

**CLIA Complexity: WAIVED**

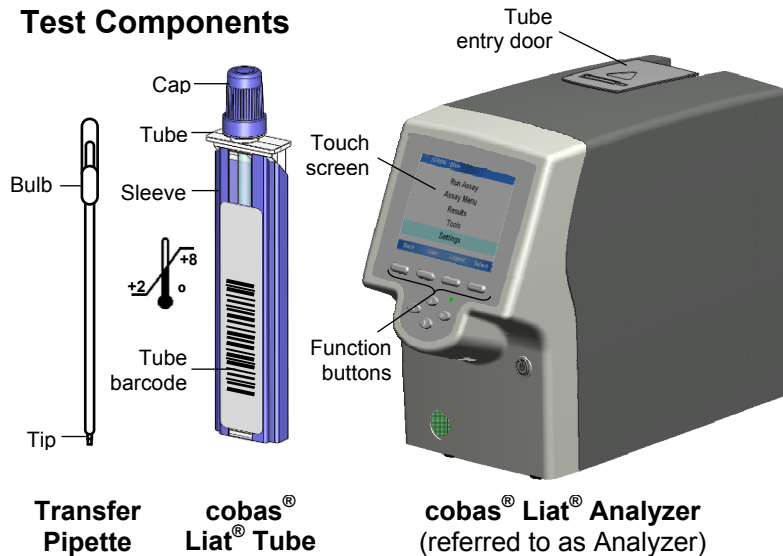
A Certificate of Waiver is required to perform this test in a CLIA Waived setting. To obtain CLIA waiver information and a Certificate of Waiver, please contact your state health department. Additional CLIA waiver information is available at the Centers for Medicare and Medicaid website at [www.cms.hhs.gov/CLIA](http://www.cms.hhs.gov/CLIA).



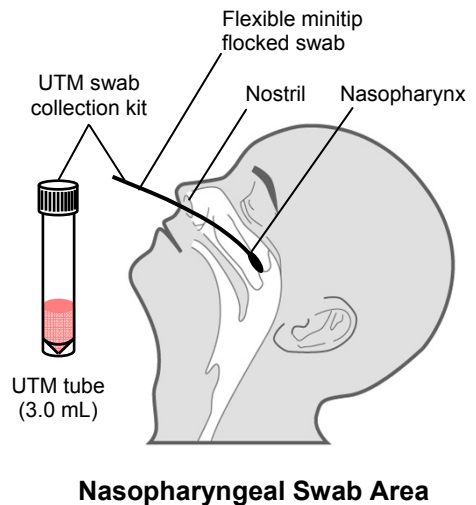
Failure to follow the instructions or modification to the test system instructions will result in the test no longer meeting the requirements for waived classification.

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

**Test Components**



**Nasopharyngeal Swab**

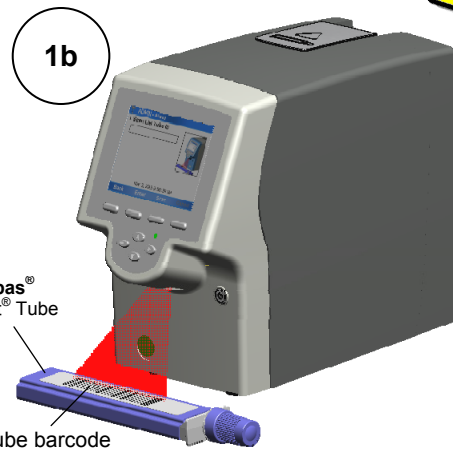
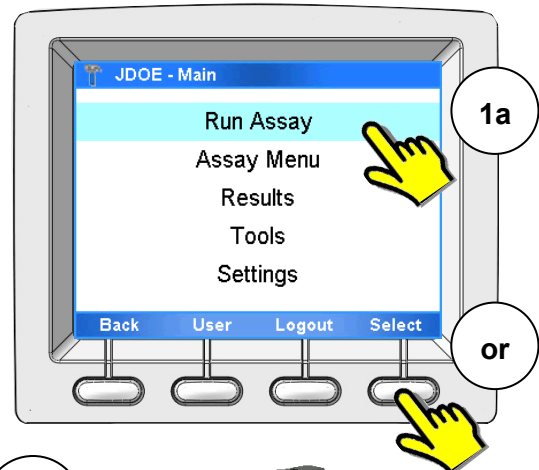


**Test Procedure**

- For use with nasopharyngeal swab specimens only
- Do not use damaged, dropped or previously used **cobas<sup>®</sup> Liat<sup>®</sup> tubes**
- Do not use any **cobas<sup>®</sup> Liat<sup>®</sup> tube** past the expiration date on the label

**1. Scan Barcode**

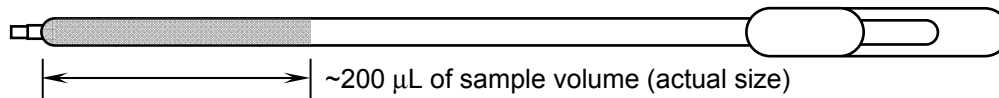
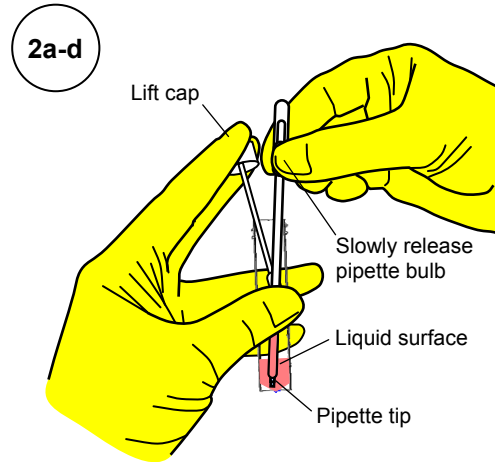
- Select **Run Assay** on the main menu using the touch screen or function button.
- Select **Scan** and scan the **cobas<sup>®</sup> Liat<sup>®</sup> tube barcode** on the Tube sleeve by placing the **cobas<sup>®</sup> Liat<sup>®</sup> tube** on the table and sliding the tube towards the Analyzer until 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 UTM sample & re-scan tube ID.”**



## 2. Add Sample

After collecting the nasopharyngeal swab, 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.

- a. 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.
- b. Obtain the transfer pipette from the **cobas<sup>®</sup> Liat<sup>®</sup>** tube pouch (actual size shown below). Firmly squeeze the bulb of the pipette until the bulb is fully flat.
- c. While holding the pipette bulb fully flat, insert the pipette tip into the sample below the liquid surface.
- d. Slowly release the bulb while keeping the pipette tip below the liquid surface, drawing up ~200 µL of sample. After releasing the bulb completely, withdraw the pipette from the sample.

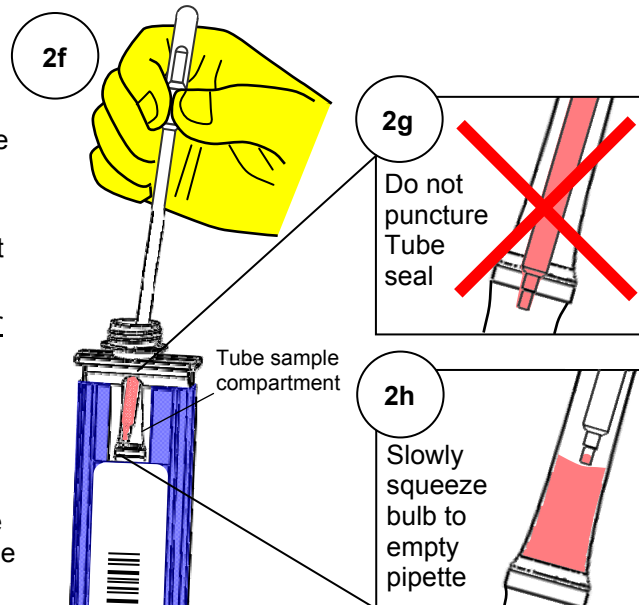


- e. Unscrew the cap from the **cobas<sup>®</sup> Liat<sup>®</sup>** tube.
- f. While watching through the viewing window in the sleeve, carefully insert the pipette into the **cobas<sup>®</sup> Liat<sup>®</sup>** tube. Place the pipette tip near the bottom of the sample compartment.
- g. Slowly squeeze the bulb to empty the contents of the pipette into the **cobas<sup>®</sup> Liat<sup>®</sup>** tube. Do not release the pipette bulb.



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

- h. While still holding the pipette bulb, withdraw the pipette from the tube. Screw the cap back on the **cobas<sup>®</sup> Liat<sup>®</sup>** tube. Dispose of the transfer pipette.





**Note:** Start the **cobas<sup>®</sup> Liat<sup>®</sup>** assay run as soon as possible, but no later than 4 hours after adding the sample to the **cobas<sup>®</sup> Liat<sup>®</sup>** tube.

### 3. Insert **cobas<sup>®</sup> Liat<sup>®</sup>** Tube

a. Select **Scan** and re-scan the **cobas<sup>®</sup> Liat<sup>®</sup>** tube barcode. The tube entry door on top of the Analyzer will open automatically.

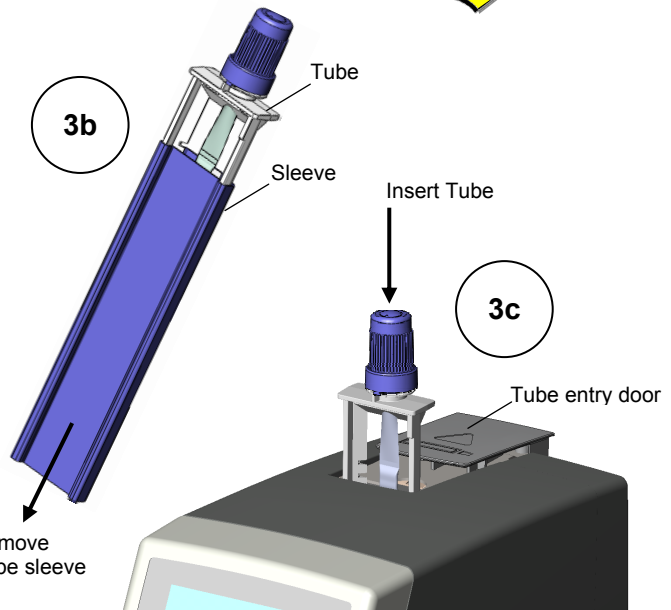
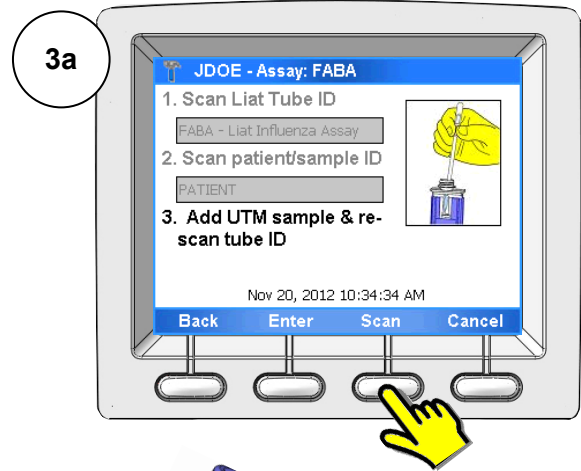
b. Remove the **cobas<sup>®</sup> Liat<sup>®</sup>** tube sleeve, and immediately...

c. ... insert the tube into the Analyzer until the Tube clicks into place. The Tube only fits in one way.

If the **cobas<sup>®</sup> Liat<sup>®</sup>** 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<sup>®</sup> Liat<sup>®</sup>** 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

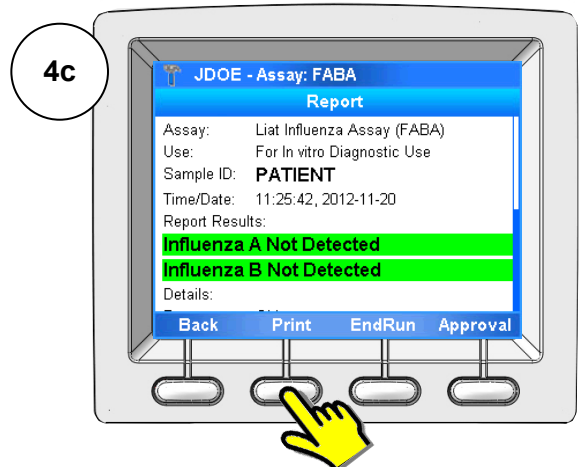
Once the test is complete, the Analyzer displays the message, “**Please remove the tube slowly...**” and opens the tube entry door automatically.

a. Lift the Tube out of the Analyzer.

b. Select **Report** to see the Result Report.

c. 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
Influenza 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.
Influenza 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.
Assay Invalid. Repeat Assay		Presence or absence of Influenza A and B cannot be determined.
[Error]. Assay Aborted		Repeat assay with same sample or, if possible, new sample.

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 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

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

### 2. Add Lot Positive Control

- Shake down a Dilution UTM tube to pool liquid at the bottom.
- Use a transfer pipette to transfer UTM liquid from the Dilution UTM tube to Positive Control tube.
- Cap Positive Control tube and shake down the tube to pool the liquid at the bottom.
- Allow Positive Control tube to sit for 5 min.
- On Analyzer used to run Negative Control, select **Scan**, and scan the Positive Control barcode from the Control Kit Barcode Card.
- Use a transfer pipette to slowly pipette the Positive Control sample up and down 10 times.
- Follow the Test Procedure (page 2-3) to run Positive Control as a sample starting at step 2b.
- 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.

## Technical Support

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

Roche Response Center: 1-800-800-5973

### Trademarks and Patents

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

### Copyright

©2017 Roche Molecular Systems, Inc.



**Roche Diagnostics GmbH**  
Sandhofer Str. 116  
68305 Mannheim  
Germany



Roche Diagnostics (Schweiz) AG  
Industriestrasse 7  
6343 Rotkreuz, Switzerland

Roche Diagnostics GmbH  
Sandhofer Strasse 116  
68305 Mannheim, Germany

Roche Diagnostics, SL  
Avda. Generalitat, 171-173  
E-08174 Sant Cugat del Vallès  
Barcelona, Spain

Roche Diagnostica Brasil Ltda.  
Av. Engenheiro Billings, 1729  
Jaguapé, Building 10  
05321-010 São Paulo, SP Brazil

Roche Diagnostics  
9115 Hague Road  
Indianapolis, IN 46250-0457 USA  
(For Technical Assistance call the  
Roche Response Center  
toll-free: 1-800-800-5973)



Roche Molecular Systems, Inc.  
1080 US Highway 202 South  
Branchburg, NJ 08876 USA  
[www.roche.com](http://www.roche.com)

Roche Diagnostics  
201, boulevard Armand-Frappier  
H7V 4A2 Laval, Québec, Canada  
(For Technical Assistance call:  
Pour toute assistance technique,  
appeler le: 1-877-273-3433)

Roche Diagnostics  
2, Avenue du Vercors  
38240 Meylan, France

Distributore in Italia:  
Roche Diagnostics S.p.A.  
Viale G. B. Stucchi 110  
20052 Monza, Milano, Italy

Distribuidor em Portugal:  
Roche Sistemas de Diagnósticos Lda.  
Estrada Nacional, 249-1  
2720-413 Amadora, Portugal