BD VERITOR™ SYSTEM FOR RAPID DETECTION OF SARS-COV2 & FLU A+B

Becton, Dickinson and Company (BD)

All individuals whose specimens are tested with this product will receive the Fact Sheet for Patients for the product.

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This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the BD Veritor System for Rapid Detection of SARS-CoV2 & Flu A+B.

WHERE CAN I GO FOR GENERAL INFORMATION ON COVID-19 AND INFLUENZA?

For general information on COVID-19 and influenza, including the symptoms of COVID-19 and influenza, infection control precautions, and other information please check the CDC COVID-19 and influenza webpages (see links provided in "*Where can I go for updates and more information?*" section at the end of this document) or your local jurisdiction's website for the most up to date information.

WHAT DO I NEED TO KNOW ABOUT COVID-19 AND INFLUENZA TESTING WITH THIS PRODUCT?

- The BD Veritor System for Rapid Detection of SARS-CoV2 & Flu A+B can be used to test anterior nasal swab samples.
- The BD Veritor System for Rapid Detection of SARS-CoV2 & Flu A+B should be ordered for the detection and differentiation of SARS-CoV-2, influenza A and influenza B antigens by a healthcare provider.
- The BD Veritor System for Rapid Detection of SARS-CoV2 & Flu A+B is authorized for use in individuals who are suspected of a viral respiratory infection consistent with COVID 19 by a healthcare provider within the first six (6) days of symptom onset when tested at least twice over three days with at least 48 hours between tests.
- Consistent with serial testing recommendations for SARS-CoV-2, for multi-analyte tests such as the BD Veritor System for Rapid Detection of SARS-CoV2 & Flu A+B, symptomatic individuals who test positive for influenza A or B on the initial test but test negative for SARS-CoV-2 should be tested again in 48 hours to evaluate for co-infection with SARS-CoV-2. Please refer to the healthcare provider instructions for use for more information on serial testing.
- The BD Veritor System for Rapid Detection of SARS-CoV2 & Flu A+B 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, high or waived complexity tests.
- The BD Veritor System for Rapid Detection of SARS-CoV2 & Flu A+B is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.
- Please refer to the BD Veritor System for Rapid Detection of SARS-CoV2 & Flu A+B Instructions for Use for additional information.
- There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to the lower sensitivity of the test technology. This means that there is a higher chance this test will give a false negative result in an individual with COVID-19 or influenza as compared to a molecular test, especially in samples with low viral load.

Specimens should be collected with appropriate infection control precautions. 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, refer to CDC *Interim Guidelines for Collecting and Handling of Clinical Specimens for COVID-19 Testing.*

WHAT DOES IT MEAN IF THE SPECIMEN TESTS POSITIVE FOR SARS-COV-2, INFLUENZA A, OR INFLUENZA B VIRUSES?

A positive test result for COVID-19 or influenza indicates that antigens from either SARS-CoV-2, influenza A or influenza B were detected, and therefore the individual being tested 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 determining individual diagnosis and patient management decisions and should follow current CDC guidelines.

The BD Veritor System for Rapid Detection of SARS-CoV2 & Flu A+B has been designed to minimize the likelihood of false positive test results. However, in the event of a false positive result, risks could include the following: a needless recommendation for the patient to isolate that might limit contact with family or friends and the ability to work, delayed diagnosis and treatment for the true infection causing the patient's symptoms, potentially increased likelihood that the patient could contract COVID-19 or influenza from other potentially COVID-19 or influenza positive patients isolated in the same areas, unnecessary prescription of a treatment or therapy, needless monitoring of close contacts for symptoms, or other unintended adverse effects. False positive results for any virus are more likely when prevalence of that virus in the community are low.

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 SARS-COV-2, INFLUENZA A, AND INFLUENZA B VIRUSES?

COVID-19 negative samples should be repeated as per the FDA Serial Testing Guidance (see link provided in "*Where can I go for updates and more information?*" section at the end of this document). A negative serial test result for this test means that SARS-CoV-2, influenza A and influenza B antigens were not present in the specimen above the limit of detection. All SARS-CoV-2 negative results are presumptive and confirmation with a molecular assay, if necessary for patient management, may be performed. All negative influenza A and B test results are presumptive. It is recommended these results be confirmed by an FDA-cleared influenza A and B molecular assay. However, a negative result does not rule out COVID-19 or influenza and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions (such as discontinuation of isolation precautions). Antigen tests are known to be less sensitive than molecular tests that detect viral nucleic acids.

It is possible to test a person too early or too late during SARS-CoV-2, influenza A or influenza B infection to make an accurate diagnosis via the BD Veritor System for Rapid Detection of SARS-CoV2 & Flu A+B.

The amount of antigen in a sample may decrease as the duration of illness increases. For COVID-19 testing, specimens collected after day six (6) of illness may be more likely to be negative compared to a RT-PCR assay. Therefore, negative SARS-CoV-2 results from patients with symptom onset beyond six (6) days should be treated as presumptive and confirmed with a molecular assay, if necessary, for patient management.

When diagnostic testing is negative, the possibility of a false negative result should be considered in the context of an individual's recent exposures and the presence of clinical signs and symptoms consistent with COVID-19 or influenza. The possibility of a false negative result should especially be considered if the individual's recent exposures or clinical presentation indicate that COVID-19 or influenza is likely, and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative. If COVID-19 or influenza is still suspected based on exposure history together with other clinical findings, re-testing or testing with molecular methods should be considered by healthcare providers in consultation with public health authorities. Additional testing may be helpful to ensure testing was not conducted too early.

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 COVID-19 or influenza spread within the community, or other unintended adverse events.

For additional recommendations regarding infection control, refer to CDC's *Ending Isolation and Precautions for People with COVID-19: Interim Guidance* and CDC's general isolations precautions webpage (see links provided in "*Where can I go for updates and more information*?" section).

The performance of this test was established based on the evaluation of a limited number of clinical specimens collected in October 2020. The clinical performance has not been established in all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 or influenza and their prevalence, which change over time.

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 antigens from these viruses were 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 DO I NEED TO KNOW ABOUT SERIAL TESTING?

Serial testing of individuals whose initial COVID-19 test result is negative assists in identifying infected individuals earlier and facilitate timely infection control practices. A negative test result for

COVID-19 does not rule out infection in symptomatic individuals; repeating testing twice over three days with at least 48 hours between tests may decrease the risks of false negative results. If COVID-19 infection is still suspected based on symptoms, exposures, or other factors, additional testing with a laboratory-based molecular test should be considered.

For additional recommendations regarding confirmation of antigen test results, please refer to the CDC's *Guidance for Antigen Testing for SARS-CoV-2 for Healthcare Providers Testing Individuals in the Community* (see links provided in "*Where can I go for updates and more information*" section).

WHAT IS AN EUA?

The U.S. 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 the declaration is terminated or authorization is revoked sooner.

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.

WHERE DO I REPORT ADVERSE EVENTS?

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**

WHERE CAN I GO FOR UPDATES AND MORE INFORMATION?

CDC COVID-19 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/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

Discontinuation of Isolation: https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html

Antigen Testing: https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html

CDC WEBPAGES

Flu General: https://www.cdc.gov/flu/index.htm

Infection Control – Isolation Precautions: https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.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

Serial Testing: https://www.fda.gov/medical-devices/safety-communications/home-covid-19-antigen-tests-take-steps-reduce-your-risk-false-negative-results-fda-safety

BD INTEGRATED DIAGNOSTIC SOLUTIONS:

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Technical Support:

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