Quick Reference Instructions

cobas® SARS-CoV-2

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

IVD
Rx Only

CLIA Complexity: WAIVED

A Certificate of Waiver is required to perform this test in a CLIA Waived setting. To obtain CLIA waiver information and a Certificate of Waiver, please contact your state health department. Additional CLIA waiver information is available at the Centers for Medicare and Medicaid website at www.cms.hhs.gov/CLIA. Failure to follow the instructions or modification to the test system instructions will result in the test no longer meeting the requirements for waived classification.

Read the **cobas**® SARS-CoV-2 instructions for use from the Package Insert and the **cobas**® Liat® System User Guide for Intended Use, complete test procedure, result interpretation and further assay information before proceeding with the test.

Specimen collection and transportation

Collect specimen using a sterile flocked swab with a synthetic tip according to applicable manufacturer instructions and/or standard collection technique using 3 mL of transport media. Part numbers for collection kits can be found in the **cobas**® SARS-CoV-2 Package Insert. This test is only for nasopharyngeal and anterior nasal swab specimens.

For specimen transportation and shipping, follow the standards and regulations as detailed in the Package Insert.

Specimens collected in 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. For details, refer to the Package Insert.

Specimen transferred into the **cobas**® SARS-CoV-2 assay tube should be run as soon as possible or it may be stored at room temperature for up to 4 hours.

cobas® SARS-CoV-2 test procedure for clinical specimens

Obtain the following materials:

□ 1 **cobas**® SARS-CoV-2 assay tube

□ 1 transfer pipette 

□ 1 specimen in collection media (not provided in the kit)

Note: Do not use a damaged, dropped, or previously used Liat Tube.

Step 1:

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

Step 2:

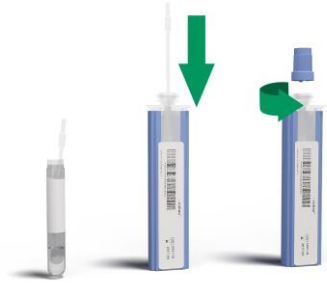
Scan the sample ID barcode or choose **Enter** to enter the ID manually.

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 in the specimen collection media tube 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 both the cobas® Liat Tube and the transfer pipette, and restart the testing procedure with new assay components.



Step 4:

Choose **Scan** and rescan 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, choose **Back** and then choose the **Main** button.

Table 1. Interpretation of results of cobas® SARS-CoV-2 when running a sample

Result Report		Interpretation
SARS-CoV-2	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)
Assay Invalid		Presence or absence of SARS-CoV-2 cannot 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.

Quality Control: Performing Lot Validation

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

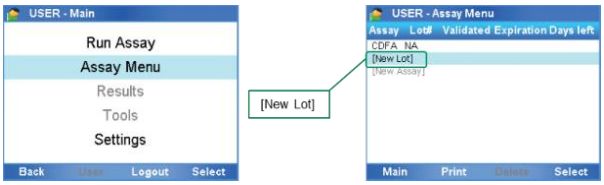
Follow the Lot Validation procedure to validate assay tube lots on the **cobas**® Liat® Analyzer (see Package Insert for full procedure).

Obtain the following materials:

From **cobas**® SARS-CoV-2 assay tube Kit:	From **cobas**® SARS-CoV-2 Quality Control Kit:
□ 2 **cobas**® SARS-CoV-2 assay tubes	□ 1 Dilution UTM tube
□ 2 transfer pipettes*	□ 1 **cobas**® SARS-CoV-2 Positive Control tube
□ Package Insert Barcode card	□ 1 transfer pipette*
	□ Negative/Positive control barcode on Control Kit Barcode card

Note: * The transfer pipettes are the same in both kits

Add Lot Negative and Positive Control



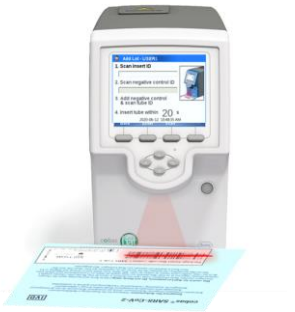
Step 1:

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

Step 2:

Choose **Scan**, and scan the Package Insert barcode from the Package Insert Barcode card.

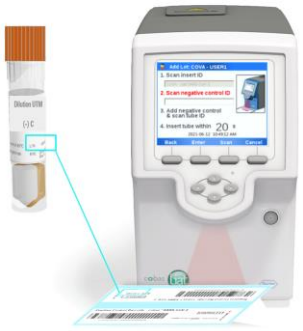
Note: ***You may be prompted to confirm that you have read the Package Insert, i.e., Instructions For Use.***



Step 3:

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

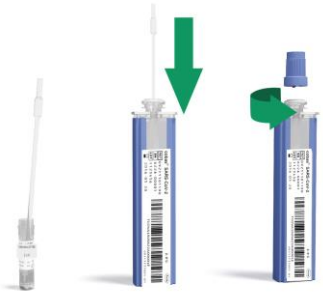
Choose **Scan** and scan the Negative control barcode from the Control Kit Barcode card.



Step 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.



Step 5:

Choose **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.

Step 8:

Choose **Back** and repeat Steps 3-7 for the Positive control and the Positive control barcode.

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 does not produce the expected result, contact your local Roche representative.

Table 2. Interpretation of results of cobas® SARS-CoV-2 when running "Lot Validation" procedure

cobas® Liat® Analyzer Display	Interpretation
Negative Control Valid	**Negative Control Valid** Control is negative for the presence of SARS-CoV-2 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 RNA.
Positive Control Invalid. Repeat Run	**Positive Control Invalid** 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.

Warnings and Precautions

Handle samples, including used **cobas**® Liat® tubes and pipettes according to standard laboratory 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 Information

Software version 3.3 or higher

P/N: 09408827001

Technical support

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

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Document revision

Document Revision Information	
Doc Rev. 2.0 02/2024	Updated **Trademarks and patents** section, including the link. Updated to current economic operators. Updated for 510(k) clearance and CLIAW application. Please contact your local Roche Representative if you have any questions.