

FACT SHEET FOR HEALTHCARE PROVIDERS

LYHER Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold)
Hangzhou Laihe Biotech Co., Ltd

Updated: February 14, 2022

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 LYHER Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold).

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

LYHER Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold) is authorized for on the detection of IgG and IgM antibodies to SARS-CoV-2 in human serum and plasma (dipotassium-EDTA, lithium-heparin, or sodium-citrate).

All individuals whose specimens are tested with this assay will receive the Fact Sheet for Recipients: LYHER Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold).

What are the symptoms of COVID-19?

Many patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, dyspnea), 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, when present, symptoms include cough, shortness of breath or dyspnea, fever, chills, myalgias, 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 throughout the world, including the United States, which poses risks for public health. Please check the CDC COVID-19 webpage (see link provided in “*Where can I*

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

go for updates and more information?” section at the end of this document) or your local jurisdiction’s website 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).

- LYHER Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold) can be ordered by healthcare providers to test human serum and plasma (dipotassium-EDTA, lithium-heparin, or sodium-citrate) to detect if there has been an adaptive immune response to COVID-19, indicating recent or prior infection.
- LYHER Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold) 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.
- LYHER Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold) is only 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 or high complexity tests.
- Please refer to the LYHER Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold) instructions for use for additional information.

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**

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When collecting and handling specimens from individuals suspected of being infected with the virus that causes 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 (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 antibodies against the virus that causes COVID-19?

A positive test result with the LYHER Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold) 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. If antibodies are present, it often indicates a past infection but does not exclude recently infected individuals who are still contagious.

The clinical significance of a positive antibody result for individuals that have received a COVID-19 vaccine is unknown.

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 LYHER Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold) 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, 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 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 LYHER Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold) is unknown.

The clinical significance of a negative antibody result for individuals that have received a COVID-19 vaccine is unknown.

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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.

The performance of this test was established based on the evaluation of a limited number of clinical specimens. The clinical performance has not been established in all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.

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?

Any tests that have received full marketing status (e.g., cleared, approved), as opposed to an EUA, by FDA can be found by searching the medical device databases

here: <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases>. A cleared or approved test should be used instead of a test made available under an EUA, when appropriate and available. FDA has issued EUAs for other tests that can be found at:

<https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>

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Where can I go for updates and more information?

CDC webpages:

General: <https://www.cdc.gov/coronavirus/2019-ncov/index.html>

Symptoms:

<https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html>

Healthcare Professionals: <https://www.cdc.gov/coronavirus/2019-nCoV/hcp/index.html>

Information for Laboratories:

<https://www.cdc.gov/coronavirus/2019-nCoV/lab/index.html>

Laboratory Biosafety: <https://www.cdc.gov/coronavirus/2019-nCoV/lab-biosafety-guidelines.html>

Isolation Precautions in Healthcare Settings:

<https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html>

Specimen Collection: <https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html>

Infection Control: <https://www.cdc.gov/coronavirus/2019-ncov/php/infection-control.html>

FDA webpages:

General: www.fda.gov/novelcoronavirus

EUAs:(includes links to fact sheet for individuals and manufacturer's instructions) <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas>

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