

Quality Control Lot Validation Guide

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



Add Lot procedure

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

Materials needed for Add Lot

- New lot of **cobas** Cdiff Nucleic acid test for use on the **cobas Liat** System (two assay tubes and pipettes)
- Package Insert ID Barcode card for the new lot of **cobas** Cdiff assay tubes.
- **cobas Liat** Cdiff Positive Control (**red** cap)
- **cobas Liat** Negative Control (**blue** cap)
- Barcode card for the **cobas Liat** Cdiff Positive Control and the **cobas Liat** Negative Control

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

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. If you do not use a barcode to login, enter user name when prompted, then select **Enter**.
4. Enter user password when prompted, select **Enter**.

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 Cdiff 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 *Package Insert or 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 **cobas Liat** Negative Control upright and lightly tap on a flat surface to collect liquid at the bottom of the tube.
10. Open a **cobas** Cdiff 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 **cobas Liat** Negative Control to the **cobas** Cdiff 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** Cdiff assay tube pouch to transfer controls and samples into the **cobas** Cdiff assay tube.
12. Carefully remove the cap of the **cobas** Cdiff 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** Cdiff assay tube. Avoid creating bubbles in the sample. Do not release the pipette bulb while the pipette is still in the **cobas** Cdiff assay tube.

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

14. Screw the cap back onto the **cobas** Cdiff assay tube. Dispose of the transfer pipette.
15. Select **Scan** and place the **cobas** Cdiff 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** Cdiff assay tube sleeve and immediately insert the **cobas** Cdiff assay tube into the **cobas Liat** analyzer until the assay tube clicks into place.
- Note:** The **cobas** Cdiff assay tube only fits in one way - the grooved side of the **cobas** Cdiff assay tube must be on the left while the cap is on top.
17. If the assay tube is not inserted by the time the door closes, rescan the **cobas** Cdiff assay tube barcode and insert the **cobas** Cdiff assay tube again. Once the **cobas** Cdiff 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, if **Negative control result accepted** displays, select **Confirm**.
- If the result is rejected, repeat the Negative Control run (**Steps 8-18**).
 - If the repeated control run does not produce the expected results, contact your local Roche representative.
19. When the test is complete, the **cobas Liat** analyzer displays the message **Remove the assay tube slowly and carefully** and automatically opens the assay tube entry door. Slowly lift the **cobas** Cdiff assay tube out of the **cobas Liat** analyzer. Dispose of the used **cobas** Cdiff assay tube in a biohazardous waste container.
20. Select **Back** to proceed with the **cobas Liat** Cdiff Positive Control test on the same instrument.
21. Similarly, follow **Steps 8-17** with a **cobas Liat** Cdiff 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 **Confirm**, then select **Back** to return to the main menu.
- If the result is rejected, repeat the **cobas Liat** Cdiff Positive Control test.
 - If repeated control runs do not produce the expected results, contact your local Roche representative.
23. Repeat **Step 19**.
24. Select **Assay Menu** to verify the new lot has been added.

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

Consult the Advanced Tools guide for details of operation..

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