This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the VITROS Immunodiagnostic Products SARS-CoV-2 Antigen Reagent Pack test.

The VITROS Immunodiagnostic Products SARS-CoV-2 Antigen Reagent Pack test authorized for use using nasopharyngeal and anterior nasal swab specimens collected from individuals who are suspected of COVID-19 by their healthcare provider within seven days of the onset of symptoms.

All patients whose specimens are tested with this assay will receive the Fact Sheet for Patients: Ortho-Clinical Diagnostics, Inc. – VITROS SARS-CoV-2 Antigen Reagent Pack.

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, when present, symptoms include cough, shortness of breath or dyspnea, fever, chills, myalgias, headache, sore throat, new loss of taste or smell, nausea or vomiting or diarrhea. Signs and symptoms may appear any time from 2 to 14 days after exposure to the virus, and the median time to symptom onset is approximately 5 days. For further information on the symptoms of COVID-19 please see the link provided in “Where can I go for updates and more information?” section.

Public health officials have identified cases of COVID-19 infection throughout the world, including 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) or your local jurisdiction’s website for the most up to date information.

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 COVID-19, appropriate personal protective equipment should be used as outlined in the CDC Interim Laboratory Guidelines.

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.
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 therefore the patient 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 making a final diagnosis and patient management decisions. Patient management should be made by a healthcare provider and follow current CDC guidelines.

The VITROS SARS-CoV-2 Antigen Reagent Pack test has been designed to minimize the likelihood of false positive test results. 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, 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 with this test means that SARS-CoV-2 antigens 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. Specimens collected after day 7 of illness may be more likely to be negative compared to a RT-PCR assay. Therefore, negative results are presumptive and confirmation with a molecular assay, if necessary, for patient management may be performed. It is possible to test a person too early or too late during COVID-19 infection to make an accurate diagnosis via the VITROS SARS-CoV-2 Antigen Reagent Pack test. 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 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 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 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).

The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between September 2020 and November 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 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 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 at
diagnosing recent or prior infection with SARS-CoV-2 by
identifying individuals with an adaptive immune response
to 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?
There are no approved available alternative tests. 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:
General: https://www.cdc.gov/COVID19
Symptoms: https://www.cdc.gov/coronavirus/2019-ncov/symptoms-
testing/symptoms.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
Discontinuation of Isolation: https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-
isolation.html

FDA webpages:
General: www.fda.gov/novelcoronavirus
EUA:(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

Distributor Contact Information:
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