

For In Vitro Diagnostic Use



Read the Package Insert and User Manual for complete test procedure and information before performing this procedure.

NOTE: For the remainder of this Quality Control Kit Insert, the **cobas® Liat® Analyzer** may be referred to as the Analyzer and the **cobas® Liat® System** may be referred to as the System.

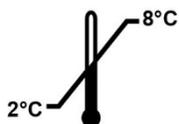
Quality Control Kit

This kit contains External Controls for use with the **cobas® Liat® Strep A** assay. External Controls are run during the Add **cobas® Strep A** tube lot procedure. Additional External Controls should be tested in accordance with local, state, federal and/or accrediting organization requirements as applicable.

Contents

Description	P/N	Qty
cobas® Strep A Positive Control (Positive Control)	07758502001	3
cobas® Strep A Dilution Amies (Dilution Amies)	07763808001	6
Transfer Pipettes, 200 µL	07898541001	11
Control Kit Barcode Card with:	07945272001	1
Negative Control Barcode Label	07945264001	1
Positive Control Barcode Label	07945256001	1

Storage and Handling



- Store the **cobas® Strep A Quality Control Kit** at 2–8°C.
- Positive Control tubes and Dilution UTM tubes contained in factory-sealed pouches are stable until expiration date indicated on the pouches. After opening a pouch, reagents are stable for 90 days at 2–8°C or until the expiration date, whichever comes first. Write the date opened on the pouch where indicated. Close the zip lock seal on the pouch after each use.

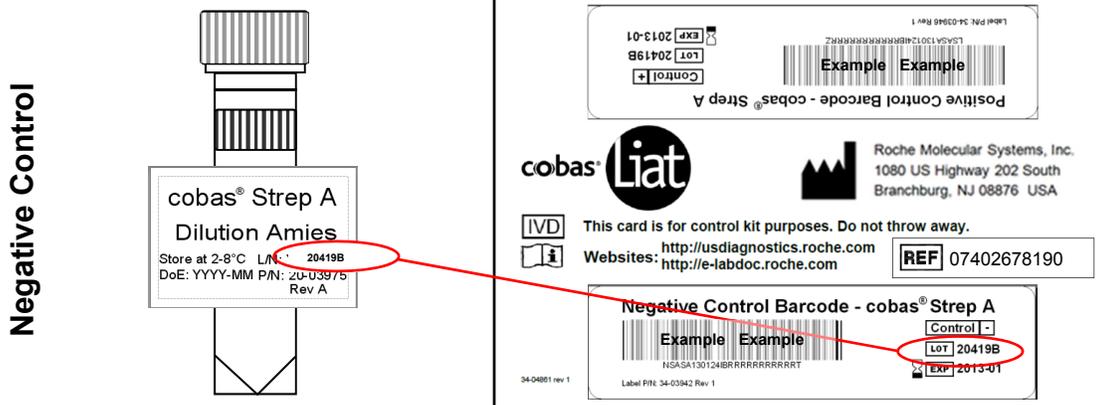
Add **cobas® Strep A** tube lot

Before using a new lot of **cobas® Strep A** tubes, Add Lot must be performed on the Analyzer to validate the **cobas® Strep A** tube lot at your site. The process comprises running a negative and a positive control sample.

Materials:

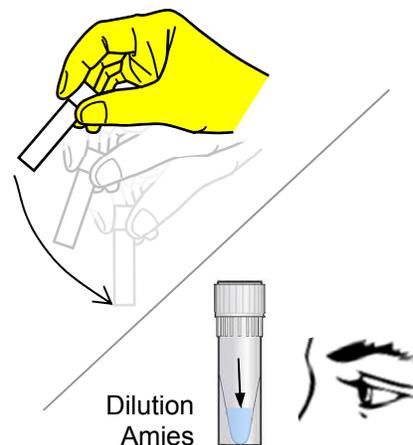
- From **cobas®** Strep A assay tube Pack:
 - ⟨ Package Insert Barcode Card: contained in the **cobas®** Strep A assay tube Pack. This barcode is lot-specific; match the lot number next to the barcode with the lot number on the **cobas®** Strep A tubes.
 - ⟨ 2 **cobas®** Strep A tubes
- From **cobas®** Strep A Quality Control (QC) Kit:
 - ⟨ Negative Control: Negative Control Barcode, (see Control Kit Barcode Card), 1 Dilution Amies tube (used as the negative control sample)
 - ⟨ Positive Control: 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

Note: Match the lot number (L/N) of the Dilution Amies tube label to the lot number (LOT) 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.



1. Prepare and test Negative Control sample

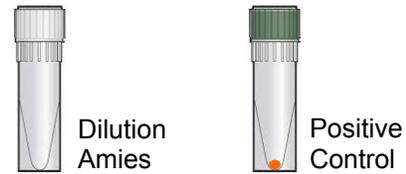
- a. Obtain:
 - < Package Insert Barcode on the Package Insert Barcode Card contained in the **cobas®** Strep A assay tube Pack
 - < Negative Control Barcode on the Control Kit Barcode Card
 - < 1 Dilution Amies tube (unit dose of Amies medium)
 - < 1 **cobas®** Strep A tube from this lot
- b. Select **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 will prompt “*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.*” is displayed at the end of the run, select **Confirm** (If software version 3.2 or lower, select **OK**). If the result is rejected, repeat the negative control run (step 1 of this procedure).
- i. Select **Confirm** (If software version 3.2 or lower, select **Back**).



2. Prepare Positive Control sample

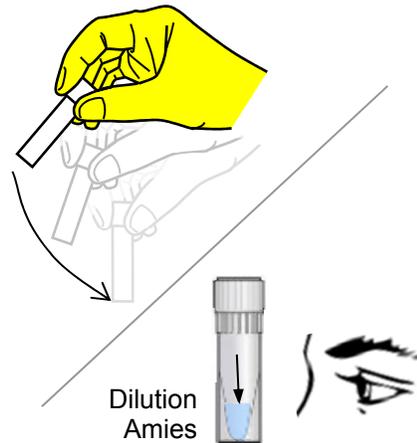
a. Obtain:

- < 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)



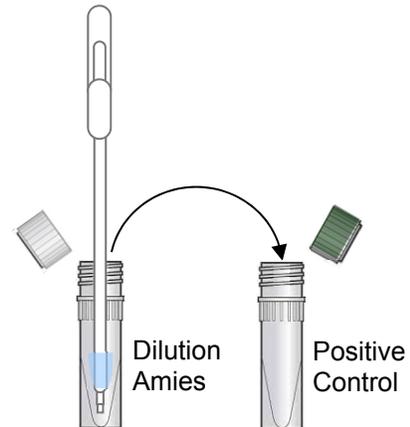
b. After opening Positive Control pouch, discard the desiccant packet.

c. Hold the Dilution 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.

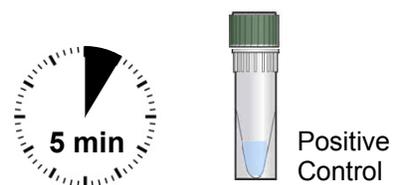


d. Transfer the Amies liquid from the Dilution Amies tube to the Positive Control tube:

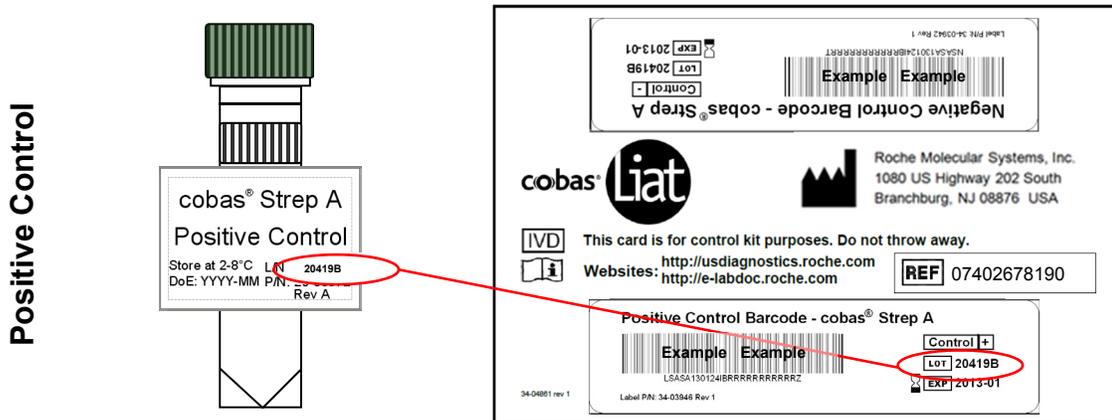
- i. Squeeze the pipette bulb until the bulb is fully flat and insert the pipette tip into the liquid in the Dilution Amies tube.
- ii. Slowly release the bulb while keeping the pipette tip below the liquid surface. A small volume of liquid will remain in the tube after the bulb is fully released.
- iii. Insert pipette into the Positive Control tube until the tip is at the bottom of the tube.
- iv. Slowly squeeze the bulb to empty the contents of pipette. Avoid creating bubbles.
- v. While still squeezing the pipette bulb, withdraw the pipette from the tube.
- vi. 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.



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



Note: Match the lot number (L/N) of the Positive Control tube label to the lot number (LOT) 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:

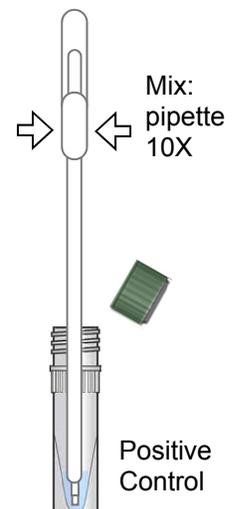
- < Positive Control Barcode on the Control Kit Barcode Card
- < 1 **cobas®** Strep A tube from this lot

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 will prompt “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®** Strep A 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 sample, run the assay following the Quick Reference Instruction, Test Procedure, step 2.c-i (Add Sample) and 3 (Insert **cobas®** Strep A tube).

e. If “Positive control result accepted.” is displayed at the end of the run, select **Confirm** (If software version 3.2 or lower, select **OK**), select **Back** to return to the assay menu. If the result is rejected, repeat the positive control run (step 2 and 3 in this procedure).



Transfer assay tube lot information

After Add Lot is completed on one Analyzer use the Advanced Tools (If software version 3.2 or lower, Advanced Tools Key) to transfer the lot information to the other 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 software specific Advanced Tools guide for details of operation.

Technical Support

If you have any questions or problems, please contact your Roche Service representative.

Trademarks and Patents

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The **cobas®** Strep A nucleic acid test for use on the **cobas®** Liat System is covered by US Patent Nos. U.S. Patent Nos. 6,780,617; 6,964,862; 7,337,072; 7,718,421; 7,833,489; 7,799,521; 7,935,504; 8,936,933; and 9,005,551; corresponding foreign patents. Other patents pending.

See <http://www.roche-diagnostics.us/patents>

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Quality Control Kit Insert
cobas® Strep A Quality Control Kit
For use on the **cobas® Liat®** System



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