

CLIA Complexity: WAIVED

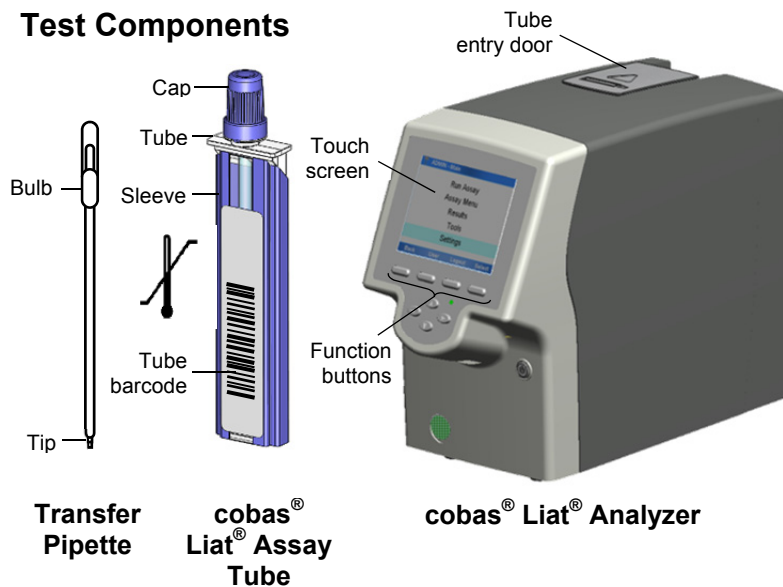
A Certificate of Waiver is required to perform this test in a CLIA Waived setting. To obtain CLIA waiver information and a Certificate of Waiver, please contact your state health department. Additional CLIA waiver information is available at the Centers for Medicare and Medicaid website at www.cms.hhs.gov/CLIA.



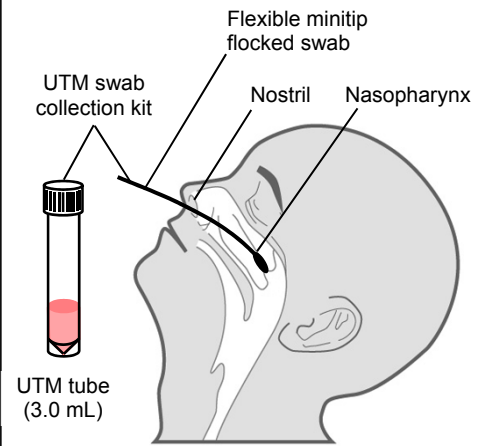
Failure to follow the instructions or modification to the test system instructions will result in the test no longer meeting the requirements for waived classification.

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

Test Components



Nasopharyngeal Swab



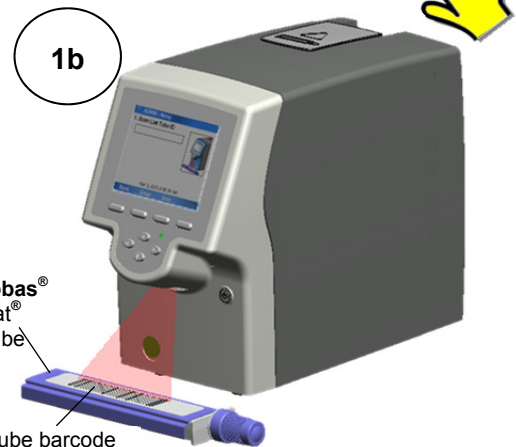
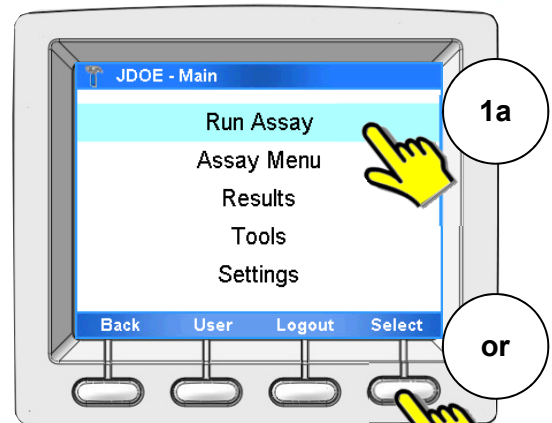
Nasopharyngeal Swab Area

Test Procedure

- For use with nasopharyngeal swab specimens only
- Do not use damaged, dropped or previously used **cobas[®] Liat[®] Assay Tube**
- Do not use any **cobas[®] Liat[®] Assay Tube** past the expiration date on the label

1. Scan Barcode

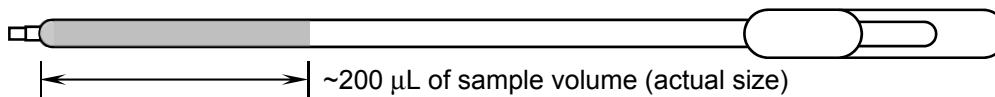
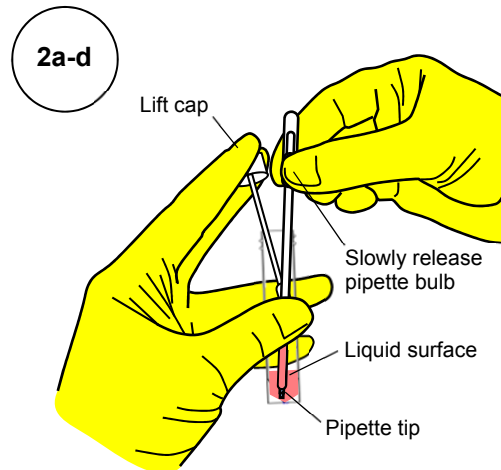
- Select **Run Assay** on the main menu using the touch screen or function button.
- Select **Scan** and scan the **cobas[®] Liat[®] Assay Tube barcode** on the Tube sleeve by placing the **cobas[®] Liat[®] Tube** on the table and sliding the Tube towards the **cobas[®] Liat[®] Analyzer** until the red 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 **cobas[®] Liat[®] Analyzer** will prompt **“Add UTM sample & re-scan tube ID.”**



2. Add Sample

After collecting the nasopharyngeal swab specimen, insert the swab into a UTM tube. Place the swab head at least ½ inch below the surface of the media, and swirl the swab in the media. Break the swab shaft and leave the swab in the UTM tube (i.e. sample tube). Attach the cap securely.

- 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.
- Obtain the transfer pipette from the **cobas[®] Liat[®] Assay Tube** pouch (actual size shown below). Firmly squeeze the bulb of the pipette until the bulb is fully flat.
- While holding the pipette bulb fully flat, insert the pipette tip into the sample below the liquid surface.
- Slowly release the bulb while keeping the pipette tip below the liquid surface to draw up the sample. After releasing the bulb completely, withdraw the pipette from the sample.

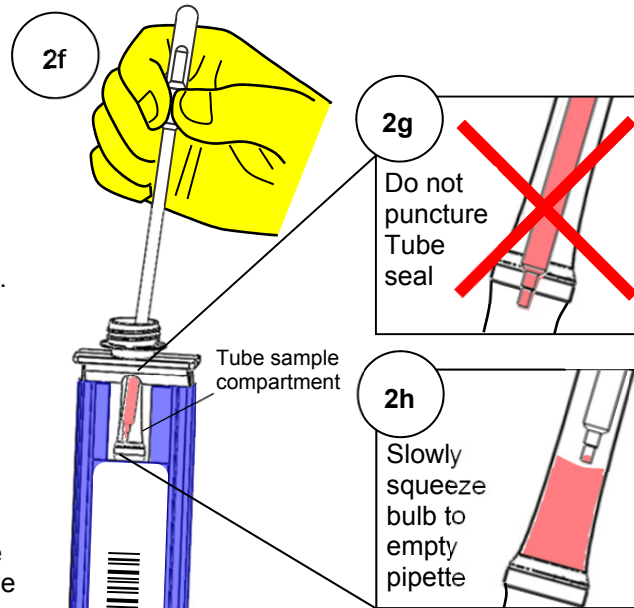


- Unscrew the cap from the **cobas[®] Liat[®] Assay Tube**.
- While watching through the viewing window in the sleeve, carefully insert the pipette into the **cobas[®] Liat[®] Assay Tube**. Place the pipette tip near the bottom of the sample compartment.
- Slowly squeeze the bulb to empty the contents of the pipette into the **cobas[®] Liat[®] Assay Tube**. Do not release the pipette bulb.



Note: Do not puncture the **cobas[®] Liat[®] Assay Tube** or the seal at the bottom of the sample compartment. If either of these is damaged, discard both the **cobas[®] Liat[®] Assay Tube** and the transfer pipette, and restart the testing procedure with new assay components.

- While still holding the pipette bulb, withdraw the pipette from the tube. Screw the cap back on the **cobas[®] Liat[®] Assay 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®** Assay Tube.

3. Insert **cobas® Liat®** Assay Tube

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

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

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

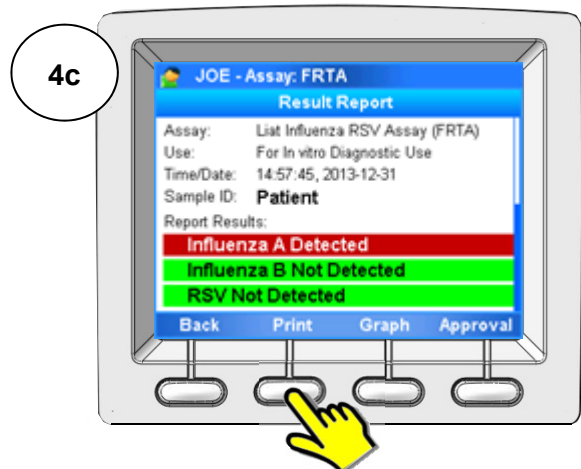
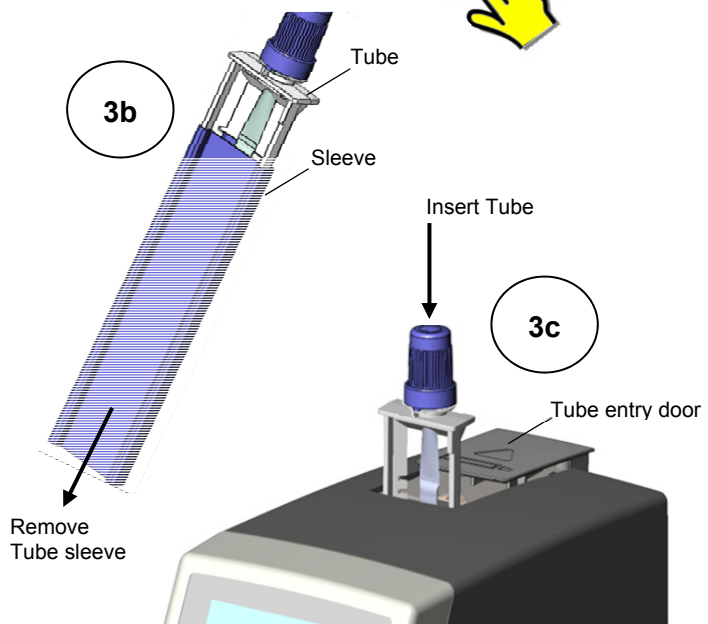
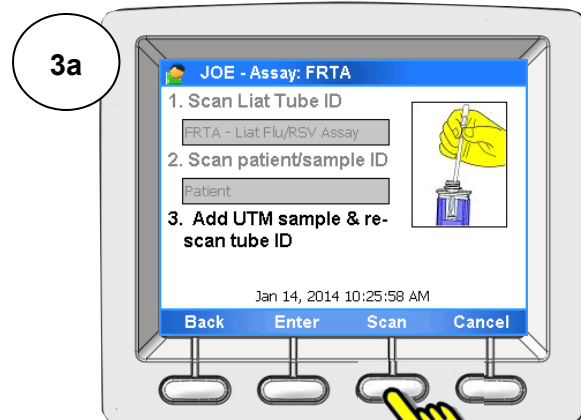
During the test, the **cobas® Liat®** Analyzer displays the running status and estimated time remaining.

4. View Result

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

- Lift the Assay Tube out of the **cobas® Liat®** Analyzer and dispose of the used Tube according to your institution’s safety guidelines for hazardous material.
- Select **Report** to see 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
Inf A	Influenza A Not Detected	Negative test for Influenza A (no Influenza A RNA detected)
	Influenza A Detected	Positive test for Influenza A (Influenza A RNA present)
	Influenza A Indeterminate. Repeat Assay.	Presence or absence of Influenza A cannot be determined. Repeat assay with same sample or, if possible, new sample.
Inf B	Influenza B Not Detected	Negative test for Influenza B (no Influenza B RNA detected)
	Influenza B Detected	Positive test for Influenza B (Influenza B RNA present)
	Influenza B Indeterminate. Repeat Assay.	Presence or absence of Influenza B cannot be determined. Repeat assay with same sample or, if possible, new sample.
RSV	RSV Not Detected	Negative test for RSV (no RSV RNA detected)
	RSV Detected	Positive test for RSV (RSV RNA present)
	RSV Indeterminate. Repeat Assay.	Presence or absence of RSV cannot be determined. Repeat assay with same sample or, if possible, new sample.
Assay Invalid. Repeat Assay		Presence or absence of Influenza A and B, and RSV cannot be determined. Repeat assay with same sample or, if possible, new sample.
[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.

Dual infections of Influenza A and Influenza B are rare. If the test result is “Influenza A Detected” and “Influenza B Detected”, the assay should be repeated with the same patient specimen, or if possible, with a newly collected specimen. Specimens that have repeat “Influenza A Detected” and “Influenza B Detected” results should be sent to a laboratory for confirmatory testing.

Quality Control

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 Quality Control Kit Insert for full procedure).

1. Add Lot Negative Control

- a. Select **Assay Menu**.
- b. Select **New Lot**.
- c. Select **Scan**, and scan Package Insert barcode from the Package Insert Barcode Card.
- d. Select **Scan**, and scan Negative Control Barcode from the Control Kit Barcode Card.
- e. Shake down a Dilution UTM tube to pool the liquid at the bottom.
- f. Follow the Test Procedure (page 2-3) to run Dilution UTM as a sample starting at step 2b.
- g. If “*Negative Control Result Accepted*” is displayed at end of run, select **OK**. If result is rejected, repeat Negative Control run.
- h. Select **Back**.

2. Add Lot Positive Control

- a. Shake down a Dilution UTM tube to pool liquid at the bottom.
- b. Use a transfer pipette to transfer UTM liquid from the Dilution UTM tube to Positive Control tube.
- c. Cap Positive Control tube and shake down the tube to pool the liquid at the bottom.
- d. Allow Positive Control tube to sit for 5 min.
- e. On **cobas[®] Liat[®] Analyzer** used to run Negative Control, select **Scan**, and scan the Positive Control barcode from the Control Kit Barcode Card.
- f. Use a transfer pipette to slowly pipette the Positive Control sample up and down 10 times.
- g. Follow the Test Procedure (page 2-3) to run Positive Control as a sample starting at step 2b.
- h. If “*Positive Control Result Accepted*” is displayed at end of run, select **OK**. If result is rejected, repeat Positive Control run.

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 & handling biological samples.

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