

FACT SHEET FOR HEALTHCARE PROVIDERS

Roche Molecular Systems, Inc.
cobas® SARS-CoV-2 Duo

June 14, 2022

Coronavirus
Disease 2019
(COVID-19)

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the cobas® SARS-CoV-2 Duo test.

The cobas® SARS-CoV-2 Duo test is authorized for use with certain respiratory specimens collected from individuals consistent with the Emergency Use Authorization (EUA).

All patients whose specimens are tested with this assay will receive the Fact Sheet for Patients: Roche Molecular Systems, Inc. - cobas® SARS-CoV-2 Duo.

What are the symptoms of COVID-19?

Many patients with COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, dyspnea), although some individuals experience only mild symptoms or no symptoms at all. The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that, when present, symptoms include cough, shortness of breath or dyspnea, fever, chills, myalgia, headache, sore throat, new loss of taste or smell, nausea or vomiting or diarrhea. Signs and symptoms may appear any time from 2 to 14 days after exposure to the virus, and the median time to symptom onset is approximately 5 days. For further information on the symptoms of COVID-19 please see the link provided in “*Where can I go for updates and more information?*” section.

Public health officials have identified cases of COVID-19 throughout the world, including the United States. Please check the CDC COVID-19 webpage (see link provided in “*Where can I go for updates and more information?*” section at the end of this document) or your local jurisdictions website for the most up to date information.

What do I need to know about COVID-19 testing?

Current information on COVID-19 for healthcare providers is available at CDC’s webpage, *Information for Healthcare Professionals* (see links provided in “*Where can I go for updates and more information?*” section).

This test is to be performed only using certain respiratory specimens- nasal (anterior nares and mid-turbinate) and nasopharyngeal swabs- collected from individuals consistent with the EUA.

- The cobas® SARS-CoV-2 Duo test is an automated real-time RT-PCR assay for the qualitative detection of SARS-CoV-2 RNA in healthcare provider instructed self-collected nasal (anterior nares and mid-turbinate) swab specimens (collected on site), and healthcare provider-collected nasal (anterior nares and mid turbinate) and nasopharyngeal swab specimens collected from individuals suspected of COVID-19 by their healthcare provider.
- This assay also performs quantitation of SARS-CoV-2 RNA levels in the collected specimen (listed above); however, only the qualitative result of the test is intended for use as an aid in the diagnosis of SARS-CoV-2 infection in patients suspected of COVID-19 by their healthcare provider.
- The cobas® SARS-CoV-2 Duo test reports SARS-CoV-2 RNA viral load in International Units (IU) per milliliter (mL), traceable to the World Health Organization (WHO) International Standard (IS) (NIBSC code: 20/146).
- The cobas® SARS-CoV-2 Duo test is authorized for use in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high or moderate complexity tests.

Specimens should be collected with appropriate infection control precautions. Current guidance is available at the CDC’s website (see links provided in “*Where can I go for updates and more information?*” section).

When collecting and handling specimens from individuals suspected of being infected with the virus that causes COVID-19, appropriate personal protective equipment should be used as outlined in the CDC *Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)*. For additional information,

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refer to CDC *Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons Under Investigation (PUIs) for Coronavirus Disease 2019 (COVID-19)* (see links provided in “Where can I go for updates and more information?” section).

What does it mean if the specimen tests positive for the virus that causes COVID-19?

A positive test result for SARS-CoV-2 indicates that RNA from SARS-CoV-2 was detected, and therefore the patient is infected with the virus and presumed to be contagious. Laboratory test results should always be considered in the context of clinical observations and epidemiological data (such as local prevalence rates and current outbreak/epicenter locations) in making a final diagnosis and patient management decisions. Patient management should be made by a healthcare provider and follow current CDC guidelines.

The **cobas**® SARS-CoV-2 Duo test reports the following results:

- “SARS-CoV-2 not detected.”: SARS-CoV-2 RNA is not detected in the sample.
- “SARS-CoV-2 detected, less than (Titer min).” Samples with this result are positive for SARS-CoV-2 and have very low SARS-CoV-2 RNA concentrations below 100 IU/mL.
- “SARS-CoV-2 detected, greater than (Titer max).” Samples with this result are positive for SARS-CoV-2 and have very high SARS-CoV-2 RNA concentrations above 1.00E+09 IU/mL (=1,000,000,000 IU/mL).
- “(Titer) of SARS-CoV-2 detected.” Samples with this result are positive for SARS-CoV-2 and will have SARS-CoV-2 RNA concentrations between 100 IU/mL and 1.00E+09 IU/mL as indicated by the provided concentration.

Clinical management of the patient should follow the clinical practice and public health recommendations for patients with positive and negative results, respectively. In the absence of respective clinical guidelines or recommendations from public health authorities, the public health and clinical implications of the quantitative SARS-CoV-2 RNA levels and assessment of SARS-CoV-2 RNA level

changes has not been established at this time and must be interpreted within the context of all relevant clinical and laboratory findings.

The **cobas**® SARS-CoV-2 Duo test has been designed to minimize the likelihood of false positive test results. However, it is still possible that this test can give a false positive result, even when used in locations where the prevalence is below 5%. In the event of a false positive result, risks to patients could include the following: a recommendation for isolation of the patient, monitoring of household or other close contacts for symptoms, patient isolation that might limit contact with family or friends and may increase contact with other potentially COVID-19 patients, limits in the ability to work, delayed diagnosis and treatment for the true infection causing the symptoms, unnecessary prescription of a treatment or therapy, or other unintended adverse effects.

All laboratories using this test must follow the standard testing and reporting guidelines according to their appropriate public health authorities.

What does it mean if the specimen tests negative for the virus that causes COVID-19?

A negative test result for this test means that SARS-CoV-2 RNA was not present in the specimen above the limit of detection. However, a negative result does not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions. It is possible to test a person too early or too late during SARS-CoV-2 infection to make an accurate diagnosis via **cobas**® SARS-CoV-2 Duo test.

In addition, asymptomatic people suspected of having COVID-19 may not shed enough virus to reach the limit of detection of the test, giving a false negative result. In the absence of symptoms, it is difficult to determine if asymptomatic people have been tested too late or too early. Therefore, negative results in asymptomatic individuals may include individuals who were tested too early and may become positive later, individuals who were tested too late and may have serological evidence of infection, or individuals who were never infected.

When diagnostic testing is negative, the possibility of a false negative result should be considered in the context

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of a patient's recent exposures and the presence of clinical signs and symptoms consistent with COVID-19. The possibility of a false negative result should especially be considered if the patient's recent exposures or clinical presentation indicate that COVID-19 is likely, and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative.

If COVID-19 is still suspected based on exposure history and clinical findings, retesting should be considered by healthcare providers in consultation with public health authorities.

Risks to a patient of a false negative test result include: delayed or lack of supportive treatment, lack of monitoring of infected individuals and their household or other close contacts for symptoms resulting in increased risk of spread of COVID-19 within the community, or other unintended adverse events.

What is an EUA?

The United States FDA has made this test available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of in vitro diagnostics (IVDs) for the detection and/or diagnosis of the virus that causes COVID-19.

An IVD made available under an EUA has not undergone the same type of review as an FDA-approved or cleared IVD. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives, and based on the totality of scientific evidence available, it is reasonable to believe that this IVD may be effective in diagnosing COVID-19.

The EUA for this test is in effect for the duration of the COVID-19 declaration justifying emergency use of IVDs, unless terminated or revoked (after which the test may no longer be used).

What are the approved available alternatives?

Any tests that have received full marketing status (e.g., cleared, approved), as opposed to an EUA, by FDA can

be found by searching the medical device databases here: <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases>. A cleared or approved test should be used instead of a test made available under an EUA, when appropriate and available. FDA has issued EUAs for other tests that can be found at: <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.

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CDC webpages:

General: <https://www.cdc.gov/coronavirus/2019-ncov/index.html>

Symptoms:

<https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html>

Healthcare Professionals:

<https://www.cdc.gov/coronavirus/2019-nCoV/hcp/index.html>

Information for Laboratories:

<https://www.cdc.gov/coronavirus/2019-nCoV/lab/index.html>

Laboratory Biosafety: <https://www.cdc.gov/coronavirus/2019-nCoV/lab-biosafety-guidelines.html>

Isolation Precautions in Healthcare Settings:

<https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html>

Specimen Collection: <https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html>

Infection Control: <https://www.cdc.gov/coronavirus/2019-ncov/php/infection-control.html>

FDA webpages:

General: www.fda.gov/novelcoronavirus

EUAs:(includes links to patient fact sheet and manufacturer's instructions) <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas>

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