Quick Reference Instructions

cobas® SARS-CoV-2 & Influenza A/B

Nucleic acid test for use on the **cobas®** Liat® System

Read the **cobas®** SARS-CoV-2 & Influenza A/B Instructions For Use and the **cobas®** Liat® System User Guide for complete test procedure, result interpretation and further assay information before proceeding with test.

Quality Control: Performing Lot Validation

External Controls must be run for each new lot of **cobas®** Liat® assay tubes.

Follow the Lot Validation procedure to validate assay tube lots on the **cobas®** Liat® Analyzer (see Instructions For Use for full procedure).

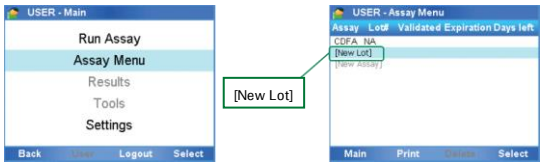
Obtain the following materials:

From **cobas®** SARS-CoV-2 & Influenza A/B assay tube Kit:	From **cobas®** SARS-CoV-2 & Influenza A/B Quality Control Kit:
□ 2 **cobas®** SARS-CoV-2 & Influenza A/B assay tubes	□ 1 Dilution UTM tube
□ 2 transfer pipettes	□ 1 **cobas®** SARS-CoV-2 Positive Control tube
□ Package Insert Barcode card	□ 1 **cobas®** Influenza A/B Positive Control tube
	□ Negative/Positive Control Barcode card

Add Lot Negative Control

Step 1:

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



Step 2:

Select **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.*

Step 3:

Check that the lot number on the Control Kit Barcode Card matches the control tube lot number.

Select **Scan** and scan the Negative Control barcode from the Control Kit Barcode Card.

Step 4:

Firmly squeeze the bulb of the transfer pipette and draw up the control. Slowly transfer the control into the assay tube and then recap the assay tube.

Note: Do not puncture the assay tube or the seal at the bottom of the sample compartment.

Step 5:

Select **Scan**, and scan the assay tube barcode.

Step 6:

Turn and remove the assay tube sleeve and insert the assay tube into the analyzer tube entry door. Processing begins automatically.

Step 7:

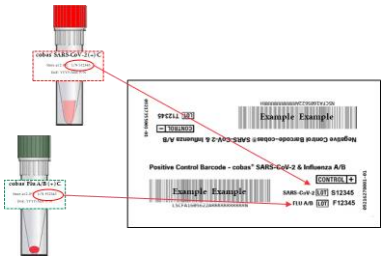
Once the Negative control result is accepted, choose **Confirm**. Then, remove and discard the assay tube. Select **Back** to continue with positive control run.

Add Lot Positive Control

Step 8:

Prepare the Positive control following the instructions provided in the Package Insert.

Prior to re-suspending the Positive control, check that the lot numbers on the Control Kit Barcode Card match the respective control tube lot numbers.



Step 9:

Resume with **Add Lot Positive Control** on the same instrument. Repeat steps 3–7.

Note: In Step 3, **Scan** the Positive Control barcode from the Control Kit Barcode Card.

When the positive control result is accepted, you can begin using the lot. Navigate **Back** to the **Main** menu.

Specimen Collection into Transport Media

Collect specimen using a sterile flocked swab with a synthetic tip (e.g., Dacron, nylon, or rayon) according to applicable manufacturer instructions and/or standard collection technique using 3 mL of viral transport media or 0.9% physiological saline solution. Part numbers for collection kits can be found in **cobas**® SARS-CoV-2 & Influenza A/B test IFU. This test is only for nasopharyngeal and nasal swab specimens.

cobas® SARS-CoV-2 & Influenza A/B test procedure for clinical specimens

Obtain the following materials:

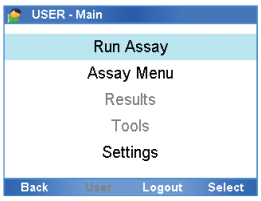
□ 1 **cobas**® SARS-CoV-2 & Influenza A/B assay tube

□ 1 transfer pipette

□ 1 specimen in collection media

Step 1:

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



Step 2:

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.*

Step 3:

Firmly squeeze the bulb of the transfer pipette, lower it into the 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

Step 4:

Scan the assay tube barcode.

Step 5:

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

Step 6:

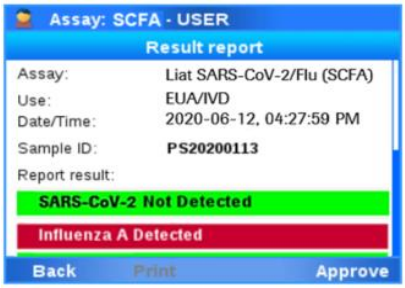
When the assay run is complete, remove and discard the assay tube.

Step 7:

Choose the **Report** button to view the result report.

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

Note: For result interpretation please refer to Interpretation of results section of the Instructions For Use.



Warnings and Precautions

Treat all biological specimens with universal precautions, including used **cobas**® Liat® tubes and pipettes.

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

REF 09211101190 Software version 3.3 or higher

Technical support

For technical support (assistance) please reach out to your local affiliate:
https://www.roche.com/about/business/roche_worldwide.htm

Trademarks and Patents:

See https://diagnostics.roche.com/us/en/about-us/patents

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Document Revision

Document Revision Information	
Doc Rev. 3.0 03/2025	Updated to be compliant with IVDR requirements. Updated **Trademarks and patents** section, including the link. Please contact your local Roche Representative if you have any questions.