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COBAS® LIAT SYSTEM – SARS- CoV-2 & Influenza A/B

Principle

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 both the ORF1 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 processes.

Results are available within approximately 20 minutes after loading the sample on the instrument.

Purpose

The cobas® SARS-CoV-2 & Influenza A/B Nucleic acid test for use on the cobas® Liat® System (cobas® SARS-CoV-2 & Influenza A/B) is an automated multiplex real-time RT-PCR assay intended for the simultaneous rapid *in vitro* qualitative detection and differentiation of SARS-CoV-2, influenza A, and influenza B virus nucleic acid in healthcare provider-collected nasopharyngeal and nasal swabs from individuals suspected of respiratory viral infection. Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar.

Positive results do not rule out co-infection with other organisms. The agent(s) detected by the cobas SARS-CoV-2 & Influenza A/B may not be the definite cause of disease.

Negative results do not preclude SARS-CoV-2, influenza A, and/or influenza B 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.

Scope

The cobas® SARS-CoV-2 & Influenza A/B test is a FDA-approved CLIA-waived test, and can be performed by licensed Clinical Laboratory Scientists (CLS) and medical laboratory technicians (MLT).

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COBAS® LIAT SYSTEM – SARS- CoV-2 & Influenza A/B , Continued

Policy

The rapid detection of SARS-CoV-2 & Influenza A/B is intended for in vitro diagnostic use only. Reporting of positive Influenza and SARS-CoV-2 results is required under Title 17, California Code of Regulations, Section 2505.

Sample type

- Nasopharyngeal swab specimens
- Nasal Swab specimens

Specimen collection

- Nasopharyngeal swab specimens
  - Mini Tip Flocked Swab
  - Transport medium (UTM or UVT, M4, M4RT, M5, and M6, or 0.9% Physiological Saline), 3 mL
- Nasal Swab specimens
  - Regular Flocked Swab
  - Transport medium (UTM or UVT, M4, M4RT, M5, and M6 or 0.9% Physiological Saline), 3 mL

Specimen collection must be performed using the required swabs listed. Inadequate or inappropriate sample collection, storage, and transport may yield incorrect or invalid test results.

Specimen transport and storage

- After the sample has been collected and placed in appropriate viral transport media, transport, and test as soon as possible.
- The specimen should be added to the assay tube immediately upon receipt.
- After adding specimen to assay tube, it should be tested immediately, but no later than 4 hours after adding to the sample assay tube.
- Refrigerate specimens at 2-8°C, (and transport with ice) if there will be a delay in testing.
- Specimens collected in appropriate viral transport media may be stored up to 4 hours at room temperature or up to 72 hours at 2-8°C if immediate testing is not possible.
- Freezing at -70°C or colder (and transportation on dry ice) is required for specimen storage or transportation beyond 72 hours.

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COBAS® LIAT SYSTEM – SARS- CoV-2 & Influenza A/B , Continued

Specimen rejection

- Improper transport media (eSwab)
- Leaky transport tube
- Improper storage of sample
- Incorrect swab used for sample collection
- Mislabeled sample
- Improper sample collection
- Improper sample type

Reagents and Materials

Reagents and controls- store at 2-8◦C. Stable until the expiration date indicated.

- cobas SARS-CoV-2 & Influenza A/B test. Each assay tube contains:
    - Internal Process Control
    - Proteinase K
    - Magnetic Glass Particles
    - Lysis Buffer- **Caution:** *Causes severe skin burns and eye damage. Harmful if swallowed or inhaled.*
    - Wash Buffer
    - Elution Buffer
    - SARS-CoV-2 & Influenza A/B Master Mix-1
    - SARS-CoV-2 & Influenza A/B Master Mix-2
    - SARS-CoV-2 & Inluenza A/B Master Mix-3
- cobas SARS-CoV-2 & Influenza A/B Quality Control kit
    - SARS-CoV-2 Positive control (Liquid. Used in reconstitution)
    - FLU A/B Positive control (Lyophilized. To be reconstituted)
    - cobas Dilution UTM, Negative control
- Disposable pipettes

Equipment and Software

- cobas® Liat® Analyzer – software version 3.3 or higher
- cobas® SARS CoV-2 & Influenza A/B Assay Script v1.2 or higher

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Before you begin

Good laboratory practices and careful adherence to the procedure is necessary. Wear laboratory gloves, laboratory coats, eye protection, Face Shield *(Required only if BSC or other protective barrier is not available)* when handling samples and reagents.

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COBAS® LIAT SYSTEM – SARS- CoV-2 & Influenza A/B , Continued

Warnings, Precautions, and Procedural Notes

- To avoid error and sample cross contamination, change gloves between samples and work on one sample at a time. DO NOT add multiple samples into multiple assay tubes at the same time.
- Due to the high sensitivity of the assay, contamination of the work area with previous positive samples may cause false positive results. Clean instrument and surrounding surfaces according to instructions provided in the cleaning section of the instrument Operator's Manual. If spills occur, follow the appropriate instructions in *Cleaning and Decontamination Procedure for Cobas LIAT PCR system,* SCPMG-PPP-0357.
- Do not use a damaged cobas® SARS-CoV-2 & Influenza A/B assay tube.
- Do not use a cobas® SARS-CoV-2 & Influenza A/B assay tube that has been dropped after removal from its foil pouch.
- Do not open the cap of the cobas® SARS-CoV-2 & Influenza A/B assay tube during or after the run on the cobas® Liat Analyzer.
- Do not use Negative Control if the color has changed from light orange-red.
- Ensure any additional labels are only placed on the back of the tube sleeve or around the side of the cap, do not place labels over barcodes or over the top of the assay tube cap.
- Dispose of a used cobas® SARS-CoV-2 & Influenza A/B assay tube, pipette and specimen tube according to your institution's safety guidelines for hazardous material.
- Use only the transfer pipettes provided. Use of alternative transfer pipettes may lead to invalid results.
- Do not use cobas® SARS-CoV-2 & Influenza A/B assay tube and cobas® SARS-CoV-2 & Influenza A/B Quality Control Kit after their expiry dates.
- Do not reuse assay tubes and transfer pipettes. They are for one-time use only.

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COBAS® LIAT SYSTEM – SARS- CoV-2 & Influenza A/B , Continued

Quality Control

1. External Quality Control should be run with each
   - New lot number
   - Each shipment
2. Controls
   - Negative: Dilution UTM. Use provided control barcode included in kit

   Do not use Negative Control if the color has changed from light orange-red.
   - Positive: Use provided control barcode included in kit
     - SARS-CoV-2 (Liquid. Used in reconstitution)
     - Influenza A/B (Lyophilized. To be reconstituted)

Note: Barcodes are lot specific. The use of barcodes other than those provided in the kit may lead to incorrect control results.

Interpretation of Control Results:

Analyzer Display	Interpretation
Positive Control Valid	**Positive Control Valid** Control is positive for the presence of SARS-CoV-2, Influenza type A virus and Influenza type B RNA
Positive Control Invalid	**Positive Control Invalid** Result is Invalid. The Positive Control should be re-tested to obtain valid result. Repeat Run.
Negative Control Valid	**Negative Control Valid** Control is negative for the presence of SARS-CoV-2, Influenza type A virus and Influenza type B RNA
Negative Control Invalid	**Negative Control Invalid** Result is Invalid. The Negative Control should be re-tested to obtain valid result. Repeat Run.

Note: If the repeated run is still invalid, do not use for patient testing. Contact technical support.

- Contamination Monitoring

  Wipe Test performed monthly. Refer to *Contamination Monitoring Procedure Using Wipe Testing for Cobas LIAT PCR System Testing for Cobas LIAT PCR System*- SCPMG-PPP-0358

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COBAS® LIAT SYSTEM – SARS- CoV-2 & Influenza A/B , Continued

Workflow

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

A. "Lot Validation" workflow

1	System start up and login.
2	Obtaining the controls and assay tubes.
3	Choosing "New Lot" under "Assay Menu"
4	Scanning the Package Insert barcode from the Package Insert Barcode Card.
5	Scanning and running the Negative Control.
6	Scanning and running the Positive Control.

Materials needed for Lot Validation

To validate Negative Control:	**To validate Positive Control:**
1 Dilution UTM vial	1 cobas® SARS-CoV-2 Positive Control vial
1 cobas® SARS-CoV-2 & Influenza A/B assay tube	1 cobas® Influenza A/B Positive Control vial
1 transfer pipette	1 cobas® SARS-CoV-2 & Influenza A/B assay tube
Package Insert Barcode card	2 transfer pipettes
Negative Control barcode on the Control Kit Barcode card	Positive Control barcode on the Control Kit Barcode card

The Package Insert Barcode card is lot-specific.
Match the lot number next to the barcode with the lot number on the cobas® SARS-CoV-2 assay tubes.

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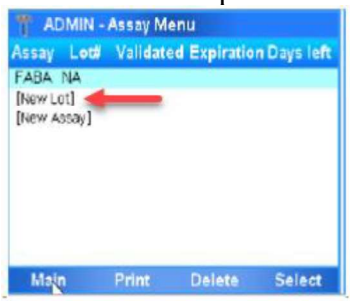
COBAS® LIAT SYSTEM – SARS- CoV-2 & Influenza A/B , Continued

B. **cobas® SARS CoV-2 & Influenza A/B workflow**

1	System start up and login.
2	Obtaining samples and assay tubes.
3	Choosing "Run Assay" on the Main Menu.
4	Scanning the cobas® SARS-CoV-2 & Influenza A/B assay tube barcode.
5	Scanning or entering the sample ID (accession number).
6	Adding the specimen sample to the cobas® SARS-CoV-2 & Influenza A/B assay tube using the transfer pipette and re-cap the tube.
7	Re-scanning the cobas® SARS-CoV-2 & Influenza A/B assay tube barcode.
8	Starting the sample run.
9	Reviewing the results.
10	Unloading and disposing of the used cobas® SARS-CoV-2 & Influenza A/B assay tube.

Procedure

Follow the steps below to

Add a New Assay Tube Lot and Run Controls	
Step	**Action**
1	Obtain: • Package Insert Barcode on the Package Insert Barcode Card contained in the assay tube pack • Negative Control Barcode on the Control Kit Barcode Card • 1 Dilution UTM tube (used as the negative control sample) • 1 assay tube from this lot
2	Select **Assay Menu** on the main menu of the analyzer 
3	Select **New Lot** option and choose the **Select** button 

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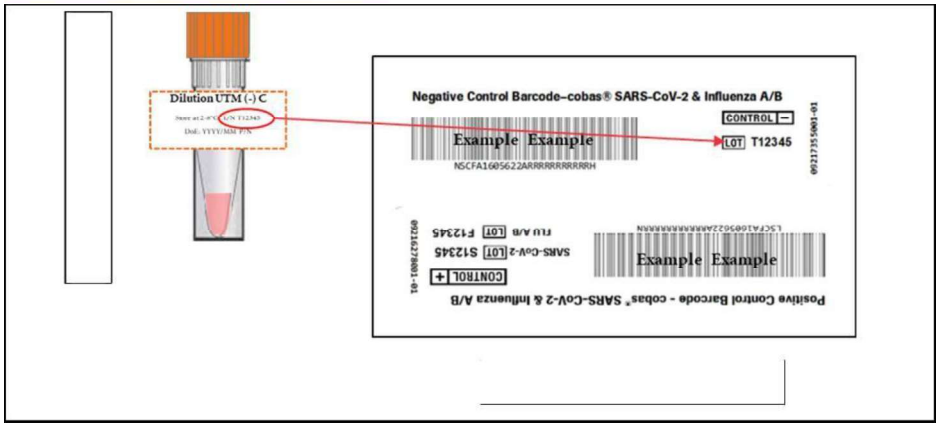
COBAS® LIAT SYSTEM – SARS- CoV-2 & Influenza A/B , Continued

Procedure, Continued

Add a New Assay Tube Lot and Run Controls, continued	
Step	**Action**
4	When prompted to **Scan insert ID,** select **Scan** and scan the appropriate barcode from the Package Insert Barcode card from the assay tube pack. Ensure that the red scan light is over the entire barcode.  ***Note: You may be prompted to confirm you have read Instructions For Use.***
5	When prompted to **Scan negative control ID,** select **Scan** and scan the Negative Control Barcode on the Control Kit Barcode Card. Ensure that the red scan light is over the entire barcode. The Analyzer will then prompt "**Add negative control & scan tube ID**".   Match the lot number (L/N) of the Dilution UTM vial label to the lot number (LOT) of the Negative Control barcode on the Control Kit Barcode card. Use the Negative Control barcode on the Control Kit Barcode card) as the sample ID when performing a negative control run.

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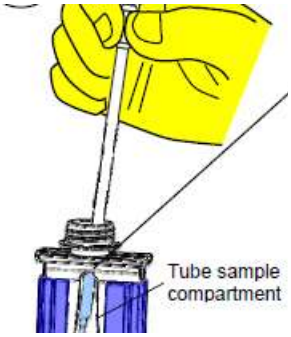
COBAS® LIAT SYSTEM – SARS- CoV-2 & Influenza A/B , Continued

Procedure, Continued

Add a New Assay Tube Lot and Run Controls, continued	
Step	**Action**
6	Take a Dilution UTM tube from the QC Kit; this is used as the negative control sample. Hold the Dilution UTM vial upright and lightly tap on a flat surface to collect liquid at the bottom of the vial. Visually check that the Dilution UTM has pooled at the bottom of the tube. If not, repeat until it shows as such.
7	Open up a cobas® SARS-CoV-2 & Influenza A/B assay tube foil pouch (from the lot to be added) and remove the contents. a. Obtain the transfer pipette from the pouch. b. Firmly squeeze the bulb of the pipette until the bulb is fully flat. While holding the pipette bulb fully flat, insert the pipette tip into the sample below the liquid surface. Slowly release the bulb while keeping the pipette tip below the liquid surface, drawing up the sample. After releasing the bulb completely, withdraw the pipette from the sample.
8	Carefully remove the cap from the cobas® Liat® SARS-CoV-2 & Influenza A/B assay tube. Place the pipette tip near the bottom of the open segment.
9	Slowly squeeze the bulb to empty the contents of the pipette into the cobas® SARS-CoV-2 & Influenza A/B 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 & 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 is damaged, discard both the cobas® SARS-CoV-2 & Influenza A/B assay tube and the transfer pipette, and restart the testing with a new cobas® SARS-CoV-2 & Influenza A/B assay tube and pipette. 

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COBAS® LIAT SYSTEM – SARS- CoV-2 & Influenza A/B , Continued

Procedure, Continued

Add a New Assay Tube Lot and Run Controls, continued	
Step	**Action**
10	While still holding the pipette bulb flat, withdraw the pipette from the tube. Screw the cap back on the tube. Dispose of the transfer pipette as biohazardous material.
11	Choose "Scan" and place the cobas® 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 barcode. The tube entry door on top of the analyzer will automatically open.
12	Remove the cobas® Liat® assay tube sleeve and immediately insert the cobas® SARS-CoV-2 & Influenza A/B assay tube into the tube entry slot until it clicks into place. Note: The cobas® SARS-CoV-2 & Influenza A/B assay tube only fits in one way – the grooved side of the cobas® SARS-CoV-2 & Influenza A/B assay tube must be on the left while the cap is on top. If the tube is not inserted by the time the door closes, re-scan the cobas® SARS-CoV-2 & Influenza A/B assay tube barcode and insert it 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.
13	During the test, the cobas® Liat® Analyzer displays the running status and estimated time remaining. When the test is complete, the cobas® Liat® Analyzer screen displays the message "*Remove the assay tube slowly and carefully*."and opens the tube entry door automatically.
14	Slowly lift the cobas® SARS-CoV-2 & Influenza A/B assay tube out of the cobas® Liat® Analyzer. Dispose of the used cobas® SARS-CoV-2 & Influenza A/B assay tube as biohazardous material.
15	Touch or click **Report** after completion of the assay. **Negative Control Results:** The Report Result must be SARS-CoV-2 & Influenza A and B not detected for the negative control to pass.
16	If *"Negative Control Result Accepted"* is displayed at the end of the run, choose "**Confirm**". If the result is rejected, repeat the negative control run.
17	Select **Back** to proceed with the cobas® SARS-CoV-2 & Influenza A/B Positive Control test on the same instrument.

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COBAS® LIAT SYSTEM – SARS- CoV-2 & Influenza A/B , Continued

Procedure,
Continued

Add a New Assay Tube Lot and Run Controls, continued	
Prepare Positive Control Sample	
Step	**Action**
1	After opening cobas® Influenza A/B Positive Control pouch, discard desiccant packet. Prior to resuspending the Positive Control,
2	After opening cobas® SARS-CoV-2 Positive Control pouch, hold the tube upright and lightly tap on a flat surface to collect liquid at the bottom of the vial. Visually check that the liquid has pooled at the bottom of the tube.
3	Use the provided transfer pipette to transfer approximately 0.2 mL of the liquid from the cobas® SARS-CoV-2 Positive Control to the cobas® Influenza A/B Positive Control tube. a) Check that the cobas® Influenza A/B Positive Control pellet is at the bottom of the vial prior to the addition of the cobas® SARS-CoV-2 Positive Control. Do not use the cobas® Influenza A/B Positive Control if a pellet is not visible prior to rehydration.b) Squeeze the pipette bulb until the bulb is fully flat. While holding the bulb fully flat, insert the pipette tip into the liquid just below the liquid surface in the cobas® SARS-CoV-2 Positive Control vial. c) Slowly release the bulb completely while keeping the pipette tip below the liquid surface. You will see the liquid rising into the pipette. After releasing the bulb completely, withdraw the pipette from the cobas® SARS-CoV-2 Positive Control vial. A small volume of liquid may remain in the vial after the bulb is fully released. d) Insert pipette into the cobas® Influenza A/B Positive Control vial until the tip is at the bottom of the vial. e) Slowly squeeze the bulb to empty the contents of pipette. Avoid creating bubbles in the sample. Do not release the pipette bulb. f) While still squeezing the pipette bulb, withdraw the pipette from the vial. Dispose of the cobas® SARS-CoV-2 Positive Control vial and transfer pipette as hazardous material. Do not reuse transfer pipettes. g) Cap the cobas® Influenza A/B Positive Control vial. Hold it by the cap and shake down the liquid in the vial using a quick, sharp, downward wrist motion.
4	Let the cobas® Influenza A/B Positive Control tube sit for 5 minutes to begin dissolving the dried material.
5	After the Positive Control vial has sat for 5 minutes, proceed to steps for Lot Validation workflow and testing Positive Control.

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COBAS® LIAT SYSTEM – SARS- CoV-2 & Influenza A/B , Continued

Procedure, Continued

Test Positive Control Sample (after 5 minutes)	
Step	**Action**
1	Obtain: • Positive Control Barcode on the Control Kit Barcode Card • 1 assay tube from this lot
2	On the Analyzer, select **Scan** and scan the Positive Control Barcode on the Control Kit Barcode Card. The Analyzer will prompt "*Add Positive Control & scan Liat Tube ID.*"
3	Use the transfer pipette from the assay tube pouch to slowly pipette the Positive Control sample up and down 10 times to dissolve and mix the positive control sample. Avoid generating bubbles. 
4	Using the Positive Control as a sample, run the assay
5	If "*Positive Control Result Accepted. Lot ... added*" is displayed at the end of the run, select "**Confirm**" and then choose "**Back**" to return to the Main menu. If the result is rejected, repeat the cobas® SARS-CoV-2 & Influenza A/B Positive Control test. Choose "**Assay Menu**" to verify that the new lot has been added. After **Add Lot** is completed on Analyzer and the positive and negative control results accepted, the assay tube lot is ready for use with patient samples.

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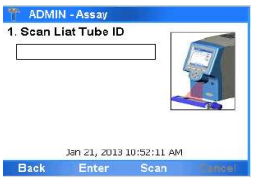
COBAS® LIAT SYSTEM – SARS- CoV-2 & Influenza A/B , Continued

Procedure, Continued

Test Patient Sample	
Step	**Action**
1	**To avoid error and sample cross contamination, change gloves between samples and work on one sample at a time. DO NOT add multiple samples into multiple assay tubes at the same time.** **Scan Barcode** Tear open the foil packaging of the requested assay(s) and remove the assay tube and the transfer pipette. a. Select **Run Assay** on the main menu of the Analyzer using the touch screen or function button.  b. Select **Scan** and scan the assay tube barcode on the assay tube sleeve by placing the assay tube horizontally on the table beneath the barcode reader and sliding the assay tube towards the Analyzer until the red scan light is over the entire barcode.   c. Select **Scan** again and scan the Patient or Sample barcode, or select Enter and type in a Sample or Patient ID. The Analyzer will prompt "Add UTM sample & re-scan tube ID." Note: In the case that the sample cannot be scanned, choose "**Enter**" to manually enter the sample ID.

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COBAS® LIAT SYSTEM – SARS- CoV-2 & Influenza A/B , Continued

2	**Add Sample** ***Do not create aerosols by aspirating sample up and down or vigorously shaking tube.** a. Carefully remove one transfer pipette from the cobas® transfer pipette pack and avoid touching other pipettes in the pack. Re-seal the pack. b. When prompted to add the sample, use the transfer pipette provided in the assay kit to transfer specimen. Firmly squeeze the bulb of the pipette into the liquid and draw the sample by slowly releasing the bulb. c. Carefully remove the cap of the cobas® SARS-CoV-2 & Influenza A/B assay tube, then insert the pipette into the opening. Place the pipette tip near the bottom of the open segment. d. Slowly squeeze the bulb to empty the contents of the pipette into the cobas® SARS-CoV-2 & Influenza A/B assay tube. 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/B assay tube and pipette. e. Re-cap the cobas® SARS-CoV-2 & Influenza A/B assay tube and dispose of the transfer pipette as biohazardous material Note: Avoid contaminating gloves, equipment, and work surfaces with the residual contents of the pipette.
3	**Insert assay tube** a. Select **Scan** and re-scan the same assay tube barcode. The assay tube entry door on top of the Analyzer will open automatically. b. Remove the assay tube sleeve. c. Immediately insert the assay tube into the Analyzer until the assay tube clicks into place. The assay tube only fits in one way – the grooved side of the cobas®SARS-CoV-2 & Influenza A/B assay tube must be on the left while the cap is on top. If the assay tube is not inserted by the time the door closes, re-scan the assay tube barcode and insert the assay tube again. Once the assay tube is properly inserted, the Analyzer will close the door automatically and begin the test.

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COBAS® LIAT SYSTEM – SARS- CoV-2 & Influenza A/B , Continued

Procedure, Continued

Test Patient Sample, continued	
Step	**Action**
4	**View Result** During the test, the Analyzer displays the running status and estimated time remaining. Once the test is complete, the Analyzer displays the message, "Remove the assay tube slowly and carefully" and opens the assay tube entry door automatically. a. Slowly lift the assay tube out of the Analyzer and dispose of the used assay tube as biohazardous material. b. Select **Report** to see the Result Report. c. Select **Print** to print the report (if applicable). d. Select **Back**, and then **Main** to return to the main menu for the next test.

Expected Results

The Analyzer reports results as "Detected" or "Not Detected" for each of Influenza A, Influenza B, and SARS-CoV-2, or "Assay Invalid."

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COBAS® LIAT SYSTEM – SARS- CoV-2 & Influenza A/B , Continued

Result Interpretation

Instrument Result Report		Laboratory Interpretation/Action	Cerner Reporting
SARS-CoV-2	SARS-CoV-2 Not Detected	Negative test for SARS-CoV-2 (no SARS-CoV-2 RNA detected)	**Not Detected**
	SARS-CoV-2 Detected	Positive test for SARS-CoV-2 (SARS-CoV-2 RNA present)	**Detected**
	SARS-CoV-2 Invalid	Presence or absence of SARS-CoV-2 cannot be determined. IPC failed to produce expected results. • Repeat assay once with original sample. • Report "Assay Invalid" if result persists.	**Assay Invalid**

Instrument Result Report		Laboratory Interpretation/Action	Cerner Reporting
Influenza A	Influenza A Not Detected	Negative test for Influenza A (no Influenza A RNA detected)	**Not Detected**
	Influenza A Detected	Positive test for Influenza A (Influenza A RNA present)	**Detected**
	Influenza A Invalid	Presence or absence of Influenza A cannot be determined. IPC failed to produce expected results. • Repeat assay once with original sample. • Report "Assay Invalid" if result persists.	**Assay Invalid**
Influenza B	Influenza B Not Detected	Negative test for Influenza B (no Influenza B RNA detected)	**Not Detected**
	Influenza B Detected	Positive test for Influenza B (Influenza B RNA present)	**Detected**
	Influenza B Invalid	Presence or absence of Influenza B cannot be determined. IPC failed to produce expected results. • Repeat assay once with original sample. • Report "Assay Invalid" if result persists.	**Assay Invalid**

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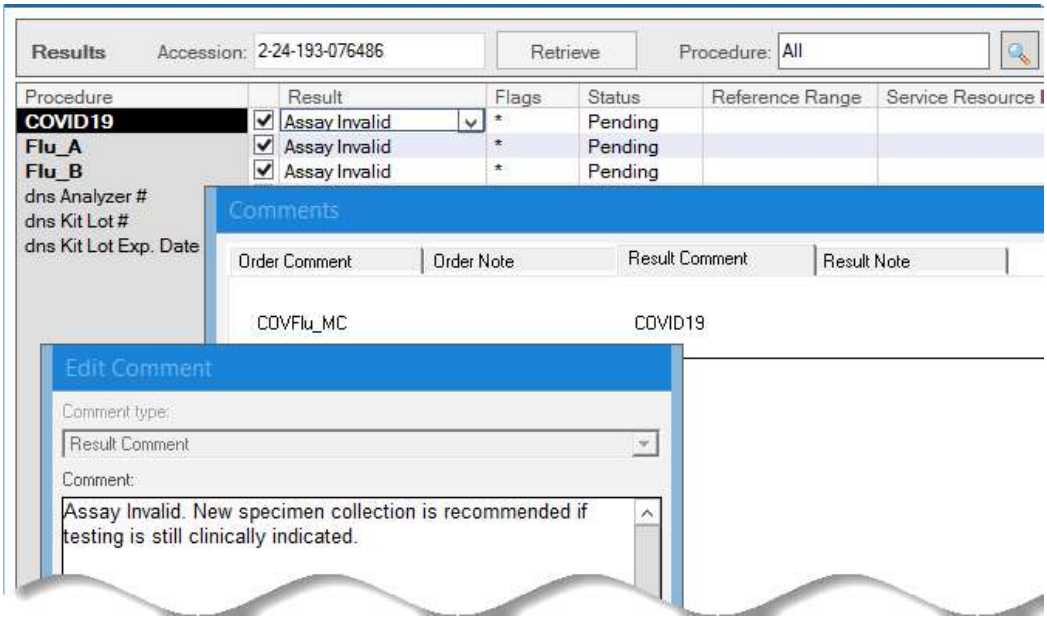
COBAS® LIAT SYSTEM – SARS- CoV-2 & Influenza A/B , Continued

Result Interpretation Continued

For Assay Invalid, add the following comment as follows and shown below: "Assay Invalid. New specimen collection is recommended if testing is still clinically indicated."



Instrument Result Report	Laboratory Interpretation/Action	Cerner Reporting
[Error]. Assay Aborted	Presence or absence of target viruses cannot be determined. Repeat assay once on another instrument. If instrument "Error" persists: 1. Cancel test order as **Instrument error, test not performed** 2. Contact Roche Service Representative to resolve Error issue.	**Instrument Error, Test Not Performed.**

Influenza A and Influenza B negative results should be considered presumptive in samples that have a positive SARS-CoV-2 result.

Competitive inhibition studies showed that SARS-CoV-2 virus, when present at concentrations above 3.6E+04 copies/mL, can inhibit the detection and amplification of influenza A and influenza B virus RNA if present at or below 1.8E+02 copies/mL or 4.9E+02 copies/mL, respectively, and may lead to false negative influenza virus results. If co-infection with influenza A or influenza B virus is suspected in samples with a positive SARS-CoV-2 result, the sample should be re-tested with another FDA cleared, approved, or authorized influenza test, if influenza virus detection would change clinical management.

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COBAS® LIAT SYSTEM – SARS- CoV-2 & Influenza A/B , Continued

Limitations

- The cobas® SARS-CoV-2 & Influenza A/B test has been evaluated only for use in combination with the cobas® SARS-CoV-2 & Influenza A/B Quality Control Kit and this Instructions For Use document. Modifications to these procedures may alter the performance of the test.
  - This test is intended to be used for the detection of SARS-CoV-2, Influenza A and Influenza B RNA in nasal and nasopharyngeal swab samples collected in a Copan UTM-RT System (UTM-RT) or BD™ Universal Viral Transport System (UVT) or Thermo Fisher™ Scientific Remel™ media. Testing of other sample types may lead to inaccurate results.
  - As with other tests, negative results do not preclude SARS-CoV-2, Influenza A or Influenza B, 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.
  - Mutations within the target regions of cobas SARS-CoV-2, influenza A, and influenza B could affect primer and/or probe binding that results in failure to detect the presence of virus.
- False negative or invalid results may occur due to interference. The Internal Control is included in cobas® SARS-CoV-2 & Influenza A/B to help identify the specimens containing substances that may interfere with nucleic acid isolation and PCR amplification.

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COBAS® LIAT SYSTEM – SARS- CoV-2 & Influenza A/B , Continued

Maintenance and Calibration

Cleaning the Cobas Analyzer

- Performed Daily
- 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, use the provided cleaning tool following the instructions included with the Cleaning tool kit.
- 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. Refer to Operator's Manual for specific handling.

Analyzer Self-check

The Cobas® Liat performs self-diagnostics during power-on startup (initialization) and utilizes an advanced error diagnostics system to monitor the Cobas® Liat's performance during an assay. An operator is not required to perform any maintenance, other than touch screen calibration. Under normal operation, the Cobas® Liat alerts the operator in the event that a malfunction or error is detected. Refer to Operator's Manual for troubleshooting.

Analyzer Auto calibration

The Cobas® Liat 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 "AutoCal started. This could take up to a minute." is displayed.
- Select OK to close this message window.
- Wait until (AutoCal) is no longer in Title Bar.
- If Calibration fails, refer to Operator's Manual

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COBAS® LIAT SYSTEM – SARS- CoV-2 & Influenza A/B , Continued

Non-Controlled Documents

The following non-controlled documents support this procedure:

- Cobas® Influenza A/B & SARS-COV-2 Test package insert Nucleic acid test, Doc Rev.5.0, literature number 09216235001-05EN 01/2024
- Cobas® LIAT Operator's Manual Version 8.0- P/N 08416214001
- College of American Pathologists Checklist Molecular-based Microbiology Testing- Waived Tests

Controlled Documents

The following controlled documents support this procedure:

- SCPMG-PPP-0358: Contamination Monitoring Procedure Using Wipe Testing for Cobas LIAT PCR System,
- SCPMG-PPP-0357: Cleaning and Decontamination Procedure for Cobas LIAT PCR system

Form
LIAT Wipe Test Form
LIAT Patient Result Log
COBAS LIAT Preventative Maintenance

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Cobas Liat SARS-CoV-2 & Influenza A_B

Operations Director Approval

Name/Signature	Title	Date	Meaning/Reason
Annaleah Raymond (Q741709)	Laboratory Operations Director	11 Aug 2024, 01:56:46 PM	Approved

Medical Director Approval

Name/Signature	Title	Date	Meaning/Reason
Mark Taira (P161328)	CLIA Director	12 Aug 2024, 01:40:05 PM	Approved