Fact Sheet For Healthcare Providers

Emergency Use of Tru-Immune SARS-CoV-2 Neutralizing Antibody ELISA Tests During the COVID-19 Pandemic

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the Tru-Immune SARS-CoV-2 Neutralizing Antibody ELISA Test.

The Tru-Immune SARS-CoV-2 Neutralizing Antibody ELISA Test is authorized for the detection of neutralizing antibodies to SARS-CoV-2 in human serum or plasma specimens.

All individuals whose specimens are tested with this assay will receive the Fact Sheet for Recipients: Tru-Immune SARS-CoV-2 Neutralizing Antibody ELISA 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).

- The Tru-Immune SARS-CoV-2 Neutralizing Antibody ELISA test can be used to test human serum or plasma specimens.
- The Tru-Immune SARS-CoV-2 Neutralizing Antibody ELISA test can be used to detect circulating neutralizing antibodies against SARS-CoV-2 that block the interaction between the receptor binding domain of the viral spike glycoprotein (RBD) with the ACE2 cell surface receptor.

This test measures human SARS-CoV-2 neutralizing antibodies that are generated as part of the human immune response to the virus and provide protective immunity by blocking the interaction between the virus and its cellular target (ACE2 cell surface receptor).

• The Tru-Immune SARS-CoV-2 Neutralizing Antibody ELISA test can be used to evaluate protective immunity to SARS-CoV-2 by measuring the functional capacity of neutralizing antibodies to inhibit the interaction between the virus and its cellular target receptor.

• The Tru-Immune SARS-CoV-2 Neutralizing 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 RNA should be performed if acute infection is suspected.

• The Tru-Immune SARS-CoV-2 Neutralizing Antibody ELISA 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 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 having 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 human SARS-CoV-2 neutralizing antibodies?

A positive test result with the Tru-Immune SARS-CoV-2 Neutralizing Antibody ELISA test indicates that functional antibodies capable of neutralizing or inhibiting the SARS-CoV-2 virus were detected in the specimen. This result indicates that the individual has potentially been exposed to COVID-19 and has produced antibodies that are now capable of blocking the interaction between the virus and its target receptor (ACE2).

The Tru-Immune SARS-CoV-2 Neutralizing Antibody ELISA test is isotype independent meaning that it can detect the inhibition capacity of all neutralizing antibodies (e.g., IgG, IgM) present in the sample. Positive test results indicate that neutralizing antibodies were detected in the specimen. Semi-quantitative results will be provided which describe the capacity of detected antibodies to block the SARS-CoV-2/ACE2 interaction. Blocking capacity of detected antibodies will be reported as a

percentage (%) where the higher the result, the greater the inhibition capacity of the neutralizing antibodies.

Neutralizing antibodies to SARS-CoV-2 generally do not begin to appear until 2-10 days after infection. When neutralizing antibodies are present, it often indicates a past infection but does not exclude recently infected individuals who are still contagious. It is unknown how long neutralizing antibodies to SARS-CoV-2 will remain present in the body after infection. Neutralizing antibodies are the best way to evaluate protective immunity to infection, however the duration of this protection is currently unknown.

A positive result for neutralizing antibodies may not mean that an 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 to guide patient management decisions.

The Tru-Immune SARS-CoV-2 Neutralizing Antibody ELISA test has been designed to minimize the likelihood of false positive results. However, in the event of a false positive result, immediate measures to consider could include the following: a recommendation for isolation of the individual, monitoring of household or other close contacts for symptoms, isolation that might limit contact with family, friends, or other potentially COVID-19 infected individuals, limits in the ability to work, 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 neutralizing antibodies against the virus that causes COVID-19?

A negative test result with this test means that SARS-CoV-2 neutralizing antibodies were not present in the specimen above the limit of detection. However, a negative result does not preclude COVID-19 infection 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 neutralizing antibody despite active infection; in addition, not all individuals will develop a detectable neutralizing response SARS-CoV-2 infection. The absolute sensitivity of the Tru-Immune SARS-CoV-2 Neutralizing Antibody ELISA test is unknown.

When diagnostic testing is negative, the possibility of a false negative should be considered in the context of an individual's recent exposures and the presence of clinical signs and symptoms consistent with COVID-19. This is especially important if the individual has had recent exposure to COVID-19, or clinical presentation suggestive of COVID-19, and diagnostic tests for other causes of illness (e.g., other respirator illness) are negative. Direct testing for virus (e.g., RT-PCR testing) should always be performed in any individual suspected of COVID-19, regardless of the Tru-Immune SARS-CoV-2 Neutralizing Antibody ELISA test result.

Risks to an individual of a false negative result include: restriction of activities deemed appropriate for individuals with evidence of a neutralizing antibody response to SARS-CoV-2, 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) 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 in the detection of neutralizing antibodies 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).

Where can I go for updates and more information?

CDC webpages:

General: https://www.cdc.gov/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

Ethos Laboratories

29 E 6th Street
Newport KY, 41071
United States of America
Website: www.ethos-labs.com
For Customer Service in the U.S. call (877) 496 2570.