FACT SHEET FOR HEALTHCARE PROVIDERS

Thermo Fisher Scientific
OmniPATH COVID-19 Total Antibody ELISA Test **October 2, 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 OmniPATH COVID-19 Total Antibody ELISA Test.

You should not interpret the results of this test as an indication or degree of immunity or protection from reinfection.

OmniPATH COVID-19 Total Antibody ELISA Test is authorized for the detection of total antibodies (including IgM/IgG/IgA) to SARS-CoV-2 in human serum.

All individuals whose specimens are tested with this assay will receive the Fact Sheet for Recipients: OmniPATH COVID-19 Total Antibody ELISA Test.

What are the symptoms of COVID-19?
Many individuals with COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g. cough, difficulty breathing), 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 symptoms include cough, shortness of breath or difficulty breathing, fever, chills, muscle pain, 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 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.

This test measures total human SARS-CoV-2 antibodies that are generated as part of the adaptive immune response to COVID-19 and is to be performed only using human serum.

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 OmniPATH COVID-19 Total Antibody ELISA Test can be ordered by healthcare providers to test human serum specimens to detect if there has been an adaptive response to COVID-19, indicating a recent or prior infection.
- The OmniPATH COVID-19 Total Antibody ELISA Test should not be used to diagnose or exclude acute infection and should not be used as the sole basis for treatment or patient management decisions. Direct testing for SARS-CoV-2 should be performed if acute infection is suspected.
- The OmniPATH COVID-19 Total Antibody ELISA Test 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 (automated method) or high (manual and automated method) complexity tests.
- Please refer to the OmniPATH COVID-19 Total Antibody ELISA Test instructions for use for additional 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 Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019*

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**

(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 total human SARS-CoV-2 antibodies?
A positive test result with the OmniPATH COVID-19 Total Antibody ELISA Test indicates that antibodies to SARS-CoV-2 were detected, and the individual has potentially been exposed to COVID-19.

Antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection. Individuals may have detectable virus present for several weeks following seroconversion. If antibodies are present, it often indicates past infection but does not exclude recently infected patients who are still contagious.

It is unknown how long antibodies to SARS-CoV-2 will remain present in the body after infection and if they confer immunity to infection.

Incorrect assumptions of immunity may lead to premature discontinuation of physical distancing requirements and increase the risk of infection for individuals, their households, and the public.

Regardless of the test result, individuals should continue to follow CDC guidelines to reduce the risk of infection, including social distancing and wearing masks.

False positive results may occur due to cross-reactivity from pre-existing antibodies or other possible causes.

The OmniPATH COVID-19 Total Antibody ELISA 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: risk of infection by exposure to persons with active COVID-19. If a recent infection is suspected a false positive result may lead to a recommendation for isolation of the individual, monitoring of household or other close contacts for symptoms, isolation that might limit contact with family or friends and may increase contact with other potentially COVID-19 individuals, limits in the ability to work, or other unintended adverse effects.

Due to the risk of false positive results, confirmation of positive results should be considered – using a second, different antibody assay that detects the same type of antibodies.

Laboratory test results should always be considered in the context of clinical observations and epidemiological data in making patient management decisions.

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 total human SARS-CoV-2 antibodies?
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, individuals tested early after infection may not have detectable antibodies despite active infection; in addition, it is not certain that all infected patients will develop a detectable antibody response to SARS-CoV-2 infection. A negative result should not be used to rule out infection. Direct testing of SARS-CoV-2 should be performed if acute infection is suspected.***

The absolute sensitivity of the OmniPATH COVID-19 Total Antibody ELISA Test is unknown.

Risks to an individual of a false negative result include: restriction of activities potentially deemed acceptable for patients with evidence of an antibody response to SARS-CoV-2, 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.

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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.

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 antibody tests that can be found at:
https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#2019-nCov.

Where can I go for updates and more information?

CDC webpages:
General: https://www.cdc.gov/coronavirus/2019-nCoV
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**