Quick Reference Instructions

cobas® liat SARS-CoV-2, Influenza A/B & RSV nucleic acid test

cobas® liat SARS-CoV-2, Influenza A/B & RSV assay kit components

- ☐ 20 assay tubes
- ☐ 2 **cobas® liat** transfer pipette packs (12 pipettes/pack)
- ☐ 1 package insert barcode card

cobas® liat SARS-CoV-2, Influenza A/B & RSV control kit components

- ☐ 3 sets of controls
- ☐ 1 negative/positive control barcode card

Specimen Collection Kit

Note: *Materials required but not provided. Refer to the Instructions for Use for a list of acceptable swabs and transport media.*

- ☐ 1 specimen collection tube with viral transport media or 0.9% physiological saline solution
- ☐ 1 nasal or nasopharyngeal swab

For use under Emergency Use Authorization (EUA) only

IVD only

Rx only

This product has not been FDA cleared or approved but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high, moderate or waived complexity tests. This product is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

This product has been authorized only for the detection and differentiation of nucleic acid from SARS-CoV-2, influenza A, influenza B, and RSV, not for any other viruses or pathogens.

The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

Transporting and storing specimen

For specimen transport and shipping, follow the standards and regulations as detailed in the Instructions for Use.

Run specimen transferred into a **cobas® liat** SARS-CoV-2, Influenza A/B & RSV assay tube as soon as possible but no later than 4 hours, with storage at room temperature (15-30 °C).

If needed, store specimens at 15-30 °C for up to 4 hours after collection, or at 2-8 °C for up to 72 hours.

Note: *Do not freeze specimens collected in saline solution.*

Collecting specimen and performing cobas® liat SARS-CoV-2, Influenza A/B & RSV test

Read the Instructions for Use and the User Guide for complete test procedure and information before proceeding with test.

This test is only for nasopharyngeal and nasal swab specimens.

Obtain the following materials:

For collecting specimen

- ☐ 1 collection media tube with a swab

Note: *Refer to applicable collection media instructions for preparation.*

For performing cobas® liat SARS-CoV-2, Influenza A/B & RSV test

- ☐ 1 **cobas® liat** SARS-CoV-2, Influenza A/B & RSV assay tube
- ☐ 1 specimen in collection media
- ☐ 1 transfer pipette

Note: *Do not use a damaged, dropped, or previously used assay tube.*

1 Collecting specimen

Collect specimen using a sterile swab according to applicable manufacturer instructions and/or standard collection technique.

2 Running a cobas® liat test

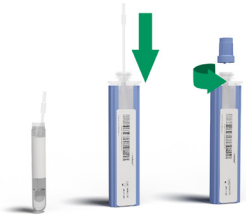
From the **Main** menu, choose **Run Assay** and choose the **Select** button. Then **Scan** the assay tube barcode.

3 Scan the sample ID barcode, or choose Enter to enter the ID manually.

Note: *Depending on analyzer configuration, if required to confirm the received patient information, choose the* **Confirm** *button.*

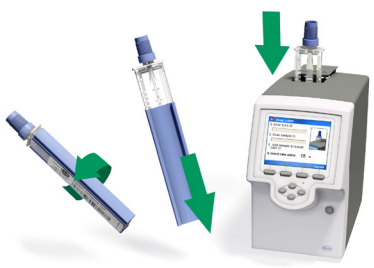
4 Firmly squeeze the bulb of the transfer pipette, lower it into the sample liquid, and release the bulb to draw up the sample. Slowly transfer the sample into the assay tube by squeezing the bulb, and then recap the assay tube.

Note: *Do not puncture the assay tube or the seal at the bottom of the sample compartment. If either of these is damaged, discard the assay tube and the transfer pipette. Restart the testing procedure with new assay components.*



5 Choose Scan and rescan the assay tube barcode.

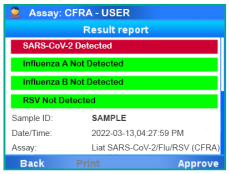
6 Turn the assay tube. Remove the assay tube sleeve and then insert the assay tube into the analyzer tube entry door. Processing begins automatically.



7 When the assay run is complete, remove and discard the assay tube.

8 Choose the Report button to view the result report.

To return to the **Main** menu, choose **Back** and then choose the **Main** button.



Note: *For result interpretation, refer to Table 1.*

Lot validation procedure

For each new lot of assay tubes, controls must be run. Use the lot validation procedure to validate assay tube lots on the **cobas® liat** analyzer.

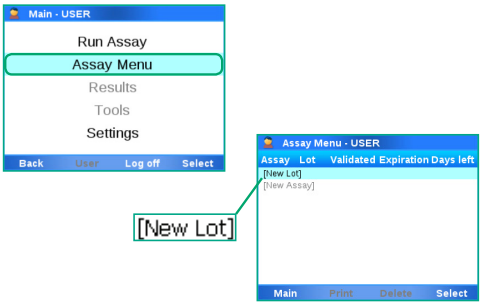
Obtain the following materials:

- ☐ 2 **cobas® liat** SARS-CoV-2, Influenza A/B & RSV assay tubes
- ☐ 1 set of controls
- ☐ 1 package insert barcode card
- ☐ Negative/positive control barcode on negative/positive control barcode card
- ☐ 2 transfer pipettes

Note: *Additional control runs should be performed in accordance with local, state, federal and/ or accrediting organization requirements.*

1 Initiating a lot validation procedure

From the **Main** menu, choose **Assay Menu**. From the **Assay Menu**, choose **[New Lot]**.

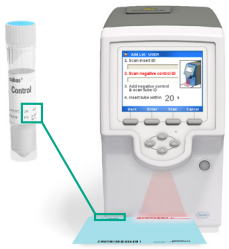


2 Choose **Scan** and scan the package insert barcode from the package insert barcode card.

Note: *You may be prompted to confirm that you have read the Package Insert, i.e. Instructions for Use.*

3 Negative control run

Check that the lot number on the negative/ positive control barcode card matches the control tube lot number.
Choose **Scan** and scan the negative control barcode from the negative/positive control barcode card.



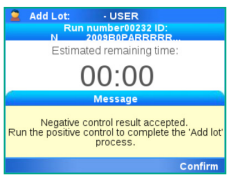
4 Firmly squeeze the bulb of the transfer pipette, lower it into the liquid, and release the bulb to draw up the control. Slowly transfer the control into the assay tube by squeezing the bulb, and then recap the assay tube.

Note: *Do not puncture the assay tube or the seal at the bottom of the sample compartment. If either of these is damaged, discard the assay tube and the transfer pipette. Restart the testing procedure with new assay components.*

5 Choose **Scan** and scan the assay tube barcode.

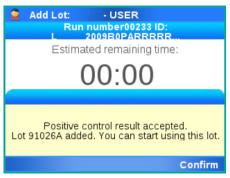
6 Turn the assay tube. Remove the assay tube sleeve and then insert the assay tube into the analyzer tube entry door. Processing begins automatically.

7 Once the negative control result is accepted, choose **Confirm**. Then remove and discard the assay tube.



8 Choose **Back** and repeat steps 3–6 for the positive control using the positive control barcode from the negative/positive control barcode card.

When the positive control result is accepted you can begin using the lot. Choose **Confirm** and navigate **Back** to the **Main** menu.
Note: *If the result is rejected, repeat the control run. If repeated control run is still rejected, contact your local Roche representative.*



Note: *For result interpretation, refer to Table 2.*

Result interpretation

Table 1. Interpretation of **cobas® liat** SARS-CoV-2, Influenza A/B & RSV results when running a sample.

cobas® liat analyzer display	**Result interpretation**
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).
SARS-CoV-2 Invalid	Presence or absence of SARS-CoV-2 could not be determined. If clinically indicated, repeat assay with same sample or, if possible, collect new sample for testing.
Influenza A Not Detected	Negative test for influenza A (no influenza A RNA detected).
Influenza A Detected	Positive test for influenza A (influenza A RNA present).
Influenza A Invalid	Presence or absence of influenza A could not be determined. If clinically indicated, repeat assay with same sample or, if possible, collect new sample for testing.
Influenza B Not Detected	Negative test for influenza B (no influenza B RNA detected).
Influenza B Detected	Positive test for influenza B (influenza B RNA present).
Influenza B Invalid	Presence or absence of influenza B could not be determined. If clinically indicated, repeat assay with same sample or, if possible, collect new sample for testing.
RSV Not Detected	Negative test for RSV (no RSV RNA detected).
RSV Detected	Positive test for RSV (RSV RNA present).
RSV Invalid	Presence or absence of RSV could not be determined. If clinically indicated, repeat assay with same sample or, if possible, collect new sample for testing.
Assay Invalid	Presence or absence of SARS-CoV-2, influenza A, influenza B, and RSV could not be determined. Repeat assay with same sample or, if possible, collect new sample for testing.
Assay Aborted by System	Run failed or aborted by system. Repeat assay with same sample or, if possible, collect new sample for testing.
Assay aborted by script: Script aborted	Run failed or aborted by script. Repeat assay with same sample or, if possible, collect new sample for testing.
Assay Aborted by User	Run aborted by user.

Table 2. Interpretation of **cobas® liat** SARS-CoV-2, Influenza A/B & RSV results when running lot validation procedure or additional control runs.

cobas® liat analyzer display	**Result interpretation**
Negative Control Valid	Control is negative for the presence of SARS-CoV-2, influenza A, influenza B, and RSV RNA.
Negative Control Invalid. Repeat Run	Result is invalid. The Negative Control should be re-tested to obtain valid result. Repeat run.*
Positive Control Valid	Control is positive for the presence of SARS-CoV-2, influenza A, influenza B, and RSV RNA.
Positive Control Invalid. Repeat Run	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.*

Roche support

If you have any questions or problems, contact your local Roche representative:
https://www.roche.com/about/business/roche_worldwide.htm

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Warnings and precautions

Handle samples, used assay tubes, and transfer pipettes according to laboratory best practices.

Clean instruments and surrounding surfaces according to instructions provided in the cleaning section of the **cobas® liat** system User Guide.

Follow your institution's safety procedures for working with chemicals and handling biological samples.

Document revision information		
Doc. Rev. 1.0	06/2024	Initial release.