FACT SHEET FOR HEALTHCARE PROVIDERS

BD Veritor™ System for Rapid Detection of SARS-CoV-2

BD Updated: December 2, 2021

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 BD Veritor™ System for Rapid Detection of SARS-CoV-2.

The BD Veritor™ System for Rapid Detection of SARS-CoV-2 is authorized for use with direct anterior nasal swab specimens collected from individuals who are suspected of COVID-19 by their healthcare provider within the first five days of the onset of symptoms or from individuals without symptoms or other epidemiological reasons to suspect COVID-19, when tested twice over two or three days with at least 24 hours and no more than 48 hours between tests.

This test is to be performed only using direct anterior nasal swab specimens collected from individuals who are suspected of COVID-19 by their healthcare provider within the first five days of the onset of symptoms or from individuals without symptoms or other epidemiological reasons to suspect COVID-19, when tested twice over two or three days with at least 24 hours and no more than 48 hours between tests.

All patients whose specimens are tested with this assay will receive the Fact Sheet for Patients: The BD Veritor™ System for Rapid Detection of SARS-CoV-2.

What are the 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 may include cough, shortness of breath or dyspnea, fever, chills, fatigue, myalgias, headache, sore throat, new loss of taste or smell, congestion or runny nose, nausea or vomiting, diarrhea. COVID-19 can present with a mild to severe illness, although some people infected with COVID-19 may have no symptoms at all. 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. Based on preliminary data, the median incubation period is approximately 5 days, but may range 2-14 days. For further information on the symptoms of COVID-19 please see the link provided in the "*Where can I go for updates and more information?*" section.

Public health officials have identified cases of COVID-19 infection throughout the world, including Canada which may pose risks for public health. Please check the Public Health Agency of Canada (PHAC) webpage for up to date information 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 PHAC's webpage, *Information for Health Professionals* (see links provided in "Where can I go for updates and more information" section).

- The BD Veritor™ System for Rapid Detection of SARS-CoV-2 can be used to test freshly collected anterior nasal swab samples directly using a dual nares collection (swab inserted in both nares, 5 rotations per naris).
- The BD Veritor™ System for Rapid Detection of SARS-CoV-2 should be ordered for the detection of COVID-19 in individuals who are suspected of COVID-19 by their healthcare provider and who are within the first five days of onset of symptoms or in individuals without symptoms or other epidemiological reasons to suspect COVID-19, when tested twice over two (or three) days with at least 24 hours (and no more than 48 hours) between tests.
- The BD Veritor™ System for Rapid Detection of SARS-CoV-2 has been authorized for sale in Canada under Interim Order;
- This test is only authorized for the duration of the Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19,

unless the authorization is terminated or revoked sooner

- This test has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.

Specimens should be collected with appropriate infection control precautions. Current guidance for COVID-19 infection control precautions are available at the Public Health Agency of Canada's website (see links provided in "Where can I go for updates and more information" section).

Use appropriate personal protective equipment when collecting and handling specimens from individuals suspected of having COVID-19 as outlined in the Public Health Agency of Canada's Interim Guidance for Acute Healthcare Settings. For additional information, refer to PHAC's *Interim Guidance for Patient care and infection prevention and control measures* (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 COVID-19 indicates that antigens from SARS-CoV-2 were detected, and the patient is infected with the virus and presumed to be contagious. Diagnostic test results should always be considered in the context of clinical observations and epidemiological data in making a final diagnosis and patient management decisions. Patient management should follow current PHAC guidelines.

The BD Veritor™ System for Rapid Detection of SARS-CoV-2 has been designed to minimize the likelihood of false positive test results. However, 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, the 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 antigens from SARS-CoV-2 were 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, including infection control decisions. Antigen tests are known to be less sensitive than molecular tests that detect viral nucleic acids.

The amount of antigen in a sample may decrease as the duration of illness increases. In symptomatic patients, specimens collected after day 5 of illness may be more likely to be negative compared to a RT-PCR assay. Therefore, negative results 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 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 together with other clinical findings, re-testing or testing with molecular methods should be considered by healthcare providers in consultation with public health authorities.

Risks to a patient from a false negative result include: delay 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.

A negative antigen test should not be the sole basis used to determine if a patient can end isolation precautions. For additional recommendations regarding infection control, refer to PHAC's Public health management of cases and contacts associated with COVID-19 (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 the month of June 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 and their prevalence, which change over time.

What do I need to know about Serial Testing in Asymptomatic Individuals?

In asymptomatic patients, serial testing may assist in identifying infected individuals and facilitate timely infection control practices. A negative test result does not rule out infection but repeat testing over two or three days may decrease the risks of false negative results. Additional clinical studies are underway to assess the performance of rapid antigen tests when used with serial testing. An initial negative test result should be the first of a minimum of two tests. An asymptomatic individual undergoing serial testing with two or more negative results may require ongoing serial testing or confirmatory testing, depending on patient history and potential exposures. An asymptomatic individual undergoing serial testing with one or more positive results indicates that SARS-CoV-2 antigen is present but does not rule out coinfection with other pathogens.

Additional confirmatory testing with a molecular test for negative results may be necessary if there is a high likelihood of SARS-CoV-2 infection, such as an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of SARS-CoV-2 infection, such as in individuals without known exposures to SARS-CoV-2 or residing in communities with low prevalence of infection. For additional recommendations regarding confirmation of antigen test results, please refer to the PHAC's interim guidance for the use of rapid antigen detection testing for the identification of SARS-CoV-2 infection.

What is the Interim Order?

Health Canada has made this test available under an expedited authorization pathway called an Interim Order. The interim order is for new COVID-19 medical devices that are not yet licensed in Canada, COVID-19 related uses for existing devices licensed under the Medical Devices Regulations or Interim Order No. 2, and COVID-19 medical devices that leverage an authorization of a device from a trusted foreign regulatory authority, whereby the Minister would maintain the ability to request additional information on a case-by-case basis.

An authorization under Interim Order No. 2 will be granted only if Health Canada determines that there is an urgent public health need for the importation or sale of the COVID-19 medical device.

This expedited authorization for sale or import does not apply to medical device licences which are currently suspended on the grounds of safety or effectiveness concerns. It is not intended to permit sale or import of previously licensed medical devices with identified safety or effectiveness concerns.

What are the approved available alternatives?
There are no approved available alternative antigen tests. Any tests that have received full marketing status (e.g., cleared, approved), as opposed to an interim order, by Health Canada can be found by searching the medical device databases here: https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/medical-devices/authorized.html. PHAC has issued other devices approved for use other than testing and can be found at: https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/medical-devices/authorized/other.html

Where can I go for updates and more information?

Public Health Agency of Canada Webpages:

Healthcare Professionals:
https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/health-professionals.html
Laboratory Biosafety:
https://www.canada.ca/en/services/health/biosafety-biosecurity/covid-19-biosafety-information-laboratories.html
Prevention and Management in Healthcare Settings: https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/prevention-risks.html
Specimen Collection:
https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/health-professionals/infection-prevention-control-covid-19-second-interim-guidance.html#a10
Infection Control: https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/health-professionals/infection-prevention-control-covid-19-second-interim-guidance.html

PHAC webpages:

General: https://www.canada.ca/en/public-health/services/diseases/coronavirus-disease-covid-19.html
Interim Order: https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/interim-order-import-sale-advertising-drugs.html

BD Integrated Diagnostic Solutions:

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Technical Support:
BD Canada Customer Technical Support: 1-800-638-8663