Lysis Buffer
Reagent 8	cobas® Liat® Wash Buffer
Reagent 8	cobas® Liat® Elution Buffer
Storage	Store at 2-8°C
Stability	Before use, reagent is stable until the expiration date indicated on label. Once opened, the reagent tube should be used immediately (patient or QC material added). The Reagent tube with the Patient/QC sample added may be stored up to 4 hours at Room Temperature before testing.

5. CALIBRATORS/STANDARDS

Not applicable

6. QUALITY CONTROL

6.1 Controls Used

Quality Control Kit	Supplier & Catalog Number
cobas® SARS-CoV-2 Quality Control Kit	Kit: Roche, Sup # 09408835190

6.2 Control Preparation and Storage

Control Kit Components:	
Control -Pos	cobas® SARS-CoV-2 (+) C
control -Neg	cobas® Dilution UTM Dilution UTM (-) C
Storage	2–8°C
Stability	Before use, stable until the expiration date indicated on label.
Preparation	Ready to use (liquid in tubes)

6.3 Number and Frequency

	QC Frequency
1	**Internal Control:** An Internal Process Control (IPC) is included in every assay. It verifies the adequate processing of the sample. Results of the IPC are not reported, but failure of the IPC will result in an Invalid test result.
2	**External Control:** External QC (both positive and negative controls) must be run: 1. At new instrument Set-up 2. For each new lot number (see Lot Validation) 3. For each new shipment to a site. 4. Every 31 Days **Note**: QC run for Lot Validation or New shipments can fulfill the 31-Day QC requirement as well. The frequency for the 31-Day QC requirement re-starts with the completion of the Lot Validation or New shipment QC.

6.4 Tolerance Limits and Criteria for Acceptable QC

A. Tolerance Limits

	Tolerance Limits
1.	Internal Process Control is performed on each test. Failure to yield a valid Internal Process Control indicates the test is invalid, and patient results cannot be resulted. If the Internal Process Control is acceptable, the Run Status will be listed as "OK."
2.	External Control runs must produce the expected result (positive or negative) prior to running patient samples. **Notes**: • For controls run during new lot testing, the report will display result as 'valid' or 'invalid' • For controls run to satisfy the 31-day frequency, the report will display individual results for all 3 targets. • For either QC scenario, results are documented on the QC log as 'valid' or 'invalid'

B. Criteria for Acceptable QC
- Each test must produce a valid Internal Process Control result.
- The patient test is valid if no flags appear for both controls, which include one negative control and one positive control: [SARS-CoV-2(+) C] and [BUF (-) C].
- If the negative control or the positive controls are flagged as Invalid, then the patient result is invalid and must be repeated.
- 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
- All rejected runs must be effectively addressed and include the following documentation:
  - Control(s) that failed (e.g., positive control with negative result or invalid controls) 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.

7. EQUIPMENT and SUPPLIES

7.1 Assay Platform

- cobas® Liat® Analyzer

7.2 Equipment

N/A

7.3 Supplies

- VTM/UTM tubes (from collection kit)
- cobas® SARS-CoV-2 Assay tubes
- cobas® SARS-CoV-2 Transfer pipettes
- Rack

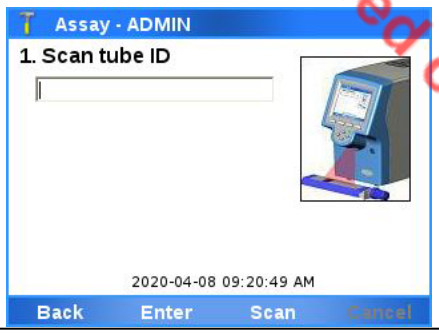
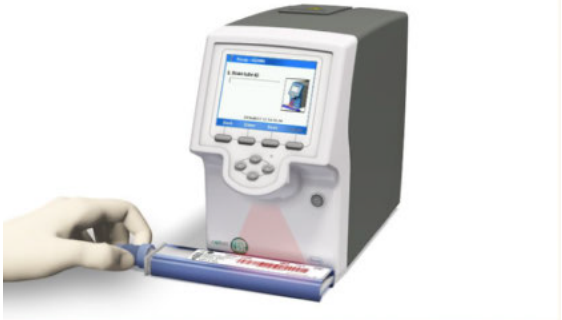
8. PROCEDURE

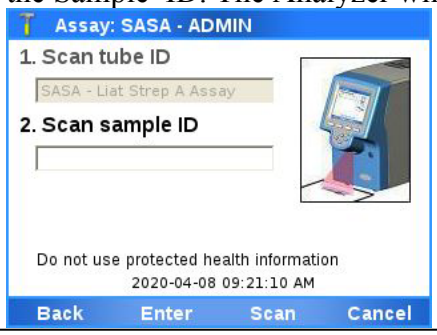
NOTE: For all procedures involving specimens, buttoned lab coats, gloves, and face protection are required minimum personal protective equipment. Report all accidents to your supervisor.

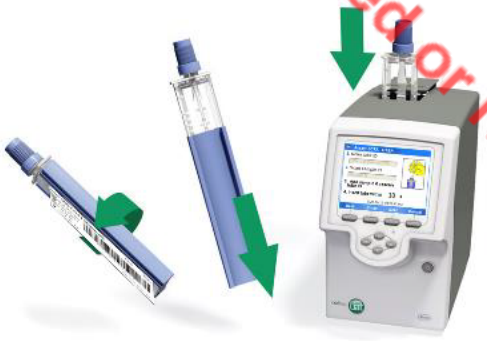
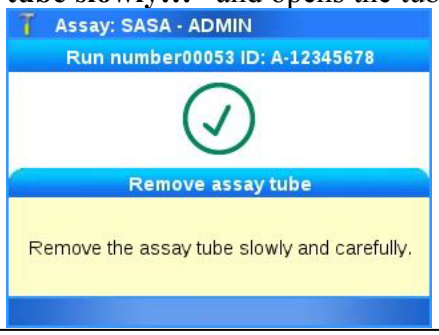
8.1	Instrument Set-up Protocol
1.	For initial set-up, refer to pages 33-38 of the cobas® Liat® System User Guide, and other sections as needed. 1. Ensure that the **cobas**® Liat® Analyzer is powered on. 2. Select **"Login"** on the screen of the **cobas**® Liat® Analyzer. 3. Enter user name when prompted, select **"OK"**. 4. Enter user password when prompted, select **"OK"**. **Note:** *You may be prompted to confirm you have read the User Manual (i.e., cobas® Liat® System User Guide or Operator's Manual).* 5. From the Main Menu, select "**Run Assay**".
2.	**<u>For set-up or New LOT # of REAGENT</u>:** At Set-up or before using a new lot of **cobas®** SARS-CoV-2 tubes, a Lot Validation procedure must be performed on the **cobas®** Liat® Analyzer to validate the **cobas® SARS-CoV-2** assay tube lot. The procedure includes running a Negative Control sample and a Positive Control sample. **Note:** Refer to **Addendum 1** for detailed instructions (or see the **cobas®** Liat® System User Guide

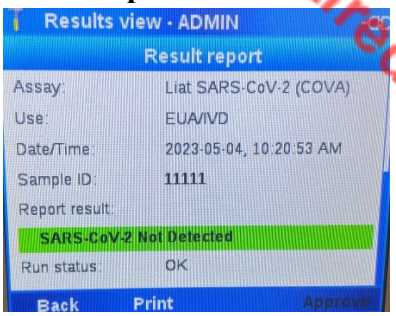
8.2	Running QC (30-Day/New Shipment)
1.	Hold a tube of Control upright and lightly tap on a flat surface to collect liquid at the bottom of the tube. Visually check that the Dilution UTM-RT® has pooled at the bottom of the tube.
2.	Open up a **cobas®** SARS-CoV-2 assay tube foil pouch (from the lot to be added) and remove the contents.
3.	Use the transfer pipette provided in the pouch to add the Control to the **cobas®** SARS-CoV-2 assay tube. Firmly squeeze the bulb of the pipette until the bulb is fully flat, then insert the tip of the pipette into the liquid and draw up the sample by slowly releasing the bulb. ***Note: Only use the transfer pipette provided in the cobas® SARS-CoV-2 assay tube pouch to transfer controls and samples into the cobas® SARS-CoV-2 assay tube.***
4.	Carefully remove the cap of the **cobas®** SARS-CoV-2 assay tube and insert the pipette into the opening. Place the pipette tip near the bottom of the open segment.
5.	Slowly squeeze the bulb to empty the contents of the pipette into the **cobas®** SARS-CoV-2 assay tube. Avoid creating bubbles in the sample. Do not release the pipette bulb while the pipette is still in the **cobas®** SARS-CoV-2 assay tube. ***Note: Do not puncture the cobas® SARS-CoV-2 assay tube or the seal at the bottom of the sample compartment. If either of these are damaged, discard both the assay tube and the transfer pipette, and restart the testing procedure with a new cobas® assay tube and pipette.***
6.	Screw the cap back onto the **cobas®** SARS-CoV-2 assay tube. Dispose of the transfer pipette as biohazardous material.
7.	Select **Scan** and scan the ***cobas®*** *Liat® tube barcode* on the Tube sleeve by placing the **cobas®** Liat® tube on the table and sliding the tube towards the Analyzer until the red scan light is over the entire barcode. The assay is determined by the barcode scanned.
8.	For New shipment: Select **Scan** again and scan the *QC barcode (provided in the QC Kit)*. The Analyzer will prompt **"Add UTM sample & re-scan tube ID**
9.	Continue with steps 5-18 in section 8.4
10.	Refer to section 10.1 for interpreting the QC results.
11.	QC results must be documented in the Quality Control Documentation form

8.3	Test Runs
1.	Minimum of 200 µL sample volume is required for the cobas® Liat® SARS-CoV2 assay. The test procedure is described in detail in the cobas® Liat® PCR System Operator's Manual, pages 77- 92. The procedure is summarized below. Quality Control material for the 30-day requirement or Competency/training is run in the same manner as patient samples. (see section 8.2)

8.3	Test Runs
2.	**Prepare analyzer:** Press the **Power** button. At **logon,** the analyzer prompts you for your user ID and password, for your badge barcode and password, or for your badge barcode only. Select **Run Assay** on the main menu using the touch screen or function button. And press the Select button.  
3.	Select **Scan** and scan the ***cobas®*** *Liat® tube barcode* on the Tube sleeve by placing the **cobas®** Liat® tube on the table and sliding the tube towards the Analyzer until the red scan light is over the entire barcode. The assay is determined by the barcode scanned. 

8.3	Test Runs
4.	Select **Scan** again and scan the *Patient or Sample barcode*, or select **Enter** and type in the Sample ID. The Analyzer will prompt **"Add UTM sample & re-scan tube ID** 
5.	Unscrew the UTM sample tube cap. Lift the cap and any attached swab to allow a pipette to be inserted into the sample tube. Avoid lifting the swab completely out of the sample tube.
6.	Obtain the transfer pipette from the **cobas®** Liat® tube pouch. Firmly squeeze the bulb of the pipette until the bulb is fully flat.
7.	While holding the pipette bulb fully flat, insert the pipette tip into the sample below the liquid surface.
8.	Slowly release the bulb while keeping the pipette tip below the liquid surface, drawing up ~200 µL of sample. After releasing the bulb completely, withdraw the pipette from the sample.
9.	Unscrew the cap from the **cobas®** Liat® tube.
10.	While watching through the viewing window in the sleeve, carefully insert the pipette into the **cobas®** Liat® tube. Place the pipette tip near the bottom of the sample compartment. 
11.	Slowly squeeze the bulb to empty the contents of the pipette into the **cobas®** Liat® tube. Do not release the pipette bulb. **Note:** Do not puncture the **cobas®** Liat® tube or the seal at the bottom of the sample compartment. If either of these is damaged, discard both the **cobas®** Liat Tube and the transfer pipette, and restart the testing procedure with new assay components
12.	While still holding the pipette bulb, withdraw the pipette from the tube. Screw the cap back on the **cobas®** Liat® tube. Dispose of the transfer pipette. **Note:** Start the **cobas®** Liat® assay run as soon as possible, but no later than 4 hours after adding the sample to the **cobas®** Liat® tube.

8.3	Test Runs
13.	Select **Scan** and re-scan the **cobas®** Liat® tube barcode. The tube entry door on top of the Analyzer will open automatically. 
14.	Remove the **cobas®** Liat® tube sleeve, and immediately insert the tube into the Analyzer until the Tube clicks into place. The Tube only fits in one way. **Note:** If the **cobas®** Liat® tube is not inserted by the time the door closes, re-scan the Tube barcode (step 3a) and insert the Tube again. 
15.	Once the **cobas®** Liat® tube is properly inserted, the Analyzer will close the door automatically and begin the test. (During the test, the Analyzer displays the running status and estimated time remaining)
16.	Once the test is complete, the Analyzer displays the message, **"Please remove the tube slowly…"** and opens the tube entry door automatically. 

8.3	Test Runs
17.	Lift the Tube out of the Analyzer 
18.	Select **Report** to see the Result Report.  Review the results on screen (use the down arrow key to scroll to see all results.
19.	To approve results: Select "**Approve"**, then select "**Release"**, then "**Yes"**.
20.	Print results by selecting "**Print"**, then select "**Confirm"**.
21.	Record the results in Sunquest
22.	Select "**Back"**, and then "**Main"** to return to the main menu for the next test.

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

None

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Data

Interpreting QC Material:

cobas® Liat® Analyzer Display	Interpretation
Negative Control Valid	**Negative Control Valid** Control is negative for the presence of SARS-CoV-2 RNA.
Negative Control Invalid. Repeat Run	**Negative Control Invalid** Result is Invalid. The Negative Control should be re-tested to obtain valid result. Repeat Run.
Positive Control Valid	**Positive Control Valid** Control is positive for the presence of SARS-CoV-2 RNA.
Positive Control Invalid. Repeat Run	**Positive Control Invalid** Result is Invalid. The positive control should be re-tested to obtain valid result. Repeat Run.

Note: If the repeated run is still invalid, contact your local Roche representative.

Interpreting Patient Results

Result Report		Interpretation
SARS-CoV-2	SARS-CoV-2 Not Detected	Negative test for SARS-CoV-2 (no SARS-CoV-2 RNA detected)
	SARS-CoV-2 Detected	Positive test for SARS-CoV-2 (SARS-CoV-2 RNA present)
Assay Invalid		Presence or absence of SARS-CoV-2 cannot be determined. Repeat assay with same sample or, if possible, collect new sample for testing.
[Error]. Assay Aborted by System		Run failed or aborted by system. Repeat assay with same sample or, if possible, collect new sample for testing.

10.2 Units of Measure

N/A

10.3 Analytical Measurement Range (AMR)

N/A

10.4 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.

10.5 Repeat Criteria and Resulting

- **see Addendum 2 for Sunquest reporting instructions**

IF the result is …	THEN…
Not detected	Result as **NTD** (Not Detected)
Detected	Result as **DET** (Detected)

IF the result is …	THEN…
Invalid / Error	**Repeat the assay with the same UTM sample and a new *cobas*® *Liat® tube***: If valid results are obtained on the repeat run, record on the QC Log and indicate the original Invalid/Error was repeated and that valid results were obtained upon repeat. If the second result remains Invalid/Error (or if the original specimen was QNS for repeat), obtain a new nasal/nasopharyngeal specimen from the patient and repeat the test. If the patient is not available for re-collection OR the recollected specimen still results as Invalid/Error, indicate on the QC Log that the test was confirmed as INVALID. Resulting repeat INVALID results: Report as **INVD** Add comment **INVLT** - this code translates to: *Unable to report. Repeat analysis of this specimen yielded invalid, inconsistent or unacceptable results.*"

11. EXPECTED VALUES

11.1 Reference Intervals

Not Detected

11.2 Critical Values (infectious disease purposes)

SARS-CoV-2 (COVID 19) Detected *(inpatients and FWMC ED only)*

11.3 Standard Required Messages

LIATC - Performed on Cobas Liat (for LCOVID orders)

Please review the "Fact Sheets" and FDA authorized labeling available for healthcare providers and patients using the following websites:
https://www.fda.gov/media/150277/download
https://www.fda.gov/media/150276/download

This test has been authorized by the FDA under an Emergency Use Authorization(EUA) for use by authorized laboratories.

12. CLINICAL SIGNIFICANCE

The **cobas®** SARS-CoV-2 Nucleic acid test for use on the **cobas®** Liat® System (**cobas®** SARS-CoV-2) is an automated real-time RT-PCR assay intended for the rapid in vitro qualitative detection of nucleic acid from SARS-CoV-2 in self-collected anterior nasal (nasal) swabs (collected in a healthcare setting with instruction by a healthcare provider) and healthcare provider-collected nasopharyngeal, mid-turbinate and anterior nasal (nasal) swabs from either individuals suspected of COVID-19 by their healthcare provider or from any individual, including individuals without symptoms or other reasons to suspect COVID-19.

Results are for the identification of SARS-CoV-2 nucleic acids. 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. Positive results do not rule out bacterial infection or co-infection with other viruses. Clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. The agent detected may not be the definite cause of disease.

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

13. PROCEDURE NOTES

- **FDA Status:** Emergency Use Authorization (EUA), waived
- **Validated Test Modifications:** None

14. LIMITATIONS OF METHOD

- **cobas®** SARS-CoV-2 test has been evaluated only for use in combination with the **cobas®** SARS-CoV-2 Quality Control Kit and this Instructions For Use document. Modifications to these procedures may alter the performance of the test.
- Due to inherent differences between technologies, it is recommended that, prior to switching from one technology to the next, users perform method correlation studies in their laboratory to qualify technology differences. One hundred percent agreement between the results should not be expected due to aforementioned differences between technologies. Users should follow their own specific policies/procedures.
- This test is intended to be used for the detection of SARS-CoV-2 RNA in nasopharyngeal, mid-turbinate and nasal swab samples collected in a Copan UTM-RT System (UTM-RT) or BD™ Universal Viral Transport System (UVT) or Thermo Fisher™ Scientific Remel™ media, Thomas Scientific MANTACC™ premeasured 3 mL 0.9% physiological saline solution or Millennium LifeSciences, Inc. Culture Media Concepts® 3mL Sterile Normal Saline (0.85%). Testing of other sample or media types may lead to inaccurate results.
- Users in a point of care environment should not prepare (formulate, measure, aliquot) 0.9% or 0.85% physiological saline. CLIA certified moderate and high complexity laboratories may

prepare and package equivalent 3 mL of physiological saline for use with **cobas**® SARS-CoV-2 test, but performance with these alternative solutions has not been established. When using physiological saline solution, ensure that the collection tube is an appropriate height for the swab such that the score mark on the swab is not higher than the height of the tube.

- As with other tests, negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment or other patient management decisions.
- False negative results may occur if a specimen is improperly collected, transported or handled, if there is insufficient RNA to be detected, or if one or more target viruses inhibits amplification of other targets.
- Invalid results may be obtained if there is insufficient sample volume or if the specimen contains inhibitory substances that prevent nucleic acid target extraction and/or amplification and detection.

14.1 Precision

Refer to package insert

14.2 Interfering Substances

Refer to package insert

14.3 Clinical Sensitivity/Specificity/Predictive Values

Refer to Package Insert

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)
- cobas® Liat® Systems User Guide Version 9.0 Software Version 3.3, rev Oct 2019
- cobas® Liat® PCR System Operator's Manual, Publication version 9.0
- cobas® SARS CoV-2 IFU, Rev 2.0
- Liat SARS-CoV-2 PCR Quality Control Log (AG.F662)

17. REFERENCES

1. Current package insert for cobas® SARS-CoV-2 Test for use on the cobas® Liat® Systems.

2. QDMD738 – Molecular Best Practices.
3. Clinical and Laboratory Standards Institute (CLSI) MM19-A. Establishing molecular testing in clinical laboratory environments; approved guideline. CLSI Document MM-19A: Wayne, PA; CLSI 2011.
4. Center for Disease Control and Prevention. Biosafety in Microbiological and Biomedical Laboratories, 5th ed. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention. National Institutes of Health HHS Publication No. (CDC) 21-1112, revised December 2009.
5. Clinical and Laboratory Standards Institute (CLSI). Protection of laboratory workers from occupationally acquired infections. Approved Guideline-Fourth Edition. CLSI Document M29-A4: Wayne, PA; CLSI, 2014

18. DOCUMENT HISTORY

Version	Date	Section	Revision	Revised By	Approved By

19. ADDENDA

Addendum	Title
1	Lot Validation Procedure
2	Reporting Results in Sunquest
3	Instrument Maintenance
4	Installing a Laser Printer Using a USB cable/port

Addendum 1

cobas® SARS-CoV-2 & assay tube Lot Validation

Before using a new lot of **cobas®** SARS-CoV-2 assay tubes, a Lot Validation procedure must be performed on the **cobas®** Liat® Analyzer to validate the **cobas®** SARS-CoV-2 assay tube lot at your site. The procedure includes running a Negative Control sample and a Positive Control sample.

Note: Refer to the **cobas®** Liat® System User Guide for detailed operating instructions.

Materials needed for Lot Validation

From **cobas**® SARS-CoV-2 assay tube Kit:

- Package Insert ID Barcode Card: contained in the **cobas**® SARS-CoV-2 assay tube Kit. This barcode is lot-specific; match the lot number next to the barcode with the lot number on the **cobas**® SARS-CoV-2 assay tubes.
- 2 **cobas**® SARS-CoV-2 assay tubes
- 2 transfer pipettes

From **cobas**® SARS-CoV-2 Quality Control Kit:

- 1 Dilution UTM-RT® tube (used as the negative control sample)
- 1 **cobas**® SARS-CoV-2 Positive Control tube
- 1 transfer pipette
- Control kit barcode card

Prepare and test Negative Control sample

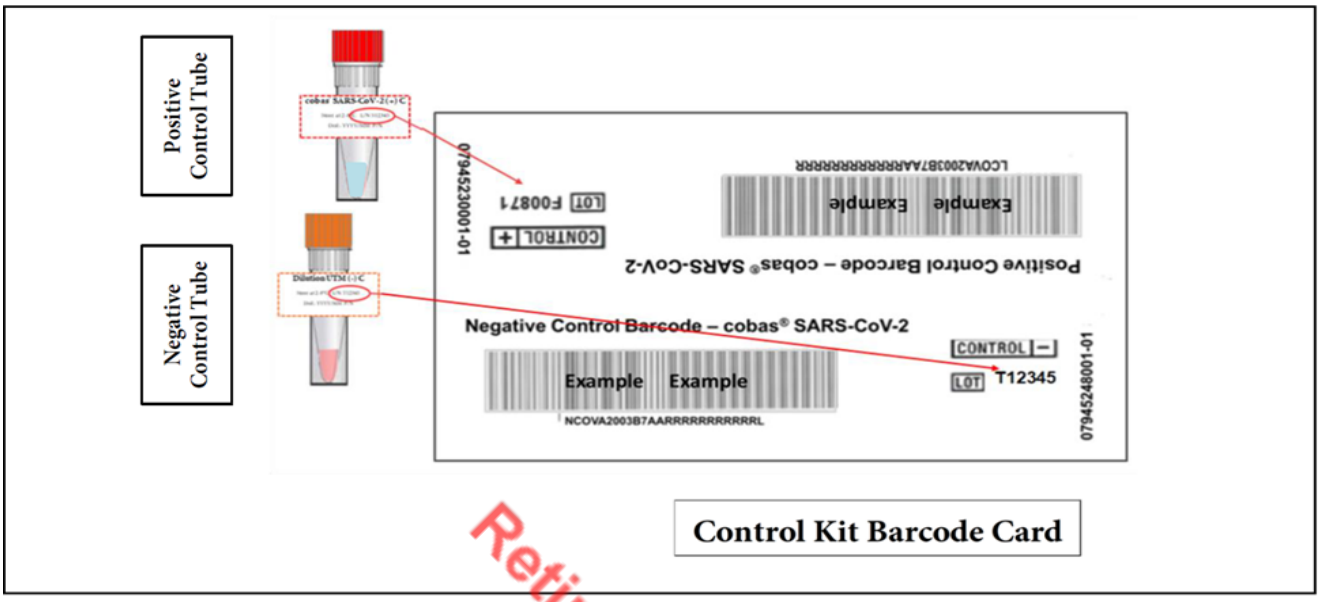
Materials needed:

- Package Insert Barcode on the Package Insert Barcode Card contained in the **cobas**® SARS-CoV-2 assay tube Kit.
- Negative Control Barcode on the Control Kit Barcode Card
- 1 Dilution UTM-RT® tube
- 1 **cobas**® SARS-CoV-2 assay tube from this lot
- 1 transfer pipette

Note: Following figure below,

- Match the lot number (L/N) of the Dilution UTM tube label to the lot number (LOT) of the Negative Control Barcode Label on the Control Kit Barcode Card and then use the Negative Control Barcode (on the Control Kit Barcode Card) as the sample ID when performing negative control run.

- Match the lot number (L/N) of the Positive Control tube label for **cobas**® SARS-CoV-2 to the lot number (LOT) of the Positive Control Barcode Label on the Control Kit Barcode Card as shown in Figure 2. Use the Positive Control Barcode (on the Control Kit Barcode Card) as the sample ID when performing positive control run.

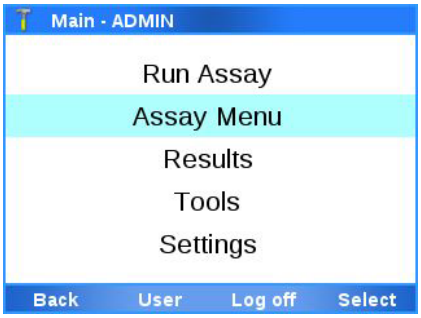


Assay tube Lot Validation workflow

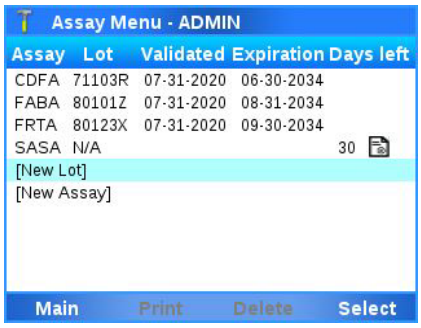
1. Press the power on/off button to start the **cobas**® Liat® Analyzer.
2. Select **"Login"** on the screen of the **cobas**® Liat® Analyzer.
3. Enter user name when prompted, select "**OK**".
4. Enter user password when prompted, select "**OK**".

   Note: You may be prompted to confirm you have read the User Manual (i.e., cobas® Liat® System User Guide or Operator's Manual).

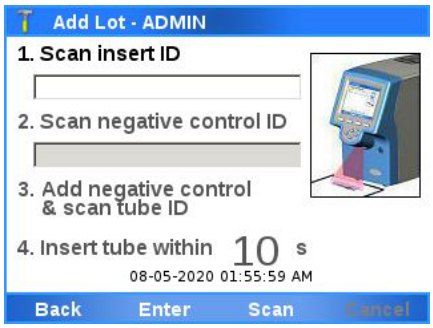
5. Select "**Assay Menu**" on the main menu of a **cobas®** Liat® Analyzer.



6. Select "**New Lot**" at the bottom of the list.



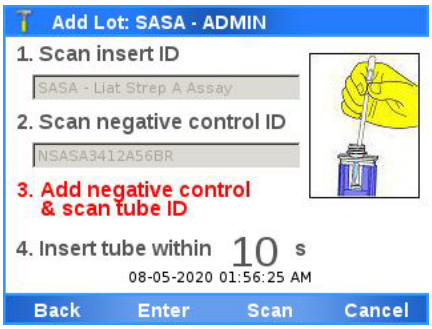
7. When prompted to **Scan the Insert ID,** select "**Scan**" and scan the **cobas®** SARS-CoV-2 Package Insert ID Barcode card. Ensure that the red scan light is over the entire barcode.



Note: You may be prompted to confirm you have read Instructions For Use.

8. When prompted to **scan the Negative Control ID**, select "**Scan**" and scan the Negative Control Barcode card included with the control kit. Ensure that the red scan light is over the entire barcode.

Next, the **cobas**® Liat® Analyzer will prompt with the message "**Add negative control & scan tube ID**".



9. Hold a tube of Negative Control upright and lightly tap on a flat surface to collect liquid at the bottom of the tube. Visually check that the Dilution UTM-RT® has pooled at the bottom of the tube.
10. Open up a **cobas®** SARS-CoV-2 assay tube foil pouch (from the lot to be added) and remove the contents.
11. Use the transfer pipette provided in the pouch to add the Negative Control to the **cobas®** SARS-CoV-2 assay tube. Firmly squeeze the bulb of the pipette until the bulb is fully flat, then insert the tip of the pipette into the liquid and draw up the sample by slowly releasing the bulb.

Note: Only use the transfer pipette provided in the cobas® SARS-CoV-2 assay tube pouch to transfer controls and samples into the cobas® SARS-CoV-2 assay tube.

12. Carefully remove the cap of the **cobas®** SARS-CoV-2 assay tube and insert the pipette into the opening. Place the pipette tip near the bottom of the open segment.
13. Slowly squeeze the bulb to empty the contents of the pipette into the **cobas®** SARS-CoV-2 assay tube. Avoid creating bubbles in the sample. Do not release the pipette bulb while the pipette is still in the **cobas®** SARS-CoV-2 assay tube.

    Note: Do not puncture the cobas® SARS-CoV-2 assay tube or the seal at the bottom of the sample compartment. If either of these are damaged, discard both the cobas® SARS-CoV-2 assay tube and the transfer pipette, and restart the testing procedure with a new cobas® SARS-CoV-2 assay tube and pipette.
14. Screw the cap back onto the **cobas® SARS-CoV-2** assay tube. Dispose of the transfer pipette as biohazardous material.
15. Select "**Scan**" and place the **cobas® SARS-CoV-2** assay tube horizontally on the table beneath the barcode reader so that the red scan light is over the entire barcode. The tube entry door on top of the **cobas**® Liat® Analyzer will open automatically once the barcode is read.

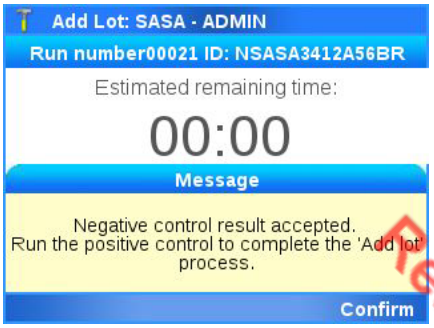
16. Remove the **cobas® SARS-CoV-2** assay tube sleeve and immediately insert the **cobas® SARS-CoV-2** assay tube into the **cobas®** Liat® Analyzer until the tube clicks into place.

    Note: The cobas® SARS-CoV-2 assay tube only fits in one way - the grooved side of the cobas® SARS-CoV-2 assay tube must be on the left while the cap is on top.

17. If the tube is not inserted by the time the door closes, re-scan the **cobas® SARS-CoV-2** assay tube barcode and insert the **cobas® SARS-CoV-2** assay tube again. Once the **cobas® SARS-CoV-2** assay tube is properly inserted, the **cobas**® Liat® Analyzer will close the door automatically and begin the test.
18. During the test, the **cobas®** Liat® Analyzer displays the running status and estimated time remaining. Once the test is complete, the **cobas®** Liat® displays the message, "*Remove tube slowly and carefully.*" and opens the tube entry door automatically. Slowly lift the **cobas® SARS-CoV-2** assay tube out of the

cobas® Liat® Analyzer. Dispose of the used **cobas® SARS-CoV-2** assay tube as biohazardous material.

19. If **"Negative control result accepted."** is displayed at the end of the run, select **"Confirm"**. If the result is rejected, repeat the negative control run (steps 8-19). If repeated control runs do not produce the expected results, contact your local Roche representative.



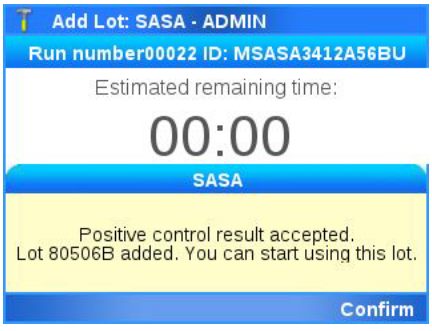
20. Select **"Back"** to proceed with the **cobas® SARS-CoV-2** Positive Control test on the same instrument.
21. Similarly, follow steps 8 to 18 with a **cobas®** SARS-CoV-2 Positive Control in place of the **cobas®** Liat® Negative Control.

Prepare cobas® SARS-CoV-2 Positive Control sample for Lot Validation

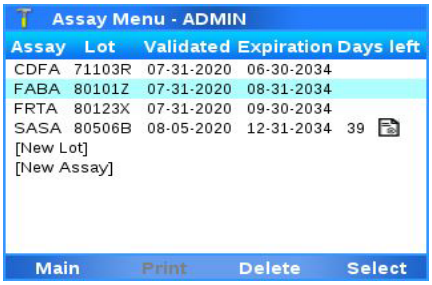
Materials needed:

- 1 transfer pipette (Use only transfer pipettes contained in the **cobas® SARS-CoV-2** Quality Control Kit)
- 1 **cobas®** SARS-CoV-2 Positive Control Tube
- 1 **cobas®** SARS-CoV-2 assay tube from this lot

22. If **"Positive control result accepted."** is displayed at the end of the run, select "**Confirm"** and then select **"Back"** to return to Main menu. If the result is rejected, repeat the **cobas® SARS-CoV-2** Positive Control test. If repeated control runs do not produce the expected results, contact your local Roche representative.



23. Select "**Assay Menu"** to verify that the new lot has been added.



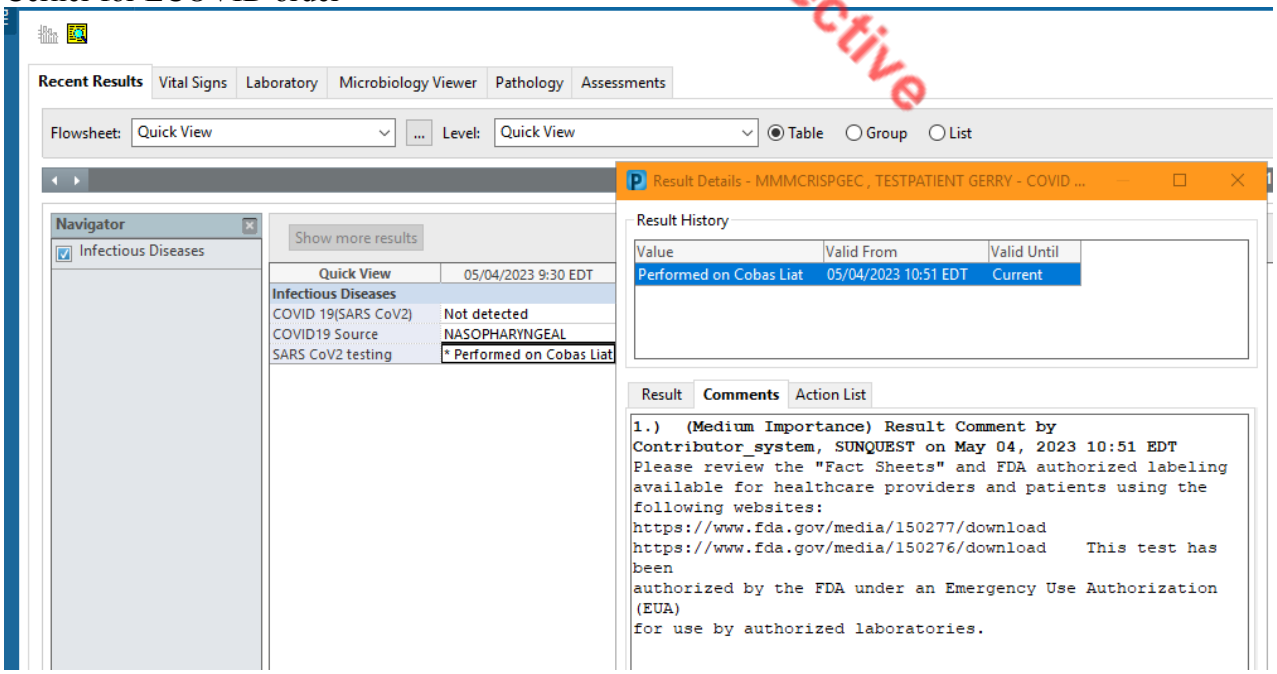
Addendum 2

Resulting Cobas Liat in Sunquest:

1. For GEC testing, results from the Cobas Liat autofile into Sunquest then Cerner.
2. For FWMC testing, results from the Coabs LIAT autofile into Sunquest then Cerner.
   **Except DET(Detected) results. These results need to be called to the nursing unit or ED and documented. To result go into OEM
3. If resulting via SmarTerm
   a. Function: MEM
   b. Worksheet:
      GIM2 - GEC
      FIM2 - FWMC
   c. TEST-1: LCOVID
   d. ACC. NO.: Type in the Accession number
   e. Type in results for
      COVNT
   f. At the SCTP test, you will see a message "Enter Type in Method code:"

```
SCTP    :          Enter       Type in Method code  :
```

   g. Type in the Cobas Liat method code **LIAT.** This will add the EUA documentation to the results.
   h. Review results with instrument print out. If results on printout match Sunquest, then accept the results in Sunquest. Results will now transmit to Cerner.
      Examples
      Cerner for LCOVID order



Addendum 3

cobas Liat Instrument Maintenance

Cleaning the analyzer

NOTICE!

Using unsuitable cleaning materials can damage the touch screen and other surfaces.

• Do not use harsh, abrasive cleaners or wipes.

• **Do not use isopropanol or bleach solution to clean the touch screen.**

• Monthly check the rear vent and bottom of the analyzer for excessive dust or debris.

• When prompted by the message "Use cleaning tool" on the screen, use the provided cleaning tool following the instructions included with the cleaning tool kit.

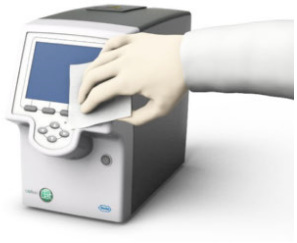
• **Only use the supplied cleaning tool when prompted by the message**. Do not attempt to clean the tube chamber of the analyzer with anything other than the cleaning tool kit.

Cleaning the outside of the analyzer

To clean the touch screen

Keep the touch screen clean from excessive fingerprints and moisture by gently wiping it with a soft, lint-free cloth.

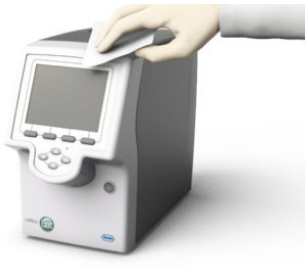
• **Do not use isopropanol or bleach solution to clean the touch screen.**



To clean the front buttons and the exterior of the analyzer

The exterior of the analyzer and front buttons can be cleaned using a soft lint-free cloth moistened with 70% isopropanol.

1. Moisten a lint-free cloth with either 70% isopropanol
2. Gently wipe the surfaces as required.



Cleaning spillages or leakages from an assay tube

In the unlikely event of a spillage or leak of an assay tube, special precautions apply because the tube contains various potentially biohazardous materials and hazardous chemicals.

CAUTION!

Contamination of cleaning tool

Do not use the cleaning tool for biohazardous contamination. The cleaning tool does not decontaminate the analyzer but becomes contaminated itself.

1. Dispose of the assay tube in accordance with the disposal policy of your institution and according to local regulations.
2. If the leak happened inside the analyzer, stop using the analyzer and immediately contact your Roche representative for further instructions.
3. Follow laboratory best practices.
   - Follow Good Laboratory Practice for working with biohazardous materials and hazardous chemicals.
   - Refer to the appropriate assay tube Safety Data Sheet and package insert or the Instructions for Use for assay-specific information.

Addendum 4

Installing a Laser Printer Using a USB cable/port

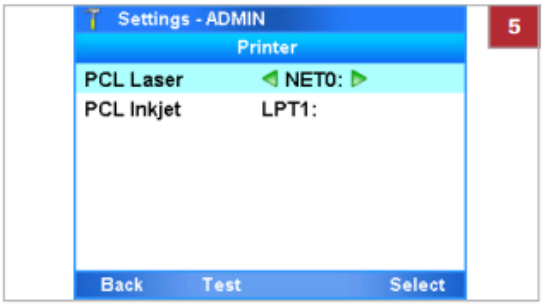
To install a USB printer

1 When you start the analyzer for the first time, make sure the USB printer is **not** connected.

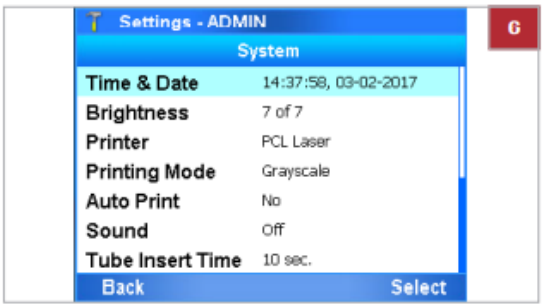
2 Log on to the analyzer.
ℹ You need Supervisor or Administrator access role.

3 Connect the printer to the analyzer.

4 Choose Main > Settings > System > Printer.



5 Choose the printer type and connection:
- For a laser printer, choose the PCL Laser item and choose the LPT1: option.
- For an inkjet printer, choose the PCL Inkjet item and choose the LPT1: option.



6 Choose the Select button. Choose the Printing Mode item:
- For a grayscale printer, keep the default Grayscale option.
- For a color printer, choose the Color option.

7 Return to the Main menu.
ℹ If you do not return to the Main menu, settings will be lost at the next restart of the analyzer.

**

Adventist HealthCare

Liat SARS-CoV-2 PCR Quality Control Log

Germantown Emergency Center
Fort Washington 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 for each new kit lot or shipment or every 31 days, whichever is more frequent.
2. **Run Status** 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#	Kit	Patient Results DET / NTD	Run Status	External Pos Control Valid = Detected / Positive		External Neg Control Valid = Not detected / Neg		Tech Code
		Lot # / Expire		OK / Not OK	Lot # / Expire	Valid / Invalid	Lot # / Expire	Valid / Invalid	

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