TP-01005
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Customer Bulletin

☑ Reagent ☐ Software ☐ Analyzer

cobas® SARS-CoV-2 & Influenza A/B Nucleic Acid Test on the cobas® Liat® System Available for Use Under Emergency Use Authorization Only

Information

Roche is pleased to announce that the U.S. Food and Drug Administration (FDA) has granted Emergency Use Authorization (EUA) of the **cobas** SARS-CoV-2 & Influenza A/B Assay for the **cobas** Liat system. The new **cobas** SARS-CoV-2 & Influenza A/B test analyzes nucleic acids from nasopharyngeal and nasal swab samples and self-collected nasal swabs (collected in a healthcare setting with instruction by a healthcare provider) to enable frontline healthcare workers to quickly identify and differentiate these similarly presenting infections. In addition to the new reagents for testing, a new assay script, **cobas** SARS-CoV-2 & Influenza A/B (SCFA) assay script version 1.0, is available for use with **cobas** Liat System software version 3.2.0 or higher.

Warning

- This test has not been FDA cleared or approved in the United States.
- This test has been authorized by FDA under an EUA for use by CLIA Certified Moderate and High-Complexity laboratories and Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.
- This test has been authorized only for the simultaneous qualitative detection and differentiation of nucleic acid from SARS-CoV-2, influenza A virus, and influenza B virus and not for any other viruses or pathogens.
- This test is only authorized in the United States for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

over...

☑ **cobas** Liat

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Assay Information

The **cobas®** SARS-CoV-2 & Influenza A/B assay, control, and approved sample collection media are listed below:

Product	Catalog Number
Assay	
cobas SARS-CoV-2 & Influenza A/B	09211101190
Control	
cobas SARS-CoV-2 & Influenza A/B Quality Control Kit	09211128190
Specimen Collection*	
Nasopharyngeal Swab Collection Kits	
Flexible minitip FLOQSwab with Universal Transport Media (UTM) from Copan Diagnostics	305C
BD Universal Viral Transport (UVT) 3-mL collection kit with a flocked flexible minitip swab	220531
Thermo Fisher Scientific Remel M4RT	R12565, R12566, R12567
Thermo Fisher Scientific Remel M4	R12550
Thermo Fisher Scientific Remel M5	R12555
Thermo Fisher Scientific Remel M6	R12563, R12568, R12569
Nasal Swab Collection Kits	
Regular FLOQSwab with Universal Transport Media (UTM) from Copan Diagnostics	306C
BD Universal Viral Transport (UVT) 3-mL collection kit with a regular flocked swab	220528

*This specimen collection material is not provided through Roche, but is available through other vendors.

Assay Script Installation Information

Confirm your system is running system software version 3.2.0 or higher by going to Settings > About Device > Versions. See Software Bulletin TP-00201 (available on diagnostics.roche.com for more information on software version 3.2.0.

If your system software version is not 3.2.0 or higher, you must update the system software. You can do so at no charge by contacting Roche Diagnostics Order Fulfillment at 1-800-428-5076.

The **cobas®** SARS-CoV-2 & Influenza A/B assay script (SCFA) is available via three different options:

1. Roche Remote Service Platform (Axeda)

If your **cobas®** Liat® systems are connected (Axeda), please contact the Roche Support Network Customer Support Center at 1-800-800-5973 and a Roche representative will help coordinate the script deployment through this method.

NOTE

You will be required to enter the Administrator password for the assay script upload via the remote service platform.

Analyzers connected to the Roche remote service platform benefit from remote installation of the assay script packages as well as automatic registration/activation of assay scripts. Installation information for customers using Roche remote service is described for any new script in the **cobas** Liat System Operator's Manual and **cobas** Liat User Assistance.

2. Digital Download

The downloadable script installation package contains a security signature file which ensures end-to-end integrity of the installation package up to, and including installation on the **cobas** Liat system. Any corrupt files will be rejected by the system.

To download the script package, a USB should be formatted with the following parameters:

Parameter	Value
USB formatting prior to copying the script package to USB	FAT32
USB allocation size	Minimum of 4 GB (recommend ≤ 32 GB)
USB version	Minimum of USB 2.0

The script installation package and instructions can be found at the following website:
https://liatsupport.roche.com/sarscov2flu/

3. Roche USB Drive (Key)

If you are unable to access the script via one of the first two options, you may order a Roche USB Key when placing your reagent order.

Order the USB key (catalog number 09260935001) from Roche. One USB key can be used to upgrade multiple **cobas** Liat systems.

For instructions on updating the software and/or installing the Assay Script, reference either of the following:

- **cobas** Liat Operator's Manual, Version 8.0, or
- **cobas** Liat User Assistance sections: *Updating the software* and *Installing and updating assays*

Registering the Assay Script

After installing the assay script, it must be registered within 30 days. You can use the unregistered assay during the registration period, but once this period has expired, the assay can no longer be used for testing until the activation is completed. Use the **cobas®** Liat® User Assistance or the **cobas** Liat Operator's Manual for instructions on registering the software and assay.

NOTE

If the analyzer is connected to the Roche remote service platform (i.e., Axeda), the analyzer automatically tries to register. If this automatic registration fails, a message is displayed and you may have to register the assay manually.

The best way to register your assay script is via the software registration portal. This will enable you to immediately receive your activation code. Please have the serial number and registration code ready for each **cobas** Liat system you register.

Follow the steps below to register your system software and assay script:

1. Go to the liatsupport.roche.com website and scroll down to the section that reads: *Ready for an update?*
2. Click on *Register software for update*.
3. Select your country of origin and select OK.
4. Select Assay Script Activation type.
5. Enter your registration key and a valid email address to receive email confirmation of the results.
6. Confirm agreement to email activation keys and select "Submit" to complete the form.

NOTE

Keep a list of your cobas Liat system serial numbers with the registration codes generated from your cobas Liat systems. This will enable accurate entry of the activation code generated from the cobas Liat website.

Documentation

Refer to the following documents on the diagnostics.roche.com website for further information:

- **cobas**® SARS-CoV-2 & Influenza A/B test Instructions for Use (IFU), document number 09216235001, Doc. Rev. 1.0
- Quick Reference Instructions, **cobas** SARS-CoV-2 & Influenza A/B nucleic acid test for use on the **cobas**® Liat® system, OS-01993-01
- **cobas** SARS-Cov-2 & Influenza A/B Nucleic Acid Test for use on the **cobas** Liat system Fact Sheet for Healthcare Providers
- **cobas** SARS-Cov-2 & Influenza A/B Nucleic Acid Test for use on the **cobas** Liat system Fact Sheet for Patients

Enclosure

Quick Reference Instructions, **cobas** SARS-CoV-2 & Influenza A/B nucleic acid test for use on the **cobas** Liat system, OS-01993

Action Required

File this Customer Bulletin for future reference.

Questions

As demand for COVID-19 testing continues to outpace supply, Roche has developed an allocation strategy and will continue to adapt prioritization of testing to support the highest patient impact. Please contact your Roche account representative if you have questions about the availability of the reagents or script for your laboratory.

Please contact the Roche Support Network Customer Support Center at 1-800-800-5973 if you need help registering your assay script or if you have questions about the information contained in the Customer Bulletin.