

# Customer Bulletin

Reagent     Software     Analyzer

## **cobas<sup>®</sup> SARS-CoV-2 Test – Expansion of Acceptable Sample Types**

### Information

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Roche is pleased to report that the U.S. Food and Drug Administration (FDA) has granted our request to update the Instructions for Use (IFU) of the **cobas** SARS-CoV-2 test, expanding sample collection and transport device claims. This updated IFU could help ease supply challenges associated with swabs and collection and transport media needed for SARS-CoV-2 testing.

The following updates have been made to the IFU for the **cobas** SARS-CoV-2 test (catalog number 09175431190):

- Expansion of specimen types to include **nasal specimens** (in addition to already granted nasopharyngeal and oropharyngeal specimens) collected according to standard collection technique using flocked or polyester-tipped swabs that are immediately placed in 3 mL of Copan Universal Transport Medium (UTM-RT)
- Clarification to use the **3 mL** volume Copan Universal Transport Medium (UTM-RT) and BD Universal Transport Medium (UVT) for specimen collection
- Expansion of specimen types and addition of specific **instructions for collecting** nasal swab specimens using the **cobas** PCR Media Uni Swab Sample Kit (catalog number 07958030190) or the **cobas** PCR Media Dual Swab Sample Kit (catalog number 07958021190)
- Expansion of specimen types to include nasal swab specimens collected according to standard collection technique using flocked or polyester-tipped swabs and immediately placed into **cobas** PCR Media tube from **cobas** PCR Media Kit (catalog number 06466281190)\*
- Expansion of specimen types to include nasal swab specimens collected according to standard collection technique using flocked or polyester-tipped swabs that are immediately placed in **3 mL of 0.9% physiological saline**
- Testing of clinician-instructed, self-collected (collected on site) and clinician-collected nasal swab specimens

The expanded sample collection and transport device claims for the **cobas** SARS-CoV-2 test to include 0.9% physiological saline, and clinician-instructed self-collected (collected on site) and clinician-collected nasal swab specimens in Copan UTM-RT or BD UVT do not require products from Roche. They represent viable options for the **cobas** SARS-CoV-2 test.

\*Not yet available in the U.S. - pending commercial launch and availability.

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## Information, continued

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Although the sample collection and transport device claims for the **cobas**<sup>®</sup> SARS-CoV-2 test are expanded to include the **cobas** PCR Media Uni Swab, **cobas** PCR Media Dual Swab, and **cobas** PCR Media Kits, **we are not able to take orders for these products for COVID-19 testing at this time due to limited supply.**

We continue to partner closely with all suppliers to help support unprecedented demand by offering more options (both from Roche and from other vendors) that customers can use for sample collection and transport devices.

Thank you for your continued, critical work to support providers and the patients we all serve.

## Documentation

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Refer to the following documents on the [diagnostics.roche.com](https://diagnostics.roche.com) website for further information:

- **cobas** SARS-CoV-2 test IFU, 09179917001-02EN, Doc Rev. 2.0
- FACT SHEET FOR HEALTHCARE PROVIDERS, COVID-19, **cobas** SARS-CoV-2 – Molecular Systems, Inc., MC US 06444

## Questions

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Please contact the Roche Support Network Customer Support Center at 1-800-526-1247 if you have questions about the information contained in this Customer Bulletin.

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