

# Quality Control Lot Validation Guide

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



## Add Lot procedure

Before using a new lot of **cobas® Strep A** tubes, **Add Lot** must be performed on the **cobas® Liat®** Analyzer to validate the **cobas® Strep A** 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 Step A assay tube Pack:

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

- 2 **cobas Strep A** assay tubes

#### From the cobas Strep A Quality Control Kit:

- **Negative Control:** (orange cap) Negative Control Barcode, (see Control Kit Barcode Card), 1 Dilution Amies tube (used as the negative control sample)
- **Positive Control:** (green cap) Positive Control Barcode, (see Control Kit Barcode Card), 1 Positive Control tube, 1 Dilution Amies 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 Strep A** assay tube Pack
- Negative Control Barcode on the Control Kit Barcode Card
- 1 Dilution Amies tube (unit dose of Amies medium)
- 1 **cobas Strep A** tube from this lot

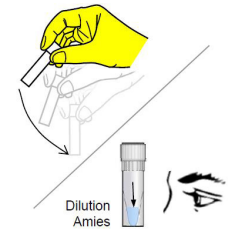
#### b. Select **Assay Menu** on the main menu of an analyzer.

#### 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 Strep A** assay tube Pack.

#### e. Select **Scan** and scan the Negative Control Barcode on the Control Kit Barcode Card. The analyzer prompts **Add negative control & scan tube ID**.

#### f. Hold the Dilution Amies tube by the tube cap and shake down the liquid using a quick, sharp, downward wrist motion (as if shaking down a mercury thermometer) to pool the liquid at the bottom of the tube.



#### g. Using the Dilution Amies as sample, run the assay following the *Quick Reference Instructions, Test Procedure, Step 2. c-i (Add Sample) and Step 3 (Insert cobas® Strep A tube)*.

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

#### i. Select **Confirm**.

Negative Control

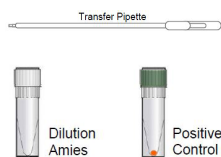


- Match the lot number (L/N) of the Dilution Amies tube label to the lot number of the Negative Control Barcode Label on the Control Kit Barcode Card and then use the Negative Control Barcode (on the Control Kit Barcode Card) as the sample ID when performing negative control runs.

## 2 Prepare Positive Control sample

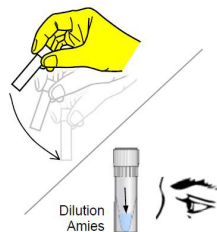
### a. Obtain:

- 1 transfer pipette
- 1 Positive Control tube (pellet comprising dried positive control material at bottom of tube)
- 1 Dilution Amies tube (unit dose of Amies medium)



### b. After opening Positive Control pouch, discard the desiccant packet.

- ### c. 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) to pool the liquid at the bottom of the tube.

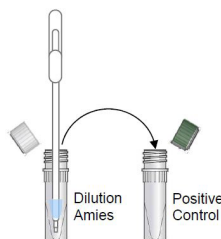


- ### d. Transfer the Amies liquid from the Dilution Amies tube into the Positive Control tube:

- Squeeze the pipette bulb until the bulb is fully flat and insert the pipette tip into the liquid in the Dilution Amies tube.
- Slowly release the bulb while keeping the pipette tip below the liquid surface. A small volume of liquid will remain in the tube after the bulb is fully released.

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

- Slowly squeeze the bulb to empty the contents of pipette. Avoid creating bubbles.



- While still squeezing the pipette bulb, withdraw the pipette from the tube.

- 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.

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



### f.

## 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

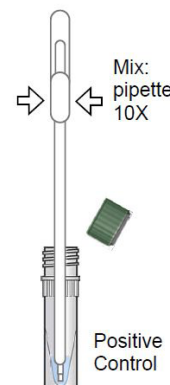
### a. Obtain:

- Positive Control Barcode on the Control Kit Barcode Card
- 1 **cobas** Strep A 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 tube ID**.

- ### c. After the Positive Control tube from **Step 2** has sat

for 5 minutes, use the transfer pipette from the **cobas Liat** Strep A assay tube pouch to slowly pipette the sample up and down 10 times to dissolve and mix the positive control. Avoid generating bubbles.



- Using the Positive Control as a sample, run the assay following the *Quick Reference Instruction, Test Procedure, Step 2c-i (Add Sample) and 3 (Insert **cobas** Strep A tube)*.
- If **Positive Control Result Accepted** displays at the end of the run, select **Confirm**, then select **Back** 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** Strep A assay tube lot without performing **Add Lot** on each analyzer.

Consult the Advanced Tools guide for details of operation.

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