

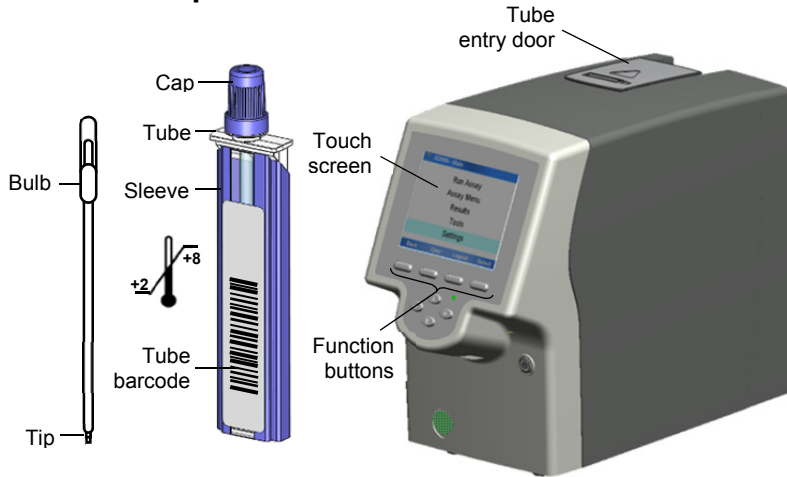
CLIA Complexity: WAIVED



Failure to follow the instructions or modification to the test system instructions will result in the test no longer meeting the requirements for waived classification.

Read the Package Insert and User Manual for complete specimen collection instruction, test procedure and other information before performing this test.

Test Components

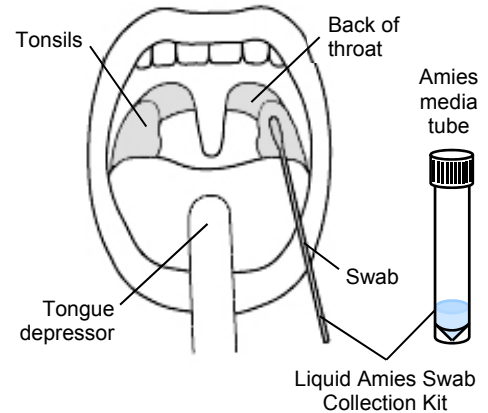


Transfer Pipette

cobas® Liat® tube

cobas® Liat® Analyzer
(referred to as **Analyzer**)

Throat Swab Collection



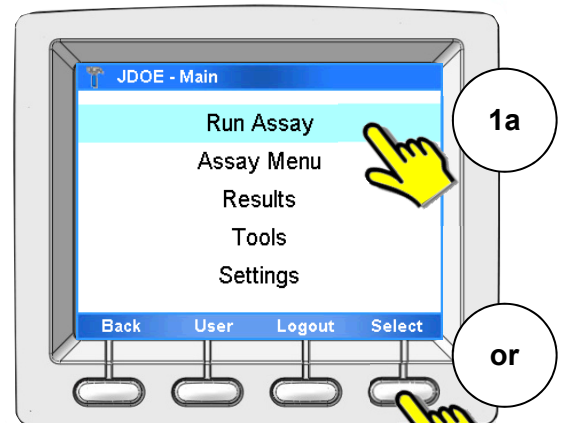
Throat Swab Area

Test Procedure

- For use with throat swab specimens only
- Do not use damaged, dropped or previously used Liat® tube
- Do not use any **cobas® Liat®** tube past the expiration date on the label

1. Scan Barcode

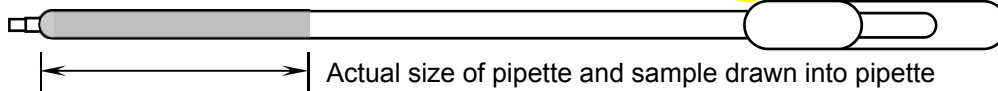
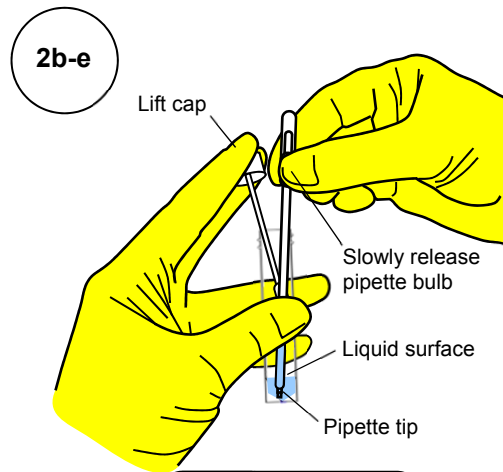
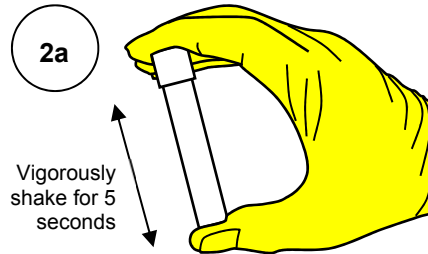
- Select **Run Assay** on the main menu using the touch screen, OR press the **Select** function button.
- Select **Scan** and scan the **cobas® Liat® tube barcode** on the Tube sleeve by placing the **cobas® Liat® tube** on the table and sliding the Tube towards the Analyzer until the red scan light is over the entire barcode.
- Select **Scan** again and scan the *Patient or Sample barcode*, or select **Enter** and type in the Sample or Patient ID. The Analyzer will prompt **“Add throat swab sample & re-scan tube ID.”**



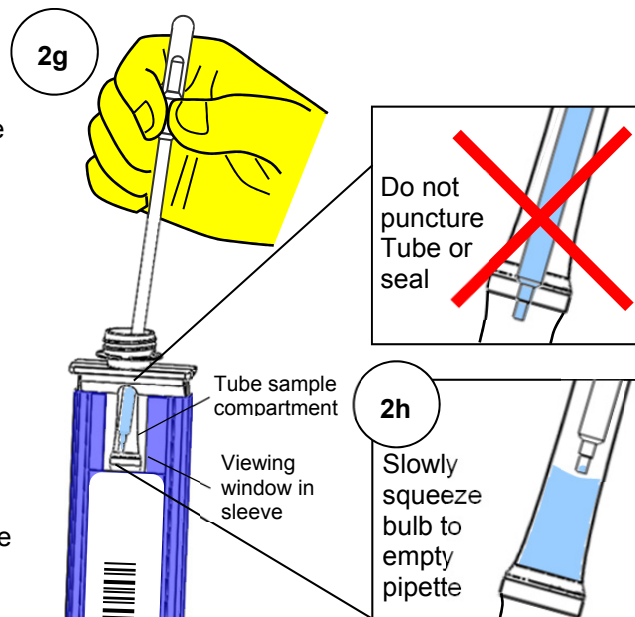
2. Add Sample

After collecting the throat swab, insert the swab into an Amies liquid transport medium tube. Swirl the swab against the inside wall of the tube 3 times. Break the swab shaft and leave the swab in the transport medium tube (i.e. sample tube). Attach the cap securely.

- a. Vigorously shake the throat swab sample tube for 5 seconds to evenly disperse the patient specimen in the liquid medium.
- b. Unscrew the sample tube cap. Lift the cap and any attached swab to allow a pipette to be inserted into the sample tube. Avoid lifting the swab completely out of the sample tube.
- c. Obtain the transfer pipette from the **cobas® Liat®** tube pouch (actual size shown below). Firmly squeeze the bulb of the pipette until the bulb is fully flat.
- d. While holding the pipette bulb fully flat, insert the pipette tip into the sample below the liquid surface.
- e. Slowly release the bulb while keeping the pipette tip below the liquid surface, drawing up the sample. After releasing the bulb completely, withdraw the pipette from the sample.



- f. Unscrew the cap from the **cobas® Liat®** tube.
 - g. While watching through the viewing window in the sleeve, carefully insert the pipette into the **cobas® Liat®** tube. Place the pipette tip near the bottom of the sample compartment.
 - h. Slowly squeeze the bulb to empty the contents of the pipette into the **cobas® Liat®** tube. Do not release the pipette bulb.
- Note:** Do not puncture the **cobas® Liat®** tube or the seal at the bottom of the sample compartment. If either of these is damaged, discard both the **cobas® Liat®** tube and the transfer pipette, and restart the testing procedure with new assay components.
- i. While still holding the pipette bulb, withdraw the pipette from the tube. Screw the cap back on the **cobas® Liat®** tube. Dispose of the transfer pipette.





Note: Start the **cobas® Liat®** Assay run as soon as possible, but no later than 4 hours after adding the sample to the **cobas® Liat®** Tube.

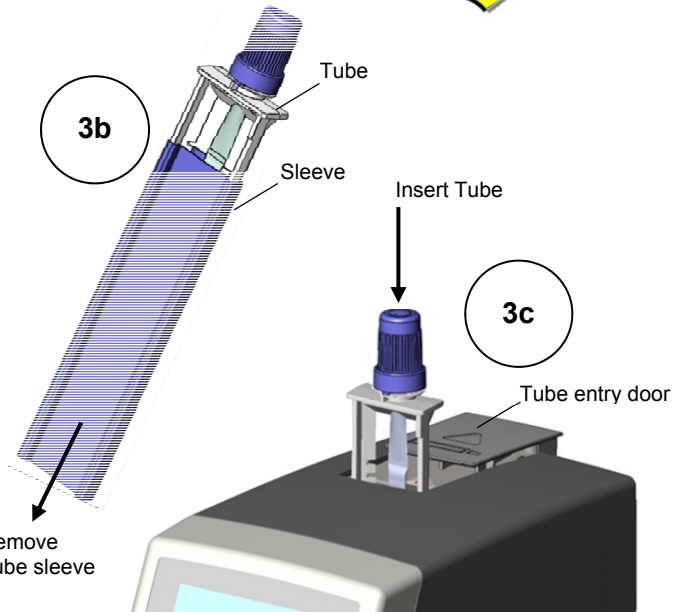
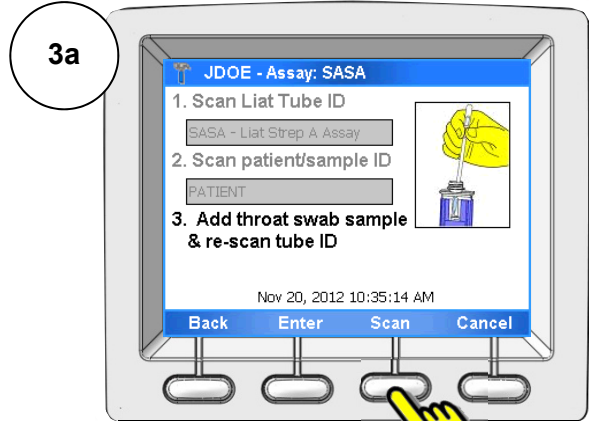
3. Insert **cobas® Liat®** Tube

- Select **Scan** and re-scan the **cobas® Liat®** tube barcode. The tube entry door on top of the Analyzer will open automatically.
- Remove the **cobas® Liat®** tube sleeve, and immediately...
- ... insert the Tube into the Analyzer until the Tube clicks into place. The Tube only fits in one way.

If the **cobas® Liat®** tube is not inserted by the time the door closes, re-scan the Tube barcode (step 3a) and insert the Tube again.

Once the **cobas® Liat®** tube is properly inserted, the Analyzer will close the door automatically and begin the test.

During the test, the Analyzer displays the running status and estimated time remaining.

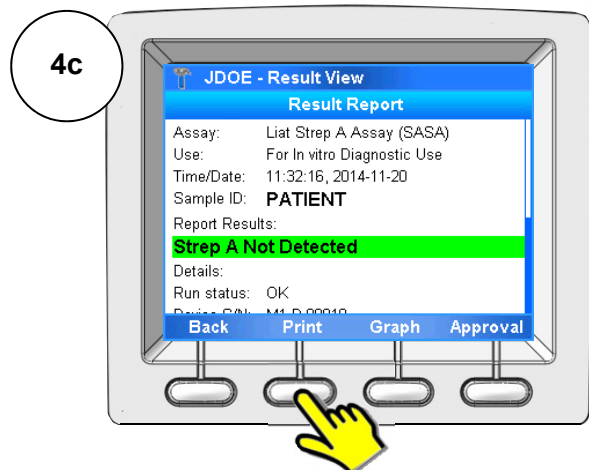


4. View Result

Once the test is complete, the Analyzer displays the message, “**Please remove the tube slowly...**” and opens the tube entry door automatically.

- Lift the Tube out of the Analyzer.
- Select **Report** to view the Result Report.
- Select **Print** to print the report.

Select **Back**, and then **Main** to return to the main menu for the next test.





Interpretation of Results

Result Report	Interpretation
Strep A Not Detected	Negative test for Strep A (no Strep A DNA detected)
Strep A Detected	Positive test for Strep A (Strep A DNA present)
Strep A Indeterminate. Repeat Assay.	Presence or absence of Strep A cannot be determined. Repeat assay with same sample or, if possible, new sample.
Assay Invalid. Repeat Assay.	
[Error] Assay Aborted	

If the test result is “Indeterminate” or “Invalid”, or if an “Error” is reported, repeat the assay with the same specimen, or if possible, with a newly collected specimen. Specimens that have repeat “Indeterminate” or “Invalid” results should be sent to a laboratory for confirmatory testing by an alternative method. Contact your local Roche representative if repeat “Errors” are reported.

Quality Control

External Positive and Negative Controls are provided in the **cobas®** Strep A Quality Control (QC) Kit. At minimum, external controls must be run for each new lot of **cobas®** Liat® assay tubes following the “Add **cobas®** Liat® Tube Lot” procedure (see Package Insert or QC Kit Insert for procedure). Additional external controls may be tested as required to verify system performance according to the procedure outlined below.

1. Negative Control

Components required from QC Kit:

- Dilution Amies tube
 - Control Kit Barcode Card
- a. Shake Dilution Amies tube to pool liquid at the bottom.
 - b. Follow the Test Procedure (page 1-3, steps 1-4) to run Dilution Amies as a sample. In step 1, scan the Negative Control Barcode on the Control Kit Barcode Card as the Sample ID. In step 2, start at step 2c.
 - c. Touch or click **Report** after completion of the assay.
 - d. The Report Result must be “*Strep A Not Detected*” for the negative control to pass.

2. Positive Control

Components required from QC Kit:

- Dilution Amies tube
 - Positive Control tube
 - Transfer pipette
 - Control Kit Barcode Card
- a. Shake Dilution Amies tube to pool liquid at the bottom.
 - b. Use transfer pipette to transfer liquid from the Dilution Amies tube to the Positive Control tube.
 - c. Cap Positive Control tube and shake liquid to the bottom.
 - d. Allow Positive Control tube to sit for 5 min.
 - e. Using a new transfer pipette from the **cobas®** Liat® tube pouch, slowly pipette the Positive Control sample up and down 10 times.
 - f. Follow the Test Procedure (page 1-3, steps 1-4) to run Positive Control as a sample. In step 1, scan the Positive Control Barcode on the Control Kit Barcode Card as the Sample ID. In step 2, start at step 2c.
 - g. Touch or click **Report** after completion of the assay.
 - h. The Report Result must be “*Strep A Detected*” for the positive control to pass.

Warnings & Precautions



- Treat all biological specimens, including used **cobas®** Liat® Tubes and pipettes, as if capable of transmitting infectious agents.
- Follow your institution’s safety procedures for working with chemicals and handling biological samples.

Technical Support

If you have any questions or problems, please contact your local Roche representative.
Roche Response Center: 1-800-800-5973

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