FACT SHEET FOR HEALTHCARE PROVIDERS

Babson Diagnostics, Inc.

Babson Diagnostics aC19G1   **June 23, 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 Babson Diagnostics aC19G1 test.

The Babson Diagnostics aC19G1 test is authorized for the detection of IgG antibodies to SARS-CoV-2 in human serum and plasma (potassium EDTA, lithium heparin).

All individuals whose specimens are tested with this assay will receive the Fact Sheet for Recipients: Babson Diagnostics aC19G1.

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). 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 or new loss of taste or smell. 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 4-5 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 for 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, including case definitions and infection control, 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 Babson Diagnostics aC19G1 can be ordered by healthcare providers to test human serum and

This test measures human SARS-CoV-2 IgG antibodies that are generated as part of the adaptive human immune response to the virus and is to be performed only using human serum and plasma (potassium EDTA, lithium heparin).

plasma (potassium EDTA, lithium heparin) to detect if there has been an adaptive immune response to COVID-19, indicating recent or prior infection.
- The Babson Diagnostics aC19G1 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 Babson Diagnostics aC19G1 test is only authorized for use at Babson Diagnostics, Inc. which is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) 42 U.S.C. §263a, and meets requirements 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)*. These specimens are only shipped for analysis to laboratories designated by CDC as qualified for analysis. 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).

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.

What does it mean if the specimen tests positive for antibodies against the virus that causes COVID-19?
A positive test result with the Babson Diagnostics aC19G1 test indicates that antibodies against 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 following infection. Individuals may have detectable virus present for several weeks following seroconversion. A positive result can indicate recent or past infection but does not exclude recently infected individuals 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.*

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

The Babson Diagnostics aC19G1 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, 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, the delayed diagnosis and treatment for the true infection causing the symptoms, unnecessary prescription of a treatment or therapy, or other unintended adverse effects**.**

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 the standard confirmatory testing and reporting guidelines according to their appropriate public health authorities.

What does it mean if the specimen tests negative for antibodies against the virus that causes COVID-19?
A negative test result for this test means that anti-SARS-CoV-2 specific antibodies were not present in the specimen above the limit of detection of the assay. *However, individuals tested early after infection may not have detectable antibody response despite active infection; in addition, not all patients will develop a detectable antibody response to SARS-CoV-2 infection. A negative result should not be used to rule out COVID-19 infection. Direct testing of SARS-CoV-2 should be performed if acute infection is suspected.*

The absolute sensitivity of the Babson Diagnostics aC19G1 test is unknown.

Risks to an individual resulting from a false negative result include: restriction of activities deemed acceptable for individuals 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.

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).

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**