FACT SHEET FOR HEALTHCARE PROVIDERS

Akston Biosciences AntiCoV-ID™ IgG ELISA May 19, 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 Akston Biosciences' AntiCoV-ID™ IgG ELISA.

The AntiCoV-ID™ IgG ELISA is authorized for the detection of IgG antibodies to the receptor binding domain (RBD) of the spike protein of the SARS-CoV-2 virus in human serum or plasma from individuals with current or prior COVID-19 infection.

All individuals whose specimens are tested with this assay will receive the Fact Sheet for Recipients: Akston Biosciences AntiCoV-ID™ IgG ELISA

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, fever, 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.

This test measures human SARS-CoV-2 IgG antibody that is generated as part of the adaptive human immune response to the virus and is to be performed only using serum or plasma specimens.

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 AntiCoV-ID™ IgG ELISA can be used to test human serum or plasma or heat-inactivated (56°C; 1 hour) human serum or plasma specimens.
- The AntiCoV-ID™ IgG ELISA should 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 AntiCoV-ID™ IgG ELISA is authorized for use in Clinical Laboratories, State Public Health Laboratories, and Other Research/Academic Laboratories performing COVID-19 clinical studies or antibody titer-based screening.
- The AntiCoV-ID™ IgG 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. Negative antibody results do not preclude an acute COVID-19 infection. Direct testing for SARS-CoV-2 should be performed if acute infection is suspected.

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 (PPE) 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 IgG antibodies against SARS-CoV-2, the virus that causes COVID-19?
A positive test result with the AntiCoV-ID™ IgG ELISA indicates that antibodies to the receptor binding domain (RBD) of SARS-CoV-2 were detected, and the individual has potentially been exposed to COVID-19.

IgG antibodies to SARS-CoV-2 generally do not begin to appear until 7 – 10 days after infection. When IgG 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 IgG antibodies to SARS-CoV-2 will remain present in the body after infection and at what levels, if any, they confer immunity to infection.

A positive result for IgG 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 AntiCoV-ID™ IgG ELISA has been designed to minimize the likelihood of false positive test results. False positive results may occur due to cross-reactivity from pre-existing antibodies or other possible causes. In the event of a false positive result, one may consider one of the following immediate measures: a recommendation for isolation of the individual, monitoring of household members or other close contacts for symptoms, isolation that might limit contact with family, friends, or other potentially COVID-19 infected individuals, or limits in the ability to work, . Due to the risk of false positive results, confirmation of positive results should be considered using a second, different IgG assay.

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 IgG antibodies against SARS-CoV-2, the virus that causes COVID-19?
A negative test result with this test means that antibodies specific for the receptor binding domain (RBD) of the SARS-CoV-2 virus 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 IgG antibody despite having an active infection; in addition, not all individuals will develop a detectable IgG response to SARS-CoV-2 infection. The absolute sensitivity of the AntiCoV-ID™ IgG ELISA is 0.0125 µg/mL.

When testing is negative, the possibility of a false negative result 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 respiratory 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 results from the AntiCoV-ID™ IgG ELISA test.

Risks to an individual of a false negative result include: delayed or lack of supportive treatment, lack of monitoring of infected individuals and their household members or other close contacts for symptoms resulting in increased risk of spread of COVID-19 within the community, or other unintended adverse consequences.

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 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 emergency, 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/lab-biosafety-guidelines.html
Isolation Precautions in Healthcare Settings:
https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html#a4
Specimen Collection:
https://www.cdc.gov/coronavirus/2019-ncov/lab/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**