FACT SHEET FOR HEALTHCARE PROVIDERS

COV-ID™ Diagnostic Kit (Colloidal Gold) for IgG/IgM Antibody to SARS-CoV-2

June 8, 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 COV-ID™ Diagnostic Kit (Colloidal Gold) for IgG/IgM Antibody to SARS-CoV-2.

The COV-ID™ Diagnostic Kit (Colloidal Gold) for IgG/IgM Antibody to SARS-CoV-2 is authorized for on the detection of antibodies to SARS- CoV-2 in fingerstick whole blood/ venous whole blood/serum/plasma.

All individuals whose specimens are tested with this assay will receive the Fact Sheet for Recipients: COV-ID™ Diagnostic Kit (Colloidal Gold) for IgG/IgM Antibody to SARS-CoV-2.

What are the symptoms of COVID-19?
Most 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 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).

This test measures human SARS-CoV-2 antibodies that are generated as part of the adaptive human immune response to the virus and is to be performed only using fingerstick whole blood/venous whole blood/serum/ plasma specimens.

- The COV-ID™ Diagnostic Kit (Colloidal Gold) for IgG/IgM Antibody to SARS-CoV-2 can be used to test fingerstick whole blood, venous whole blood (EDTA, heparin, sodium citrate), serum and plasma.
- The COV-ID™ Diagnostic Kit (Colloidal Gold) for IgG/IgM Antibody to SARS-CoV-2 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 COV-ID™ Diagnostic Kit (Colloidal Gold) for IgG/IgM Antibody to SARS-CoV-2 is only authorized for use in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high, moderate, or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.
- The COV-ID™ Diagnostic Kit (Colloidal Gold) for IgG/IgM Antibody to SARS-CoV-2 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.

Specimens should be collected with appropriate infection control precautions following CDC Interim Infection Prevention and Control Recommendations for Patients with Confirmed Coronavirus Disease 2019 (COVID-19) or Persons Under Investigation for COVID-19 in Healthcare Settings.

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.**

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).

What does it mean if the specimen tests positive for antibodies against the virus that causes COVID-19? A positive test result for this test indicates that antibodies against SARS-CoV-2 were detected, and the individual has potentially been exposed to SARS-CoV-2.

Antibodies are generally detectable several days following infection. 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.

A positive antibody result 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 in making patient management decisions.

The COV-ID™ Diagnostic Kit (Colloidal Gold) for IgG/IgM Antibody to SARS-CoV-2 has been designed to minimize the likelihood of false positive test results. However, in the event of a false positive result, risks to patients could include the following: a recommendation for isolation of the patient, monitoring of household or other close contacts for symptoms, patient isolation that might limit contact with family or friends and may increase contact with other potentially COVID-19 patients, 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 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, a negative result does not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions. A negative result does not exclude the possibility of COVID-19.

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. The absolute sensitivity of the COV-ID™ Diagnostic Kit (Colloidal Gold) for IgG/IgM Antibody to SARS-CoV-2 is unknown.

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 to detect the virus (e.g., PCR testing) should be performed, as indicated by CDC and local guidelines, in patients suspected of COVID-19 regardless of COV-ID™ Diagnostic Kit (Colloidal Gold) for IgG/IgM Antibody to SARS-CoV-2 results.

Risks to a patient resulting from a false negative result 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.

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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 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 patient fact sheet and manufacturer's instructions)
https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations

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