

# Quality Control Lot Validation Guide

**cobas**® Influenza A/B & RSV Nucleic acid test for use on the **cobas**® *Liat*® System



## Add Lot procedure

Before using a new lot of **cobas**® Influenza A/B & RSV assay tubes, an **Add Lot** procedure must be performed on the **cobas**® *Liat*® Analyzer to validate the **cobas**® Influenza A/B & RSV assay tube lot at your site. The procedure includes running a negative and a positive control sample.

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

### Materials needed:

#### From **cobas** Influenza A/B & RSV assay tube Pack:

- Package Insert Barcode Card contained in the **cobas** Influenza A/B & RSV assay tube Pack. This barcode is lot-specific; match the lot number next to the barcode with the lot number on the **cobas** Influenza A/B & RSV assay tubes.
- 2 **cobas** Influenza A/B & RSV assay tubes

#### From the **cobas** Influenza A/B & RSV Quality Control Kit:

- **Negative Control:** (orange cap) Negative Control Barcode, (see Control Kit Barcode Card), 1 Dilution UTM tube (used as the negative control sample) 1 transfer pipette
- **Positive Control:** (green cap) Positive Control Barcode, (see Control Kit Barcode Card), 1 Positive Control tube, 1 Dilution UTM tube (used to mix with the positive control), 1 transfer pipette

### 1 Prepare and Test Negative Control sample

#### a. Obtain:

- Package Insert Barcode on the Package Insert Barcode Card contained in the **cobas** Influenza A/B & RSV assay tube Pack
- Negative Control Barcode on the Control Kit Barcode Card
- 1 Dilution UTM tube (unit dose of UTM)
- 1 **cobas** Influenza A/B & RSV assay tube from this lot

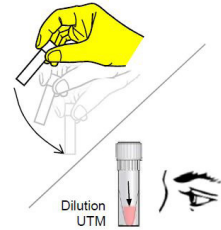
#### b. Select **Assay Menu** on the main menu of an analyzer.

#### c. Select **New Lot** at the bottom of the list.

#### d. Select **Scan** and scan the Package Insert Barcode on the Package Insert Barcode Card from the **cobas** Influenza A/B & RSV assay tube Pack.

#### e. Select **Scan** and scan the Negative Control Barcode on the Control Kit Barcode Card. The Analyzer will prompt **Add Negative Control & scan Liat Tube ID**.

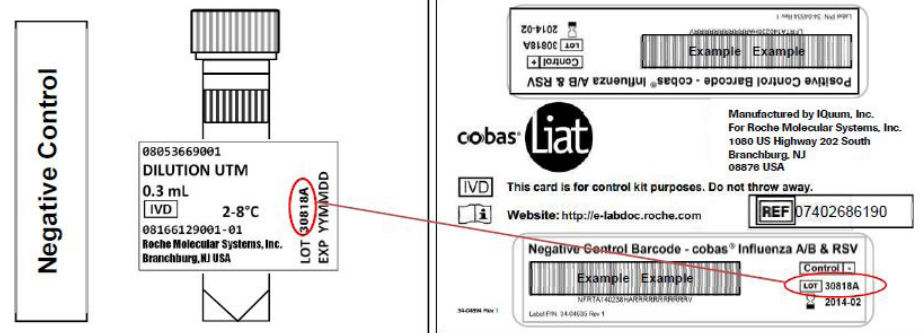
- #### f. Hold the Dilution UTM tube by the tube cap and shake down the liquid using a quick, sharp, downward wrist motion (as if shaking down a mercury thermometer). Visually check that the Dilution UTM has pooled at the bottom of the tube. If not, repeat the shake down procedure.



- #### g. Using the Dilution UTM as sample, run the assay following the *Quick Reference Instructions, Test Procedure, Step 2. b-h (Add Sample) and Step 3 (Insert cobas® Influenza A/B & RSV assay tube)*.

- #### h. If **Negative Control Result Accepted** displays at the end of the run, select **OK**. If the result is rejected, repeat the negative control run (**Step 1** of this procedure).

- #### i. Select **Back**.

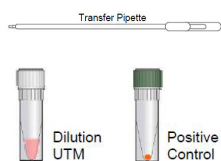


- Match the lot number (L/N) of the Dilution UTM tube label to the lot number of the Negative Control Barcode Label on the Control Kit Barcode Card and then use the Negative Control Barcode (on the Control Kit Barcode Card) as the sample ID when performing negative control run.

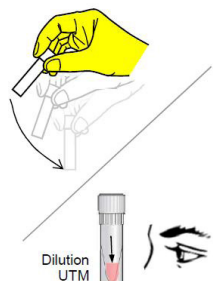
## 2 Prepare Positive Control sample

### a. Obtain:

- 1 transfer pipette (Use only transfer pipettes contained in the **cobas** Influenza A/B & RSV Quality Control Kit. Use of alternative transfer pipettes may lead to invalid results.)
- 1 Positive Control tube (pellet comprising dried positive control material at bottom of tube)
- 1 Dilution UTM tube (unit dose of UTM)



- ### b. Hold the Dilution UTM tube by the tube cap and shake down the liquid using a quick, sharp, downward wrist motion (as if shaking down a mercury thermometer).



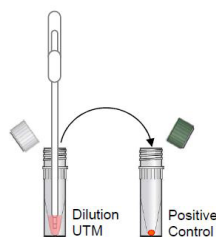
- Visually check that the Dilution UTM has pooled at the bottom of the tube. If not, repeat the shake down procedure
- ### c. Using a provided transfer pipette, transfer the UTM liquid from the Dilution UTM tube into the Positive Control tube:

- #### i. Check that the Positive Control pellet is at the bottom of the tube prior to addition of the

Dilution UTM. Do not use the Positive Control if a pellet is not visible prior to rehydration.

- #### ii. Squeeze the pipette bulb until the bulb is fully flat. While holding the bulb fully flat, insert the pipette tip into the liquid just below the liquid surface in the Dilution UTM tube.
- #### iii. Slowly release the bulb completely while keeping the pipette tip below the liquid surface. You will see the liquid UTM rising into the pipette. After releasing the bulb completely, withdraw the pipette from the Dilution UTM tube. A small volume of liquid may remain in the tube after the bulb is fully released.

- #### iv. Insert pipette into the Positive Control tube until the tip is at the bottom of the tube.



- #### v. Slowly squeeze the bulb to empty the contents of pipette. Avoid creating bubbles in the sample. Do not release the pipette bulb.

- #### vi. While still squeezing the pipette bulb, withdraw the pipette from the tube. Dispose of the transfer pipette according to your institution's guidelines

for safe disposal of hazardous material. Do not reuse transfer pipettes.

- #### vii. Cap the Positive Control tube. Hold the Positive Control tube by the cap and shake down the liquid in the tube using a quick, sharp, downward wrist motion.

- #### d. Let the Positive Control tube sit for 5 minutes to begin dissolving the dried positive control material.



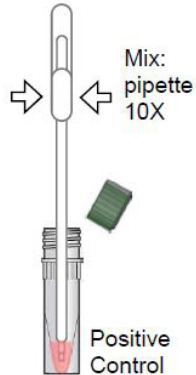
## Positive Control



- Match the lot number (L/N) of the Positive Control tube label to the lot number of the Positive Control Barcode Label on the Control Kit Barcode Card, and then use the Positive Control Barcode (on the Control Kit Barcode Card) as the sample ID when performing positive control runs.

### 3 Test Positive Control sample

- a. Obtain:
- Positive Control Barcode on the Control Kit Barcode Card
  - 1 **cobas** Influenza A/B & RSV assay tube from this lot
- b. On the analyzer used for the Negative Control test, select **Scan** and scan the Positive Control Barcode on the Control Kit Barcode Card. The analyzer prompts **Add Positive Control & scan Liat Tube ID**.
- c. After the Positive Control tube from **Step 2** has sat for 5 minutes, use the transfer pipette from the **cobas Liat** Influenza A/B & RSV assay tube pouch to slowly pipette the sample up and down 10 times to dissolve and mix the positive control. Avoid generating bubbles.



- d. Using the Positive Control as a sample, run the assay following the *Quick Reference Instruction, Test Procedure, Step 2b-h (Add Sample) and 3 (Insert cobas Influenza A/B & RSV assay tube)*.
- e. If **Positive Control Result Accepted. Lot ... added** displays at the end of the run, select **OK** to return to the assay menu. If the result is rejected, repeat the positive control run (**Steps 2-3** in this procedure).

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** Influenza A/B & RSV assay tube lot without performing **Add Lot** on each analyzer.

Consult the Advanced Tools guide for details of operation.

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