

Xpert Xpress SARS CoV 2/Flu/RSV

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the Xpert Xpress SARS-CoV-2/Flu/RSV test.

The Xpert Xpress SARS-CoV-2/Flu/RSV test is authorized for use with certain respiratory specimens collected from individuals suspected of respiratory viral infection consistent with COVID-19 by their healthcare provider.

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,

FACT SHEET FOR HEALTHCARE PROVIDERS

Cepheid

Updated: October

302-4508 Rev. B

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**

FACT SHEET FOR HEALTHCARE PROVIDERS

Cepheid

Xpert Xpress SARS CoV 2/Flu/RSV

Updated: October 1, 2020

Coronavirus
Disease 2019
(COVID 19)

What does it mean if the specimen tests negative for influenza A, influenza B and/or RSV?

A negative test result for influenza A, influenza B, and/or RSV means that influenza A, influenza B and/or RSV RNA was not present in the specimen above the limit of detection. However, a negative result does not rule out influenza A, influenza B, and/or RSV 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 has been exposed to someone with influenza-like illness (ILI) or if the patient has symptoms consistent with influenza.

For more information, visit <https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home> or call 1-800-FDA-1088.

FACT SHEET FOR HEALTHCARE PROVIDERS

Cepheid

Updated: October 1, 2020

Xpert Xpress SARS CoV 2/Flu/RSV

302-4508 Rev. B

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**