Quality Control Lot Validation Guide

cobas® *SARS-CoV-2 Nucleic acid test for use on the* **cobas**® **Liat**® *System*
For use under the Emergency Use Authorization (EUA) only

Lot Validation procedure

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

Refer to the **cobas Liat** *System User Guide (VV-07723)* for detailed operating instructions.
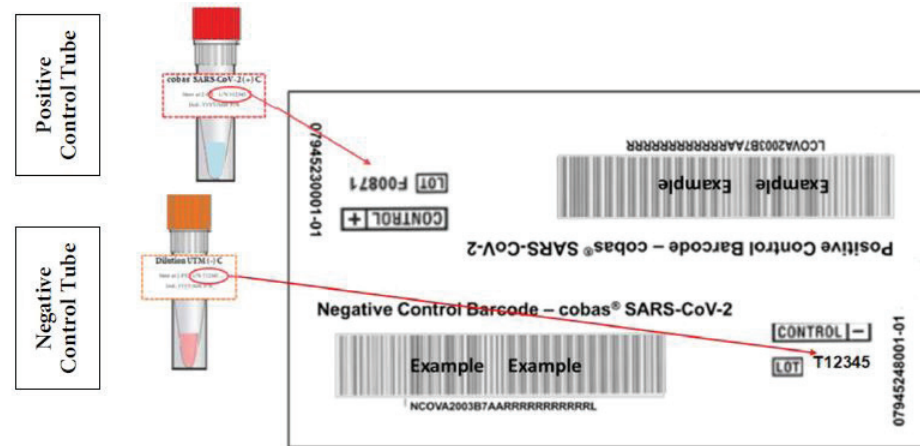
Materials needed Lot Validation

From the cobas SARS-CoV-2 assay tube Kit to validate Negative Control:

• 1 Dilution UTM-RT® tube
• 1 **cobas**® SARS-CoV-2 assay tubes from this lot
• 1 transfer pipette
• Package Insert Barcode Card
• Negative Control Barcode on the Control Kit Barcode Card

From the cobas SARS-CoV-2 Quality Control Kit to validate Positive Control:

• 1 **cobas**® SARS-CoV-2 Positive Control tube
• 1 **cobas**® SARS-CoV-2 assay tubes from this lot
• 1 transfer pipette
• Positive Control barcode on the Control Kit Barcode Card

Control Kit Barcode Card

• Match the lot number (L/N) of the Dilution UTM tube label to the lot number of the Negative Control Barcode Label on the Control Kit Barcode Card and then use the Negative Control Barcode (on the Control Kit Barcode Card) as the sample ID when performing negative control run.

• Match the lot number (L/N) of the Positive Control tube label for cobas® SARS-CoV-2 to the lot number of the Positive Control Barcode Label on the Control Kit Barcode Card as shown in Figure 2. Use the Positive Control Barcode (on the Control Kit Barcode Card) as the sample ID when performing positive control run.

Assay tube Lot Validation workflow

1. **Press the power on/off button to start the cobas Liat** analyzer.

2. Select **Login** on the screen of the **cobas Liat** analyzer.

3. Enter user name when prompted, select **OK**.

4. Enter user password when prompted, select **OK**.

   Note: You may be prompted to confirm you have read the **cobas Liat** *System User Guide*.

5. Select **Assay Menu** on the main menu of the **cobas Liat** analyzer.

6. Select **New Lot** at the bottom of the list.

7. When prompted to Scan Insert ID, select **Scan** and scan the **cobas** *SARS-CoV-2 Package Insert ID Barcode card*. Ensure the red scan light is over the entire barcode.

   Note: You may be prompted to confirm you have read the *Instructions For Use*.

8. When prompted to Scan Negative Control ID, select **Scan** and scan the Negative Control Barcode card included with the control kit. Ensure the red scan light is over the entire barcode. Next, the **cobas Liat** analyzer prompts with the message **Add negative control & scan tube ID**.

9. Hold a tube of Negative Control upright and lightly tap on a flat surface to collect liquid at the bottom of the tube. Visually check that the Dilution UTM has pooled at the bottom of the tube.

10. Open a **cobas** SARS-CoV-2 assay tube foil pouch (from the lot to be added) and remove the contents.

11. Use the transfer pipette provided in the pouch to add the Negative Control to the **cobas** SARS-CoV-2 assay tube. Firmly squeeze the bulb of the pipette until the bulb is fully flat, then insert the tip of the pipette into the liquid and draw up the sample by slowly releasing the bulb.

    Note: Only use the transfer pipette provided in the **cobas** SARS-CoV-2 assay tube pouch to transfer controls and samples into the **cobas** SARS-CoV-2 assay tube.

12. Carefully remove the cap of the **cobas** SARS-CoV-2 assay tube and insert the pipette into the opening. Place the pipette tip near the bottom of the open segment.

13. Slowly squeeze the bulb to empty the contents of the pipette into the **cobas** SARS-CoV-2 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 assay tube.

    Note: Do not puncture the **cobas** SARS-CoV-2 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 assay tube and the transfer pipette, and restart the testing procedure with a new **cobas** SARS-CoV-2 assay tube and pipette.

14. Screw the cap back onto the **cobas** SARS-CoV-2 assay tube. Dispose of the transfer pipette as biohazardous material.

15. Select **Scan** and place the **cobas** SARS-CoV-2 assay tube horizontally on the table beneath the barcode reader so that the red scan light is over the entire barcode. The assay tube entry door on top of the **cobas Liat** Analyzer opens automatically once the barcode is read.

16. Remove the **cobas** SARS-CoV-2 assay tube sleeve and immediately insert the **cobas** SARS-CoV-2 assay tube into the **cobas Liat** analyzer until the tube clicks into place.

    Note: The **cobas** SARS-CoV-2 assay tube only fits in one way - the grooved side of the **cobas** SARS-CoV-2 assay tube must be on the left while the cap is on top.

17. If the tube is not inserted by the time the door closes, rescan the **cobas** SARS-CoV-2 assay tube barcode and insert the **cobas** SARS-CoV-2 assay tube again. Once the **cobas** SARS-CoV-2 assay tube is properly inserted, the **cobas Liat** analyzer closes the door automatically and begins the test.

18. During the test, the **cobas Liat** analyzer displays the running status and estimated time remaining. Once the test is complete, the **cobas Liat** displays the message, **Remove the assay tube slowly and carefully** and automatically opens the assay tube entry door. Slowly lift the **cobas** SARS-CoV-2 assay tube out of the **cobas Liat** analyzer. Dispose of the used **cobas** SARS-CoV-2 assay tube as biohazardous material.

19. If **Negative control result accepted** displays at the end of a run, select **Confirm** (If software version 3.2, select **OK**). If the result is rejected, repeat the negative control run (**Step 8-19**). If repeated control runs do not produce the expected results, contact your local Roche representative.

20. Select **Back** to proceed with the **cobas Liat** SARS-CoV-2 Positive Control test on the same instrument.

21. Similarly, follow **Steps 8-18** with a **cobas** SARS-CoV-2 Positive Control in place of the cobas Liat Negative Control.

22. If **Positive Control Result Accepted. Lot ... added** displays at the end of the run, select **OK** and then select **Back** to return to Main menu. If the result is rejected, repeat the **cobas Liat** SARS-CoV-2 Positive Control test. If repeated control runs do not produce the expected results, contact your local Roche representative.

23. Select **Assay Menu** to verify the new lot has been added.

After **Lot Validation** workflow is completed on one analyzer, use the tools function in the **cobas Liat** Menu to transfer the lot information to the other analyzers at your site. This allows the other analyzers to use this **cobas** SARS-CoV-2 assay tube lot without performing **Lot Validation** on each analyzer.

Consult the Advanced Tools guide for details of operation.

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