FACT SHEET FOR HEALTHCARE PROVIDERS

Roche Molecular Systems, Inc.

cobas® SARS-CoV-2 & Influenza

Updated December 15, 2020

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 & Influenza A/B** assay.

Testing is to be conducted on specimens from individuals suspected of respiratory viral infection consistent with COVID-19 by their healthcare provider. Symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar.

What are the signs and symptoms of COVID-19?
Many patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, dyspnea). The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that symptoms include cough, shortness of breath or dyspnea, fever, chills, myalgias, headache, sore throat or new loss of taste or smell. Based on what is known about the virus that causes COVID-19, signs and symptoms may appear any time from 2 to 14 days after exposure to the virus, and the median incubation period is approximately 5 days. For further information on the symptoms of COVID-19 please see the link at the end of the document.

Public health officials have identified cases of COVID-19 throughout the world, including in 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) for the most up to date information.

All individuals whose specimens are tested with this assay must receive the *Fact Sheet for Patients: Roche Molecular Systems, Inc. - cobas® SARS-CoV- 2 & Influenza A/B.*

What are the signs and symptoms of influenza?
The signs and symptoms of influenza usually develop suddenly and are similar to those of COVID-19. Common signs and symptoms of influenza are fever, cough, sore throat, runny/stuffy nose, body aches, headaches, and fatigue.

This test is to be performed using healthcare provider-collected nasal and nasopharyngeal swab specimens and self-collected nasal swab specimens (collected in a healthcare setting with instruction by a healthcare provider) from individuals suspected of respiratory viral infection consistent with COVID-19 by their healthcare provider.

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).

The **cobas®** SARS-CoV-2 & Influenza A/B assay:

- can be used to test healthcare provider-collected nasopharyngeal or nasal swab specimens, and self-collected nasal swab specimens (collected in a healthcare setting with instruction from a healthcare provider).
- can be ordered for the detection and differentiation of nucleic acid from SARS-CoV-2, influenza A, and/or influenza B viruses in individuals suspected of respiratory viral infection consistent with COVID-19 by their healthcare provider.
- 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 moderate or high complexity tests.

Specimens should be collected using 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 at the end of this document).

When collecting and handling specimens from individuals suspected of being infected with 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, refer to the CDC *Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19) (*see links provided in "Where can I go for updates and more information" section at the end of this document).

What does it mean if the specimen tests positive for SARS-CoV-2, the virus that causes COVID-19?
A positive test result for SARS-CoV-2 indicates that RNA from this virus was detected, and therefore the patient is infected with the virus and is presumed to be contagious. Laboratory test results should always be considered in the context of clinical findings and observations and epidemiological data in making a final diagnosis. Patient management decisions should be made by a healthcare provider and follow current CDC guidelines.

The **cobas**® SARS-CoV-2 & Influenza A/B assay has been designed to minimize the likelihood of false-positive test results. However, in the event of a false-positive result, risks to individuals 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 might increase contact with other individuals with COVID-19, limits in the ability to work, delayed diagnosis and treatment for the actual infection causing the symptoms, and unnecessary prescription of a treatment or therapy.

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

What does it mean if the specimen tests negative for SARS-CoV-2, the virus that causes COVID-19?
A negative test result for SARS-CoV-2 means that RNA from this virus 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.

When diagnostic testing results are negative, the possibility of a false-negative result should be considered in the context 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 test results for other causes of illness (e.g., other respiratory illnesses) 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 an individual from a false-negative **cobas**® SARS-CoV-2 & Influenza A/B assay result include delayed or lack of supportive treatment; lack of monitoring of infected patients 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 does it mean if the specimen tests positive for influenza A and/or B viruses?
A positive test result for influenza A virus or influenza B virus indicates that RNA from one or both of these viruses was detected, the patient is infected with the virus(es) and is presumed to be contagious. Laboratory test results should always be considered in the context of clinical findings and observations and epidemiological data in making a final diagnosis. Patient management decisions should be made by a healthcare provider and follow current CDC guidelines.

The **cobas**® SARS-CoV-2 & Influenza A/B assay has been designed to minimize the likelihood of false-positive test results. However, in the event of a false-positive result, risks to individuals 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 of friends, limits in the ability to work, delayed diagnosis and treatment for the true infection causing the symptoms, unnecessary prescription of an antiviral medication or other therapy, or other unintended adverse effects.

What does it mean if the specimen tests negative for influenza viruses?
A negative test result for influenza viruses means that influenza A and/or B RNA was not present in the specimen above the limit of detection. However, a negative result does not rule out influenza virus infection and should not be used as the sole basis for treatment or patient management decisions.

When diagnostic testing results are negative, the possibility of a false-negative result should be considered in the context of a patient's recent exposures and the presence of clinical signs and symptoms consistent with influenza. The possibility of a false-negative result should especially be considered if the patient's recent exposures or clinical presentation indicate that influenza is likely, and diagnostic test results for other causes of illness (e.g., other respiratory illness) are negative. If influenza is still suspected based on exposure history and clinical findings, re-testing should be considered by healthcare providers in consultation with public health authorities.

Risks to a individuals from a false-negative **cobas**® SARS-CoV-2 & Influenza A/B result for influenza A or B include: delayed or lack of supportive treatment; lack of monitoring of infected patients and their household or other close contacts for symptoms, resulting in increased risk of spread of influenza within the community; or other unintended adverse events.

Laboratory test results should always be considered in the context of clinical findings and observations and/or epidemiological data in making a final diagnosis. Patient management decisions should be made by a healthcare provider and follow current CDC guidelines. Results (positive and negative) for influenza should be interpreted with caution. If an influenza result is inconsistent with clinical presentation and/or other clinical and epidemiological information, FDA-cleared Influenza NAATs are available for confirmation if clinically indicated.

What does it mean if the specimen tests positive for SARS-CoV-2 and one or both influenza (A and/or B) viruses? Is co-infection possible?

Yes, it is possible for an individual to be infected with influenza A virus, influenza B virus, and/or SARS-CoV-2 simultaneously. A positive test result for the viruses that cause COVID-19 and influenza A and/or B indicates that RNA from these viruses was detected, the patient may be co-infected, and is presumed to be contagious. Laboratory test results should always be considered in the context of clinical findings and observations and epidemiological data in making a final diagnosis. Patient management decisions should be made with a healthcare provider and follow current CDC guidelines.

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 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 the detection of the virus that causes 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?
FDA has approved/cleared certain influenza tests, however there are no approved available alternative tests for the combined detection and differentiation of nucleic acid from SARS-CoV-2, influenza A, and/or influenza B viruses. 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.

Where can I go for updates and more information?

CDC webpages:

COVID-19:
General: https://www.cdc.gov/COVID19

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

Healthcare Professionals:
https://www.cdc.gov/coronavirus/2019- nCoV/guidance-hcp.html

Information for Laboratories: https://www.cdc.gov/coronavirus/2019-nCoV/guidance-laboratories.html

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

Isolation Precautions in Healthcare Settings:
https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html

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

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

Influenza:
https://www.cdc.gov/flu/index.htm

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/vitro-diagnostics-euas

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Report Adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) or by calling **1-800-FDA-1088**