



KAISER PERMANENTE®

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| OWNER: | CHANGE NUMBER: |

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 sample-to-result time is ~20minutes.

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.

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 RNA in healthcare provider-collected nasopharyngeal and nasal swabs from individuals suspected of respiratory viral infection consistent with COVID-19 by their healthcare provider. Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar.

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

cobas® SARS-CoV-2 & Influenza A/B is only for use under the **Food and Drug Administration's Emergency Use Authorization**. It is to be used in the simultaneous rapid *in vitro* detection and differentiation of SARS-CoV-2, influenza A virus, and influenza B virus nucleic acids in clinical specimens and is not intended to detect influenza C virus. SARS-CoV-2, influenza A and influenza B viral RNA is generally detectable in respiratory specimens during the acute phase of infection. The cobas® SARS-CoV-2 & Influenza A/B test is performed by licensed Clinical Laboratory Scientists and MLTs.

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

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Policy This test may be ordered by authorized providers only. 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.

Specimen sources

- 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 testing should be performed 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 at 2-8°C, (and transportation on wet ice) if there will be a delay in testing, the nasopharyngeal swab specimens collected in appropriate viral transport media are stable for up to 72 hours.
- 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 & Influenza 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

cobas® Liat® Analyzer – software version 3.2 or higher

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

Warnings and Precautions

- 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.
 - 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.
 - 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.
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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
 - 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 |
|---|--|
| Negative Control Valid | Negative Control Valid Control is negative for the presence of SARS-CoV-2, Influenza type A virus and Influenza type B virus 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, Influenza type A virus and Influenza type B virus RNA |

3. 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 ,

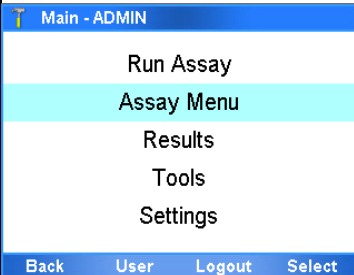
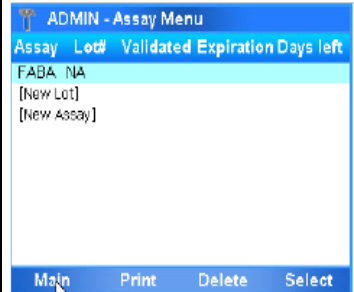
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Before you begin

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.

Procedure

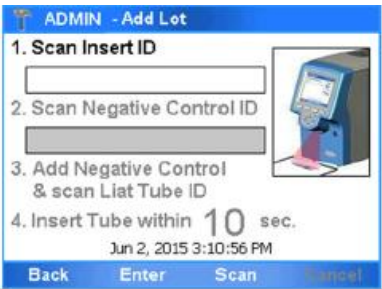
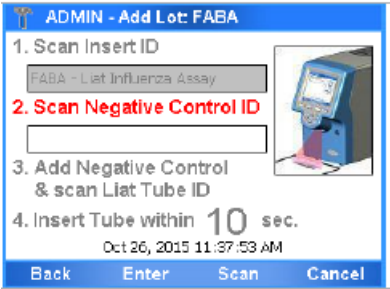
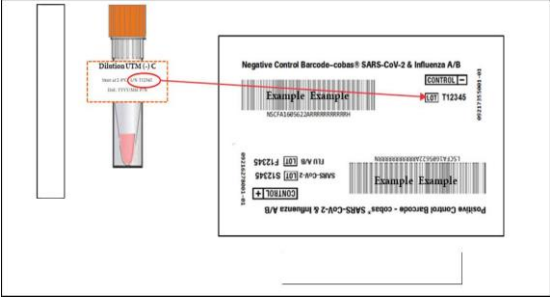
Follow the steps below to

| Add a New Assay Tube Lot and Run Controls | |
|--|---|
| Step | Action |
| 1 | Obtain: <ul style="list-style-type: none"> • 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

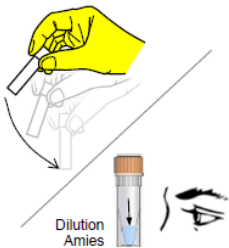
**Procedure,
 Continued**

| Add a New Assay Tube Lot and Run Controls, continued | |
|---|---|
| Step | Action |
| 4 | <p>Select Scan and scan the appropriate barcode from the <u>package Insert Barcode card</u> from the assay tube pack.</p>  |
| 5 | <p>Select Scan and scan the <u>Negative Control Barcode</u> on the Control Kit Barcode Card. The Analyzer will prompt “<i>Add Negative Control & scan Liat Tube ID.</i>”</p>   |

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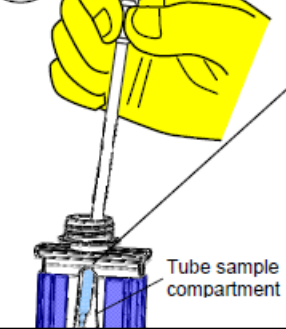

**Procedure,
 Continued**

| Add a New Assay Tube Lot and Run Controls, continued | |
|---|---|
| Step | Action |
| 6 | <p>Take a Dilution UTM tube from the QC Kit; this is used as the negative control sample. Hold the Dilution UTM tube by the tube cap and shake down the liquid in the tube using a quick, sharp, downward wrist motion (as if shaking down a mercury thermometer). Visually check that the Dilution UTM has pooled at the bottom of the tube. If not, repeat the shake down procedure.</p>  |
| 7 | <p>Obtain the transfer pipette from the pouch. Firmly <u>squeeze the bulb of the pipette</u> until the bulb is fully flat. While holding the pipette bulb fully flat, insert the pipette tip into the sample below the liquid surface. <u>Slowly release the bulb while keeping the pipette tip below the liquid surface</u>, drawing up the sample. After releasing the bulb <u>completely</u>, withdraw the pipette from the sample.</p> |
| 8 | <p>Unscrew the cap from the Cobas® Liat® assay tube. While watching through the viewing window in the sleeve, carefully insert the pipette into the tube placing the pipette tip near the bottom of the sample compartment.</p> |

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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 |
| 9 | <p><u>Slowly</u> squeeze the bulb to empty the contents of the pipette into the sample compartment of the tube. Do not release the pipette bulb. Note: <u>Do not puncture the tube or the seal at the bottom of the sample compartment.</u> If either of these is damaged, discard both the tube and the transfer pipette and restart the testing with new assay components.</p>  |
| 10 | <p>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.</p> |
| 11 | <p>Scan the tube sleeve barcode again. The tube entry door on top of the analyzer will automatically open.</p>  |

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

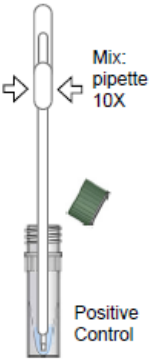
| | |
|----|---|
| 12 | Remove the Cobas® Liat® assay tube sleeve and immediately insert the tube into the tube entry slot until it clicks into place. The tube only fits in one way. If the tube is not inserted by the time the door closes, re-scan the Cobas® Liat® assay tube barcode and insert the Cobas® |
|----|---|

| Add a New Assay Tube Lot and Run Controls, continued | |
|---|--|
| Step | Action |
| 13 | When the test is complete, the Cobas® Liat® Analyzer screen displays the message “Please remove the tube slowly.” |
| 14 | Lift the tube out of the Cobas® Liat® Analyzer and discard following all applicable biohazard safety precautions |
| 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 “ <i>Negative Control Result Accepted</i> ” is displayed at the end of the run, select OK . If the result is rejected, repeat the negative control run. |
| 17 | Select Back . |
| Prepare Positive Control Sample | |
| Step | Action |
| 1 | After opening cobas® Influenza A/B Positive Control pouch, discard desiccant packet. |
| 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. |
| 4 | Let the cobas® Influenza A/B Positive Control tube sit for 5 minutes to begin dissolving the dried material |

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

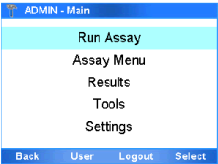
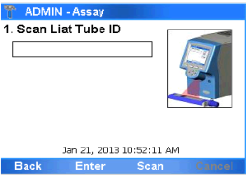

Procedure, Continued

| Test Positive Control Sample (after 5 minutes) | |
|---|---|
| Step | Action |
| 1 | Obtain: <ul style="list-style-type: none"> • Positive Control Barcode on the Control Kit Barcode Card • 1 assay tube from this lot |
| 2 | On the Analyzer, select Scan and scan the <u>Positive Control Barcode</u> on the Control Kit Barcode Card. The Analyzer will prompt “ <i>Add Positive Control & scan Liat Tube ID.</i> ” |
| 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 “ <i>Positive Control Result Accepted. Lot ... added</i> ” is displayed at the end of the run, select OK to return to the assay menu. If the result is rejected, repeat the positive control run <p>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.</p> |

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

Procedure,
 Continued

| Test Patient Sample | |
|----------------------------|--|
| Step | Action |
| 1 | <p>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.</p> <p>Scan Barcode</p> <p>Tear open the foil packaging of the requested assay(s) and remove the assay tube and the transfer pipette.</p> <p>a. Select Run Assay on the main menu of the Analyzer using the touch screen or function button.</p>  <p>b. Select Scan and scan the assay tube barcode on the assay tube sleeve by placing the assay tube on the table and sliding the assay tube towards the Analyzer until the red scan light is over the entire barcode.</p>   <p>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.”</p> |

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

| | |
|---|---|
| 2 | <p>Add Sample</p> <p>*Do not create aerosols by aspirating sample up and down or vigorously shaking tube.</p> <p>Use the transfer pipette to load ~200 µL of the sample into assay tube. You do not need to measure the sample volume; the Analyzer will adjust the sample volume if more sample was loaded or output an error if not enough sample was loaded.</p> |
|---|---|

**Procedure,
 Continued**

| Test Patient Sample, continued | |
|---------------------------------------|--|
| Step | Action |
| 3 | <p>Insert assay tube</p> <ol style="list-style-type: none"> a. Select Scan and re-scan 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. 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

| | |
|---|--|
| 4 | <p>View Result</p> <p>During the test, the Analyzer displays the running status and estimated time remaining. Once the test is complete, the Analyzer displays the message, “Please remove the tube slowly...” and opens the assay tube entry door automatically.</p> <ol style="list-style-type: none">a. Lift the assay tube out of the Analyzer and dispose of the used assay tube according to your institution’s safety guidelines for hazardous 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 |
|--------------------------|--------------------------|--|----------------------|
| 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 |
| | Assay Invalid | Presence or absence of Influenza A cannot be determined. IPC failed to produce expected results. <ul style="list-style-type: none"> • 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 |
| | Assay Invalid | Presence or absence of Influenza B cannot be determined. IPC failed to produce expected results. <ul style="list-style-type: none"> • 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

| 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 |
| | Assay Invalid | Presence or absence of SARS-CoV-2 cannot be determined. IPC failed to produce expected results. <ul style="list-style-type: none"> Repeat assay once with original sample. Report “Assay Invalid” if result persists. | Assay Invalid |

| 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: <ol style="list-style-type: none"> Cancel test order as Instrument error, test not performed 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 ,

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Limitations

- **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.
 - 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.1.0, literature number 09216243001-02 09/2020
 - 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 |

Author(s) Mickey Amos
 Phillip Lansang

Signature Manifest

Document Number: OC-PPP-0596

Revision: 02

Title: Cobas Liat SARS-CoV-2 & Influenza A/B

Effective Date: 29 Jan 2021

All dates and times are in Pacific Standard Time.

Cobas Liat SARS-CoV-2 & Influenza A/B

Operations Director Approval

| Name/Signature | Title | Date | Meaning/Reason |
|-----------------------------|------------------------|--------------------------|----------------|
| Mary Lou Beaumont (A335097) | Director of Operations | 13 Jan 2021, 04:32:15 PM | Approved |

Medical Director Approval

| Name/Signature | Title | Date | Meaning/Reason |
|------------------------|-------------|--------------------------|----------------|
| Albert Huang (C137273) | Pathologist | 16 Jan 2021, 11:10:58 PM | Approved |