

Alabama Clinics COVID-19 Tests

Alabama Clinics currently offers COVID-19 Antibody testing, also known as serology testing. This test can check for different types of antibodies developed after exposure to the SARS-CoV-2 virus that causes COVID-19. This type of COVID-19 test is for individuals who think they may have previously had COVID-19 and do not currently have symptoms. Alabama Clinics offer access to COVID-19 antibody testing without having to go into a doctor's office.

Note: antibody testing should not be used as the sole basis to diagnose or exclude infection.

This blood test checks for a type of antibody called immunoglobulin M (IgM) and immunoglobulin G (IgG) that is the result of past or recent exposure to COVID-19, also known as the novel coronavirus.

IgM Antibody

This test detects IgM antibodies. IgM is usually the first antibody produced by the immune system when a virus attacks. A positive IgM test indicates that you may have been infected and that your immune system has started responding to the virus. When IgM is detected you may still be infected or you may have recently recovered from a COVID-19 infection.

IgG Antibody

This test detects IgG antibodies that develop in most patients within seven to 10 days after symptoms of COVID-19 begin. IgG antibodies remain in the blood after an infection has passed. These antibodies indicate that you may have had COVID-19 in the recent past and have developed antibodies that may protect you from future infection. It is unknown at this point how much protection antibodies might provide against another infection with SARS-CoV-2.

Test results may help identify if you were previously exposed to the virus and, if exposed, can check whether or not your body has produced antibodies. Currently, the FDA supports antibody testing with the following important points:

Antibody tests can play a critical role in the fight against COVID-19

Testing can help identify who may have been exposed to SARS-CoV-2, the virus that causes the COVID-19 infection, and potentially developed an immune response

Right now, it is unclear whether these individuals may be less susceptible to infection, but in the future, broad use of antibody tests and clinical follow-up will provide more information on this point

Experience with other viruses suggests that individuals who have antibodies, provided they are recovered and not currently infected with the virus, may be able to resume work and other daily activities in society

Multiple sources, including the CDC and healthcare experts, recommend you discuss your test results and whether to return to work with your healthcare provider and employer.

If you were never diagnosed with COVID-19, this test can help determine if you may have been previously exposed to the virus.

If you were diagnosed with COVID-19, this test can check whether or not your body has produced antibodies.

Source: <https://www.cdc.gov/coronavirus/2019-ncov/testing/serology-overview.html>

FAQ:

What is the COVID-19 IgM-IgG RapidTest?

W.H.P.M. Inc.'s Covid-19 IgM-IgG Rapid Test is a lateral flow immunoassay used to qualitatively detect IgG and IgM antibodies to SARS-COV-2 virus in human whole blood, serum or plasma.

How quickly can the COVID-19 IgM/IgG Rapid Test yield results?

Results can be interpreted at 10~15 minutes after sample and buffer are combined in the cassette sample well.

Where was the test made?

W.H.P.M is made in United State of America

What is the cost of the test?

Most major insurances will cover all the cost of the test. The test is free for uninsured patients.

IMPORTANT NOTIFICATION:

According to Section D in the FDA Guidance document entitled “Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency”, revised 5-4-2020, please note the following requirements (actual verbiage from guidance document):

“The policy described in this subsection applies to developers of serology tests that identify antibodies (e.g., IgG, IgM) to SARS-CoV-2 from clinical specimens. Unless and until an EUA is issued that authorizes additional testing environments for a specific test, under CLIA, use of that test is limited to laboratories certified to perform high complexity testing, and at the point-of-care when covered by the laboratory’s CLIA certificate for high-complexity testing. This policy does not apply to at-home testing, including at-home specimen collection, due to additional considerations that require FDA review.” The entire guidance can be viewed in their “Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency” document.

Considering that serology tests are less complex than molecular tests and are solely used to identify antibodies to the virus, FDA does not intend to object to the development and distribution by commercial manufacturers or development and use by laboratories of serology tests to identify antibodies to SARS-CoV-2, where the test has been validated, notification is provided to FDA, and information along the lines of the following is included in the test reports: ·

This test has not been reviewed by the FDA.

Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.

Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.

Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.

FDA recommends that developers planning to submit an EUA for serological testing as the sole basis to diagnose or inform infection status, include information along the lines of the statements above in their test reports until data is submitted and an EUA is authorized for additional uses.