This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the Detect Covid-19 Test.

The Detect Covid-19 Test is a molecular diagnostic test for the qualitative detection of nucleic acid from the novel coronavirus SARS-CoV-2 that causes COVID-19. This test is authorized for non-prescription home use with self-collected anterior nasal (nasal) swab samples from individuals aged 14 years or older suspected of COVID-19. This test is also authorized for non-prescription home use with adult-collected anterior nasal swab samples from individuals aged 2 years or older suspected of COVID-19.

This test is also authorized for non-prescription home use with self-collected anterior nasal (nasal) swab samples from individuals aged 14 years or older, or adult collected anterior nasal swab samples from individuals aged 2 years or older, without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests.

All individuals whose specimens are tested with this test will have access to the Fact Sheet for Individuals: Detect, Inc. - Detect Covid-19 Test.

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 include cough, shortness of breath or dyspnea, fever, chills, myalgias, headache, sore throat or new loss of taste or smell. 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. For further information on the symptoms of COVID-19 please see the link

This test is to be performed only using self-collected or adult-collected anterior nasal swab samples from either individuals suspected of COVID-19 OR individuals without symptoms or other epidemiological reasons to suspect COVID-19, when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests. This test is authorized for non-prescription home use with self-collected anterior nasal swab samples from individuals aged 14 years or older or with adult-collected anterior nasal swab samples from individuals aged 2 years or older.

provided in the "*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, which may pose risks for public health. Please check the CDC webpage for the most up to date information. 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).

- The Detect Covid-19 Test is authorized for non-prescription home use with self-collected anterior nasal (nasal) swab samples from individuals aged 14 years or older suspected of COVID-19.
- The Detect Covid-19 Test is authorized for non-prescription home use with adult-collected anterior nasal swab samples from individuals aged 2 years or older suspected of COVID-19.
- The Detect Covid-19 Test is also authorized for non-prescription home use with self-collected anterior nasal (nasal) swab samples from individuals aged 14 years or older, or adult collected anterior nasal

swab samples from individuals aged 2 years or older, without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between 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, 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 COVID-19 indicates that RNA from SARS-CoV-2 was detected, and the individual is infected with the virus and presumed to be contagious. COVID-19 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 decisions should be made by a healthcare provider and follow current CDC guidelines.

The Detect Covid-19 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 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 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 healthcare providers 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 test 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. It is possible to test a person too early or too late during SARS-CoV-2 infection to make an accurate diagnosis via the Detect Covid-19 Test.

In addition, asymptomatic people infected with 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. Negative results with the Detect Covid-19 Test in an asymptomatic individual are presumptive and confirmation with a molecular assay performed in a laboratory, if necessary, for patient management may be performed.

The performance of this test was established based on the evaluation of a limited number of clinical specimens. 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 overtime.

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 an alternative method 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 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 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 CDC's *Discontinuation of Isolation for Persons with COVID-19 Not in Healthcare Settings* (Interim Guidance) (see links provided in "*Where can I go for updates and more information?*" section).

NOTE: False negative results are possible in individuals who take high dose biotin (vitamin B7) supplements. Consider testing with different molecular test for individuals that are reporting Biotin usage and have obtained a negative result with the Detect Covid-19 Test. In addition, invalid results may occur in individuals using certain nasal sprays used to fight allergies such as dexamethasone or flunisolide-containing products.

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. 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 RNA is present, but does not rule out coinfection with other pathogens.

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 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 it is terminated, or authorization is revoked (after which the test may no longer be used).

What are the approved available alternatives?
There are no approved available alternative at-home testing kits. 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-

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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.

What is the performance of the Detect Covid-19 Test?

For performance of the Detect Covid-19 Test please refer to the test's instructions for use posted on FDA's webpage: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2

Where can I go for updates and more information?

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 fact sheet for individuals 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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