ROCHE COBAS® LIAT SYSTEM POINT OF CARE SARS-COV-2 & INFLUENZA A/B ASSAY

PURPOSE

To describe the policies and procedures related to the Point of Care Roche **cobas®** Liat Analyzer for SARS-CoV-2 & influenza A/B nucleic acid testing.

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SCOPE / APPLICABILITY

This procedure applies to all currently certified operators trained to perform SARS-CoV-2 & influenza A/B nucleic acid testing using the **cobas®** Liat System.

PRINCIPLE

The **cobas®** Liat is for *in vitro* diagnostic use. It is designed to identify and/or measure the presence of genetic material in a biological sample. The system automates all nucleic acid test (NAT) processes, including reagent preparation, target enrichment, inhibitor removal, nucleic acid extraction, amplification, real-time detection, and result interpretation in a rapid manner.

The system consists of an instrument and preloaded software for running tests and viewing the results. The system requires the use of a single-use disposable **cobas®** Liat® SARS-Cov-2 & Influenza A/B Tube that holds the sample purification and RT-PCR reagents and hosts the sample preparation and RT-PCR processes.

The **cobas®** SARS-CoV-2 & Influenza A/B 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 the ORFI a.b non-structural region and nucleocapsid protein gene that are unique to SARS-CoV-2, a well-conserved region of the matrix gene of Influenza A, and the non-structural protein gene of Influenza B. 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 process.

INSTRUMENT / SUPPLIES

Cobas® Liat Analyzer
Calibrated disposable pipette

REAGENT & MATERIAL STORAGE

Reagent	Storage Temperature	Storage Time
cobas® SARS-CoV-2 & Influenza A/B	2–8°C (36 - 46◦F)	Stable until the expiration date indicated Do not use past expiration date.

TRAINING AND COMPETENCY ASSESSMENT

Training and Competency assessment will be assessed initially by successfully performing a Liat flu test, completion of the competency checklist and an assessment quiz. Competency assessment for all individuals testing patient specimens consists of initial competency assessment before performing patient testing and then annual assessment thereafter.

SPECIMEN

Acceptable sample type: Nasopharyngeal swab
Acceptable Sample Collection Materials: sterile flocked swab in 1-3mL of viral transport media (VTM) or universal transport media (UTM)

Nasopharyngeal Sample Collection Procedure

1. Identify patient according to established protocols.
2. Explain the purpose and steps of the procedure to the patient.
3. Collect the sample as per established procedures for COVID testing.

Specimen storage and handling

- Ideally, specimens should be tested immediately after collection
- Specimens not tested immediately can be refrigerated (2-8C) for up to 72 hours

Rejection Criteria for Nasopharyngeal Samples

- Improper transport media
- Leaky transport tube
- Improper storage of sample
- Incorrect swab used for collection of samples
- Mislabeled sample
- Improper collection of samples

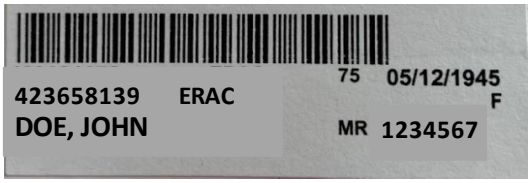
SAFETY INFORMATION

- Observe Standard Precautions at all times during sample collection, testing, instrument maintenance, and waste disposal.
- Personal protective equipment must be worn during all steps of testing.
- Use aseptic technique.
- Disinfect the analyzer after use with approved hospital disinfectant.
- Adhere to all biohazard and safety guidelines pertaining to the handling and disposal of body fluids.

PATIENT SPECIMEN TESTING PROCEDURE

1. Provider places an order for the “Liat SARS-COV-2/Influenza A/B NAAT POC” in Cerner PowerChart.
2. Nurses will see the new orders on their tracking shell under “RN Review”.
3. Obtain a Cobas SARS-CoV-2 & Influenza A/B assay tube pouch and take out the assay tube.

4. Label the assay tube with a patient chart barcode label ("white patient label", see below). **DO NOT COVER THE MANUFACTURER BARCODE ON THE ASSAY TUBE**



5. Use the transfer pipette provided in the assay tube pouch to transfer specimen:
   5.1. Firmly squeeze the bulb of the pipette until the bulb is fully flat, then insert the tip of the pipette into the collected patient specimen liquid and draw up the sample by slowly releasing the bulb.
   5.2. Carefully remove the cap of the Cobas® SARS-CoV-2 & Influenza A/B assay tube and insert the pipette into the opening.
   5.3. Place the pipette tip near the bottom of the open segment.
   5.4. Slowly squeeze the bulb to empty the contents of the pipette into the cobas® SARS-CoV-2 & Influenza A/B assay tube, careful not to create any air bubbles. Do not release the pipette bulb while the pipette is still in the Cobas ® SARS-CoV-2 & Influenza A/B assay tube.

   Note : Do not puncture the cobas ® SARS-CoV-2 & Influenza A/B 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 & Influenza A/B assay tube and the transfer pipette, and restart the testing procedure with a new cobas ® SARS-CoV-2 & Influenza A/8 assay tube and pipette.
6. Re-cap the cobas® SARS- CoV-2 & Influenza A/8 assay tube and dispose of the transfer pipette as biohazardous material.
7. Ensure that the List Analyzer is powered on.
8. Select "Login" on the screen of the analyzer.
9. Scan the barcode on your badge.

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   Note: You may be prompted to confirm you have read the user manual upon first logon (i.e., **cobas** Liat System User Guide or Operator's Manual).
10. From the Main Menu, select "Run Assay."
11. When prompted to scan List Tube ID, press "Scan" and place the SARS-CoV-2 & Influenza A/B assay tube horizontally on the table beneath the barcode reader so that the red scan light is over the entire manufacturer placed barcode (see below).

12. When prompted to scan sample ID, press “Scan” to scan the patient chart barcode, previously placed on the assay tube. In the case that the sample cannot be scanned, press “Enter” to manually enter the sample ID.
13. If patient verification is activated, the Analyzer will display the status of verification.
    13.1. Successful verification: analyzer may prompt confirmation of entered information before proceeding with running the assay.
    13.2. Failed verification: the analyzer may display notification that verification failed and may (1) require acknowledgement before proceeding with running the assay or (2) if unable to proceed, contact the Point of Care Laboratory Staff (POCT) at (718) 780-3663/3704.
14. The user will be prompted to scan List tube ID a second time. Press ”Scan" and rescan the same cobas® SARS- CoV-2 & Influenza a A/B assay tube barcode. The tube entry door on top of the cobas® Liat® Analyzer will open automatically.
15. Remove the cobas® SARS-CoV- 2 & Influenza A/B assay tube sleeve and immediately insert the cobas® SARS-CoV-2 & Influenza A/B assay tube SLEEVE into the cobas® Liat® Analyzer until it clicks into place (see below).

    Note : The SARS-CoV-2 & Influenza A/8 assay tube sleeve only fits in one way- the grooved side of the cobas® SARS-CoV-2 & Influenza A/8 assay tube sleeve must be on the left while the cap is on top.

Assay Tube

Assay Tube Sleeve

**Note: after inoculating patient sample into assay tube and securing cap, user will have to gently pull on the cap to remove the assay tube sleeve from inside the assay tube. Only the sleeve is placed into the analyzer.

16. If the assay tube is not inserted by the time the door closes, re-scan the cobas® SARS CoV-2 & Influenza A/B assay tube manufacturer barcode and insert the cobas® SARS-CoV-2 & Influenza A/B assay tube sleeve again. Once the cobas® SARS-CoV-2 & Influenza A/B assay tube is properly inserted, the cobas® Liat Analyzer will close the door automatically and begin the test.
17. During the test, the cobas® Liat® Analyzer displays the running status and estimated time remaining.
18. Once the test is complete, the cobas® Liat® Analyzer displays the message, "Remove tube slowly and carefully" and opens the tube entry door automatically.
19. Slowly lift the cobas® SARS-CoV-2 & Influenza A/ B assay tube out of the cobas® Liat® Analyzer.
20. Dispose of the used cobas® SA RS-CoV-2 & Influenza A/B assay tube as biohazardous material.
21. Press "Report" to see the Result Report.
22. Press "Back", and then "Main" to return to the main menu to perform the next test.

RESULTS REPORTING AND INTERPRETATION

- One approved, the result is transmitted to RALS data management system which sends the result to the patient's EMR.
- Influenza A and Influenza B negative results should be considered presumptive in samples that have a positive SARS-CoV-2 result.

Result Report		Interpretation
	SARS-Co V-2 Not Detected	Negative test for SARS-CoV-2 (no SARS-CoV-2 RNA detected)

SARS-CoV-2	SARS-CoV-2 Detected	Positive test for- SARS-CoV-2 (SARS CoV-2 RNA present)
	SARS-CoV-2 Invalid	Presence or absence of SARS-CoV-2 cannot be de- termined. If clinically indicated, repeat assay with same sample or, if possible, collect new sample for testing.
Influenza A	Influenza A Not Detected	Negative test for In- fluenza A (no influ- enza A R A detected)
	Influenza A Detected	Positive test for In- fluenza A (Influ- enza A RNA pre- sent)
	Influenza A Invalid	Presence or absence of Influenza A cannot be de- termined. If clinically indicated, repeat assay with same sample or, if possible, collect new sample for testing.
Influenza B	Influenza B Not Detected	Negative test for Influenza B (no Influenza B RNA detected)
	Influenza B Detected	Positive test for Influenza B (Influ- enza B RNA pre- sent)
	Influenza B Invalid	Presence or absence of Influenza B cannot be de- termined. If clinically indicated, re peat assay with same sample or, if possible, collect new sample for testing.
Assay Invalid		Presence or absence of SARS-CoV- 2, Influenza A, and Influenza B cannot be determined. Repeat as- say with same sample or, if possible, collect new sample for testing.
[Error]. As- say Aborted		Presence or absence of SARS-CoV-2, Influenza A, and Influenza B cannot be determined. Repeat assay with same sample or, if possible, collect new sample for testing.

ALTERNATIVE METHOD of TESTING

Any samples/results that are inconsistent with patient condition, in need of confirmation, or encounter repeat error should be referred to the Microbiology Laboratory for testing. Follow sample collection procedures for Microbiology SARS CoV-2 & Influenza A/B testing.

QUALITY CONTROL

Internal and external quality control testing are conducted according to the following schedule:

Type of QC Testing	Frequency	Notes
Internal Processing Control (IPC)	With each control or patient test run-occurs automatically.	IPC is integrated into each cobas® Liat ® SARS-CoV-2, Influenza type A and B virus RNA tube and verifies adequate processing of the sample. The PIC "passes" if purification and target amplification meet validated acceptance criteria. No action from operator is required.
External positive and negative controls	Validation of every new cobas® Liat® that is added to the system and subsequently: ***Positive and negative control will be done on each shipment /new lot of reagents by the laboratory.***	The cobas® Liat ® System requires the validation of new tube lots as part of its *"Add Lot" function* and will not allow testing with a new tube lot without successful completion of positive and negative external control testing.

External Quality Control will be performed by Point of Care Testing Laboratory staff as per laboratory SOP.

CALIBRATION

The **cobas®** Liat® Analyzer requires no adjustment or calibration from the operator. The **instrument** periodically performs automatic recalibration. During auto calibration, "(AutoCal)" is displayed on the title bar. If the user selects Run Assay at this time, a message appears stating, "AutoCal started. This could take up to a minute." Select **OK** to close this message window. Wait until (AutoCal) is no longer in title bar.

**NOTE: A user may inadvertently touch one item on the screen, but activate another item. The touch screen will require recalibration. Supervisor or higher security level user is required, please contact the Point of Care Testing Laboratory (POCT) staff as per below.

SYSTEM MAINTENANCE

- The analyzer should be cleaned after every patient use.
- Keep the touch screen clean from excessive fingerprints and moisture by gently wiping it with a soft, lint free cloth.
- The exterior of the **cobas®** Liat® Analyzer and front buttons can also be cleaned using a soft lint free cloth moistened with either 70% isopropanol or 5-10% bleach solution. If bleach is used, it must be wiped twice using 70% isopropanol to remove all bleach residues.
- Periodically check the rear vent and bottom of the **cobas®** Liat® Analyzer for excessive dust or debris.
- When prompted by the message "Use cleaning tool" on the **cobas®** Liat® Analyzer screen, contact the POCT as per below.

TROUBLESHOOTING and TECHNICAL SUPPORT

The **cobas®** Liat® Analyzer monitors its operation and logs abnormal events. Based on the severity, the **cobas®** Liat® Analyzer tries to recover or fix errors while running. If the error is unrecoverable, the **cobas®** Liat® Analyzer stops. If repeating the test as suggested in the results table below does not yield a clear positive or negative result contact POCT staff.

Failure Codes	Sample
g0*	IPC out of range. Repeat run.
g1	
g2	
g3	
g4	

x4	One or more targets out of range. Repeat the run.

Warning! Only a Roche-qualified service representative can service the system or perform preventative maintenance. Never attempt to repair or adjust the system yourself. Disassembly could result in electrical hazards.

POCT staff can be reached at (718) 780-3663/3704. The POCT laboratory staff will contact vendor support whenever necessary.

REFERENCE(S):

1. cobas® SARS-CoV-2 & Influenza A/B Nucleic acid test for use on the cobas® Liat® System manual 2020.
2. cobas® SARS-CoV-2 & Influenza A/B Nucleic acid test Package Insert.

RELATED DOCUMENT(S):

POLICY: LIAT QC SOP