# FACT SHEET FOR HEALTHCARE PROVIDERS

**VITROS Immunodiagnostic Products Anti-SARS-CoV2 Total Reagent Pack**
**Ortho-Clinical Diagnostics, Inc.** **Updated: May 9, 2020**

**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 VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack test.

The VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack test is authorized for the detection of total antibody (including IgG, IgA and IgM) to SARS-CoV-2 in human serum and plasma (K2 EDTA).

**All individuals whose specimens are tested with this assay will receive the Fact Sheet for Recipient: *VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack test*.**

**What are the symptoms of COVID-19?**
Many individuals with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing). However, limited information is currently available to characterize the full spectrum of clinical illness associated with COVID-19. 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.

Public health officials have identified cases of COVID-19 infection throughout the world, including the United States, which poses risks to public health. Please check the CDC webpage 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).

**This test measures total human SARS-CoV-2 antibodies, that are generated as part of the adaptive immune response to the virus and is to be performed only using serum and EDTA plasma specimens.**

- The VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack test can be used to test serum and EDTA plasma specimens.
- The VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack test can be ordered by a healthcare provider to detect if there has been an adaptive immune response to COVID-19, indicating a recent or prior infection.
- The VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack test is only authorized for use in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform moderate or high complexity tests.

Specimens should be collected with appropriate infection control precautions. Current guidance for COVID-19 infection control precautions are available at the CDC'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 being infected with COVID-19 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 SARS-CoV-2 antibody?**
A positive test result with the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack test indicates that antibodies to SARS-CoV-2 were detected,

and the individual has potentially been exposed to COVID-19.

The VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack test detects total antibody as indicative of an adaptive immune response to SARS-CoV-2 infection in individuals suspected of SARS-CoV-2 infection.

The VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total assay detects the presence of IgM, IgA, and/or IgG antibodies but does not identify each separately. IgM antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although levels over the course of infection are not well characterized. IgG antibodies to SARS-CoV-2 become detectable later following infection, although detection of IgG antibodies does not exclude recently infected individuals who are still contagious. Positive results for both IgG and IgM could occur after infection and can be indicative of acute or recent infection. It is unknown how long IgM, IgA, and/or IgG antibodies to SARS-CoV-2 will remain present in the body after infection and if they confer immunity to infection.

A positive result with VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack test may not mean that a individual's current symptoms are due to COVID-19 infection. Laboratory test results should always be considered in the context of clinical observations and epidemiological data in making a final diagnosis and patient management decisions.

The VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack test has been designed to minimize the likelihood of false positive test results. However, in the event of a false positive result, risks to individuals could include the following: a recommendation for isolation of the individual, monitoring of household or other close contacts for symptoms, individual isolation that might limit contact with family or friends and may increase contact with other potentially COVID-19-infected individuals, 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 standard confirmatory 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 antibody?**

A negative test result with this test means that SARS-CoV-2 specific antibodies 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, patient management decisions, or to rule out active infection.

Individuals tested early after infection may not have detectable total antibody despite active infection; in addition, not all individuals will develop a detectable total antibody response to SARS-CoV-2 infection. The absolute sensitivity of the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack test is unknown.

When diagnostic testing is negative, the possibility of a false negative result should be considered in the context of a individual'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 individual's recent exposures or clinical presentation indicates that COVID- 19 is likely and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative. Direct testing for virus (e.g., PCR testing) should always be performed in any individual suspected of COVID-19, regardless of the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack test result.

Risks to a individual of a false negative 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.

**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 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 the detection of 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).

## Where can I go for updates and more information?

**CDC webpages:**
**General:** https://www.cdc.gov/COVID19
**Healthcare Professionals:**
https://www.cdc.gov/coronavirus/2019-nCoV/guidance-hcp.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

**FDA webpages:**
**General:** www.fda.gov/novelcoronavirus
**EUAs:**(includes links to recipient fact sheet and manufacturer's instructions) https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations

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**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**