

For In Vitro Diagnostic Use



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

Quality Control Kit

This kit contains External Controls for use with the **cobas®** Influenza A/B & RSV assay. External Controls are run during the Add **cobas®** Influenza A/B & RSV assay 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® Influenza A/B & RSV Positive Control (Positive Control)	07758537001	3
NEG BUF	09587373001	6
Transfer Pipettes, 200 µL	07898541001	11
Control Kit Barcode Card	08165564001	1

Note: NEG BUF refers to Negative Buffer

Storage and Handling



- Store the **cobas®** Influenza A/B & RSV Quality Control Kit at 2-8°C.
- Positive Control tubes and Negative Buffer 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.

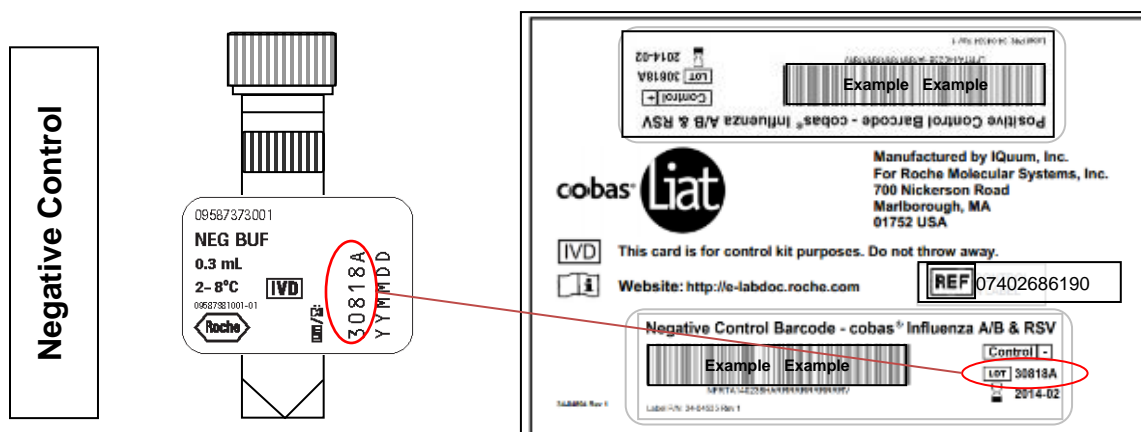
Add cobas[®] Influenza A/B & RSV assay tube lot

Before using a new lot of **cobas[®] Influenza A/B & RSV** assay tubes, an Add Lot procedure must be performed on the Analyzer to validate the **cobas[®] Influenza A/B & RSV** assay tube lot at your site. The process comprises running a negative and a positive control sample.

Materials:

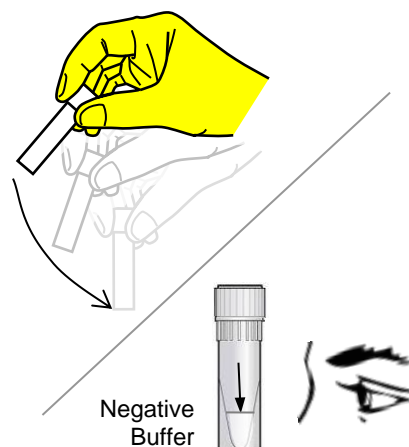
- From **cobas[®] Influenza A/B & RSV** assay tube Pack:
 - ⟨ Package Insert Barcode Card: contained in the **cobas[®] Influenza A/B & RSV** assay tube Pack. This barcode is lot-specific; match the lot number next to the barcode with the lot number on the **cobas[®] Influenza A/B & RSV** assay tubes.
 - ⟨ 2 **cobas[®] Influenza A/B & RSV** assay tubes
- From **cobas[®] Influenza A/B & RSV** Quality Control (QC) Kit:
 - ⟨ Negative Control: Negative Control Barcode, (see Control Kit Barcode Card), 1 Negative Buffer tube (used as the negative control sample)
 - ⟨ Positive Control: Positive Control Barcode, (see Control Kit Barcode Card), 1 Positive Control tube, 1 Negative Buffer tube (used to mix with the positive control), 1 transfer pipette

Note: Match the lot number (L/N) of the Negative Buffer 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

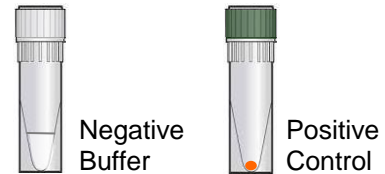
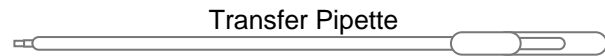
- a. Obtain:
 - < Package Insert Barcode on the Package Insert Barcode Card contained in the **cobas®** Influenza A/B & RSV assay tube Pack
 - < Negative Control Barcode on the Control Kit Barcode Card
 - < 1 Negative Buffer tube (unit dose of Buffer)
 - < 1 **cobas®** Influenza A/B & RSV assay tube 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®** Influenza A/B & RSV 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 Negative Buffer tube by the tube cap and shake down the liquid using a quick, sharp, downward wrist motion (as if shaking down a mercury thermometer). Visually check that the Negative Buffer has pooled at the bottom of the tube. If not, repeat the shake down procedure.
- g. Using the Negative Buffer as sample, run the assay following the Quick Reference Instructions, Test Procedure, step 2. b-h (Add Sample) and step 3 (Insert **cobas®** Influenza A/B & RSV assay tube).
- h. If “*Negative control result accepted.*” is displayed 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**.



2. Prepare Positive Control sample

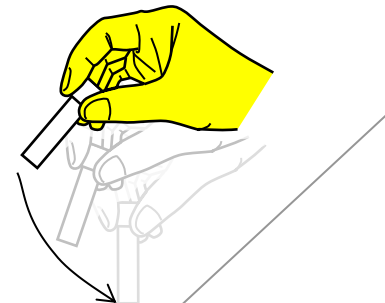
a. Obtain:

- < 1 transfer pipette (Use only transfer pipettes contained in the **cobas[®] Influenza A/B & RSV Quality Control Kit**. Use of alternative transfer pipettes may lead to invalid results.)
- < 1 Positive Control tube (pellet comprising dried positive control material at bottom of tube).
- < 1 Negative Buffer tube



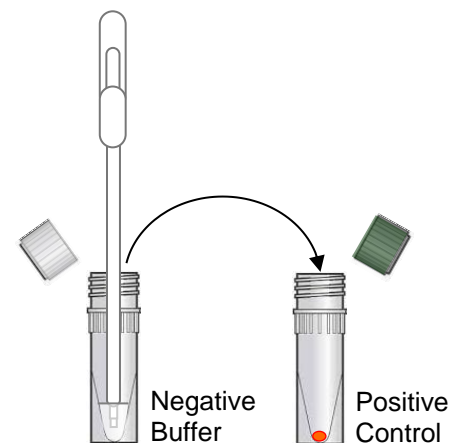
b. After opening Positive Control pouch, discard the desiccant packet.

c. Hold the Negative Buffer tube by the tube cap and shake down the liquid using a quick, sharp, downward wrist motion (as if shaking down a mercury thermometer). Visually check that the Negative Buffer has pooled at the bottom of the tube. If not, repeat the shake down procedure.



d. Using a provided transfer pipette, transfer the liquid from the Negative Buffer tube into the Positive Control tube:

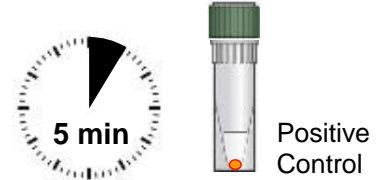
- i. Check that the Positive Control pellet is at the bottom of the tube prior to addition of the Negative Buffer. Do not use the Positive Control if a pellet is not visible prior to rehydration.
- ii. Squeeze the pipette bulb until the bulb is fully flat. While holding the bulb fully flat, insert the pipette tip into the liquid just below the liquid surface in the Negative Buffer tube.
- iii. Slowly release the bulb completely while keeping the pipette tip below the liquid surface. You will see the liquid rising into the pipette. After releasing the bulb completely, withdraw the pipette from the Negative Buffer tube. A small volume of liquid may remain in the tube after the bulb is fully released.
- iv. Insert pipette into the Positive Control tube until the tip is at the bottom of the tube.
- v. Slowly squeeze the bulb to empty the contents of pipette. Avoid creating bubbles in the sample. Do not release the pipette bulb.



cobas® Influenza A/B & RSV Quality Control Kit
 For use on the **cobas® Liat® System**



- vi. While still squeezing the pipette bulb, withdraw the pipette from the tube. Dispose of the transfer pipette according to your institution's guidelines for safe disposal of hazardous material. Do not reuse transfer pipettes.
- vii. 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.

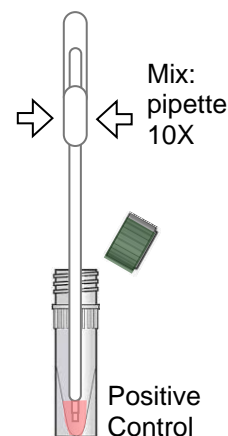


Note: Match the lot number (L/N) of the Positive Control tube label to the lot number (LOT) of the Positive Control Barcode Label on the Control Kit Barcode Card, and then use the Positive Control Barcode (on the Control Kit Barcode Card) as the sample ID when performing positive control runs.



3. Test Positive Control sample

- a. Obtain:
 - < Positive Control Barcode on the Control Kit Barcode Card.
 - < 1 **cobas®** Influenza A/B & RSV assay 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®** Liat® Influenza A/B & RSV assay 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 a sample, run the assay following the Quick Reference Instruction, Test Procedure, step 2.b-h (Add Sample) and 3 (Insert **cobas®** Influenza A/B & RSV assay tube).
- e. If “*Positive control result accepted.*” is displayed at the end of the run, select **Confirm**, select **Back** to return to the assay menu. If the result is rejected, repeat the positive control run (steps 2 and 3 in this procedure).



Transfer assay tube lot information

After Add Lot is completed on one Analyzer use the Advanced Tools to transfer the lot information to the other Analyzers at your site. This allows the other Analyzers to use this **cobas®** Influenza A/B & RSV assay tube lot without performing Add Lot on each Analyzer. Consult the software specific Advanced Tools Guide for details of operation.

Table of Symbols

Age/DOB Age or Date of Birth	Device not for near-patient testing	QS IU/PCR QS IU per PCR reaction, use the QS International Units (IU) per PCR reaction in calculation of the results.
Ancillary Software	Device not for self-testing	SN Serial number
Assigned Range [copies/mL] Assigned Range (copies/mL)	Distributor <i>(Note: The applicable country/region may be designated beneath the symbol)</i>	Site Site
Assigned Range [IU/mL] Assigned Range (IU/mL)	Do not re-use	Procedure Standard Standard Procedure
EC REP Authorized representative in the European Community	Female	STERILE EO Sterilized using ethylene oxide
BARCODE Barcode Data Sheet	For IVD performance evaluation only	Store in dark
LOT Batch code	GTIN Global Trade Item Number	Temperature limit
Biological risks	Importer	TDF Test Definition File
REF Catalogue number	IVD In vitro diagnostic medical device	This way up
CE marking of conformity; this device is in conformity with the applicable requirements for CE marking of an in vitro diagnostic medical device	LLR Lower Limit of Assigned Range	Procedure UltraSensitive Ultrasensitive Procedure
Collect Date Collect date	Male	UDI Unique Device Identifier
Consult instructions for use	Manufacturer	ULR Upper Limit of Assigned Range
Contains sufficient for <n> tests	CONTROL - Negative control	Urine Fill Line Urine Fill Line
CONTENT Content of kit	Non-sterile	Rx Only US Only: Federal law restricts this device to sale by or on the order of a physician.
CONTROL Control	Patient Name	Use-by date
Date of manufacture	Patient number	
Device for near-patient testing	Peel here	
Device for self-testing	CONTROL + Positive control	
	QS copies / PCR QS copies per PCR reaction, use the QS copies per PCR reaction in calculation of the results.	

Technical Support

For technical support (assistance) please reach out to your local affiliate:
https://www.roche.com/about/business/roche_worldwide.htm

Trademarks and Patents

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

Copyright

©2022 Roche Molecular Systems, Inc.

Rx Only



Roche Diagnostics GmbH
Sandhofer Str. 116
68305 Mannheim
Germany



Roche Molecular Systems, Inc.
1080 US Highway 202 South
Branchburg, NJ 08876 USA
www.roche.com

Made in USA

Distributed by
Roche Diagnostics
9115 Hague Road
Indianapolis, IN 46250-0457 USA
(For Technical Assistance call the
Roche Response Center
toll-free: 1-800-526-1247)²



Roche Diagnostics GmbH
Sandhofer Strasse 116
68305 Mannheim, Germany

¹Symbol text required by USA only.
²For USA only.

EC Importer¹

Document revision

Document Revision Information	
Doc Rev. 4.0 12/2021	Replace material 08053669001 with material 09587373001. Update references, instructions and graphics. Increment revision number. Added the harmonized symbol page. Updated distributors addresses. Updated Technical support section. Added Made in statement. Added document revision table. Updated footer to include doc rev. number. Please contact your local Roche Representative if you have any questions.
Doc Rev. 5.0 06/2022	Update Negative Control graphic. Removed software version 3.2 references. Please contact your local Roche Representative if you have any questions.