Antibody Tests for COVID-19

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What is Covid-19

Widely known as coronavirus, Covid-19 is an infectious disease that is caused by SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2). The SARS-CoV-2 emerged in the Chinese province of Hubei (Wuhan) in December 2019 and has been declared a pandemic by WHO on 11 March 2020. This outbreak has spread rapidly, with millions of reported cases and thousands of deaths worldwide. Currently, there is no medication or vaccine available against infection with this new virus.

What are the symptoms?

The majority of people infected with the virus will experience mild to moderate respiratory illness. However, COVID-19 might affect people in different ways. According to the World Health Organization (WHO), the most **common** symptoms are: fever, dry cough, tiredness. The most **serious** symptoms are difficulty breathing or shortness of breath, chest pain or pressure, loss of speech or movement. Generally healthy individuals with mild syndromes will recover without any hospitalization, nevertheless, vulnerable persons with health issues, as well as patients who experience serious symptoms, should seek immediate medical attention.

Testing Methods for COVID-19

Two types of testing for the coronavirus disease are used: those that detect the presence of the virus itself and those that indicate the presence of antibodies against it. The first type of tests are the molecular techniques (RT-PCR) that detect the virus's genetic material, and the antigen tests that detect specific proteins on the surface of the virus. On the other hand, serological tests (ELISA, CLIA & Lateral Flow Immunoassays) detect the antibodies that are produced by the immune system in response to the virus

Antibody Testing

Serological tests detect antibodies presence in the blood, serum or plasma specimens, when the body has responded to SARS-CoV-2. Antibody tests detect the body's immune response to the infection caused by the virus rather than detecting the virus itself. Antibody tests can be used along with RT-PCR molecular technique to provide complete clinical diagnosis and strengthen the reliability of the results.

Moreover, antibody tests can be used to understand how many asymptomatic patients exist in a population providing important data for scientific authorities and medical professionals. When used for surveillance, the results can help determine how widely the virus has spread in communities. Serological tests also offer valuable data about the infection phase of the patients.

Testing individuals may help identify who has developed antibodies against SARS-CoV-2. The result of ongoing research are needed before it is known whether these antibodies are associated with protection from future infection. Current results can help inform who may qualify to donate blood that can be used to manufacture convalescent plasma, an investigational product for use with those who are seriously ill from COVID-19.

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What does positive result for SARS-CoV-2 antibodies mean?

A positive test result indicates that antibodies to SARS-CoV-2 were detected, and the individual has potentially been exposed to COVID-19.

The serology tests detect IgM, IgG or total antibodies (IgM, IgA, and/or IgG) as indicative of an adaptive immune response to SARS-CoV-2 infection in individuals suspected of SARS-CoV-2 infection.

IgM antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although levels over the course of infection are not well characterized. IgG antibodies to SARS-CoV-2 become detectable later following infection, although detection of IgG antibodies does not exclude recently infected patients who are still contagious. Positive results for IgM, IgA, and IgG could occur after infection and can be indicative of acute or recent infection. It is unknown how long IgM IgA, and/or IgG antibodies to SARS-CoV-2 will remain present in the body after infection and if they confer immunity to infection.

A positive result for antibodies may not mean that an individual's current or past symptoms were due to COVID-19 infection. Laboratory test results should always be considered in the context of clinical observations and epidemiological data in making a final diagnosis and patient management decisions.

ProGnosis Biotech's antibody tests have 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. 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. If a recent infection is suspected a false positive result may lead to 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-infected individuals, limits in the ability to work, or other unintended adverse effects.

All laboratories, medical professional or individuals using antibody tests must follow standard confirmatory testing and reporting guidelines according to their appropriate public health authorities.

What does negative result for SARS-CoV-2 antibodies mean?

A negative result with serology tests means that SARS-CoV-2 specific antibodies were not present in the specimen above the limit of detection. However, a negative result does not rule out COVID-19 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 active infection; in addition, not all individuals will develop a detectable IgM and/or IgG response to SARS-CoV-2 infection. The absolute sensitivity of the antibody tests 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. The possibility of a false negative result should especially be considered if the individual's recent exposure or clinical presentation indicate that COVID- 19 is likely and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative. Direct testing for virus (e.g., PCR testing) should always be performed in any individual suspected of COVID-19, regardless of the antibody test result.

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 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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Authorizations for Antibody Tests

CE-IVD Mark

CE Marking is required for all in vitro diagnostic (IVD) devices sold in Europe. CE Marking indicates compliance with the European In-Vitro Diagnostic Devices Directive (98/79/EC) and therefore that the device can be legally sold and commercialized within the EU, European Free Trade Area (EFTA), Switzerland, Turkey and some other countries wishing to join the EU.

To get access to the full European directive: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31998L0079&from=EN

Moreover, the European Parliament & Council has proposed a new in-vitro diagnostic regulation which will come into force in 2022

To get full access: *https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0746&from=EN*

FDA approval

The U.S. Food and Drug Administration (FDA) regulates, among other products, tests intended for the diagnosis of a disease or condition (a type of "device") under the Federal Food, Drug, and Cosmetic Act. Outside of a declared public health emergency, serological tests generally require FDA premarket review through one of the established premarket pathways (de novo, 510(k) or PMA). For the coronavirus pandemic, FDA has issued emergency use authorizations (EUAs), an authorization available to certain products in a declared public health emergency, for some antibody tests based on the data submitted to the Agency after determining that the applicable statutory criteria had been met.

In order the antibody tests to be approved, their data must demonstrate 90.0% positive percent agreement and overall 95.0% negative percent agreement. For tests that demonstrate specifically IgM & IgG, a minimum positive percent agreement of 70% and 90% respectively is required.

Fore more info about the criteria of issuance an Authorization: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31998L0079&from=EN

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ProGnosis Biotech Antibody Tests
Clinical Performance Results

Bio-Shield 2019-nCoV IgG, C1148/C1196

Clinical Diagnostic Specificity

91/91 specimens 100%

Clinical Diagnostic Sensitivity

Days between onset of symptoms and sample collection	Reactive Specimens	Nonreactive specimens	Total	%
≤7 days	2	0	2	100%
8-14 days	35	2	37	94.59%
15-21 days	12	0	12	100%
22-28 days	9	0	9	100%
≥29 days	15	0	15	100%
Total	**73**	**2**	**75**	**97.33%**

Bio-Shield 2019-nCoV IgM, C1248/C1296

Clinical Diagnostic Specificity

91/91 specimens 100%

Clinical Diagnostic Sensitivity

Days between onset of symptoms and sample collection	Reactive Specimens	Nonreactive specimens	Total	%
≤7 days	2	0	2	100%
8-14 days	26	11	37	70,27%
15-21 days	12	0	12	100%
22-28 days	8	1	9	88.8%
≥29 days	14	1	15	93.33%
Total	**62**	**13**	**75**	**82.66%**

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Clinical Performance Results

Bio-Shield 2019-nCoV Total Immunoglobulins, C1348/C1396

Clinical Diagnostic Specificity

86/86 specimens 100%

Clinical Diagnostic Sensitivity

Days between onset of symptoms and sample collection	Specimens	Nonreactive specimens	Total	%
≤7 days	11	1	12	91.67%
8-14 days	14	0	14	100%
15-21 days	17	0	17	100%
22-28 days	15	0	15	100%
≥29 days	18	0	18	100%
Total	**75**	**1**	**76**	**98.68%**

Rapid Test 2019-nCoV Total Immunoglobulins, V1210/V1230

Clinical Diagnostic Specificity

114/114 specimens 100%

Clinical Diagnostic Sensitivity

Days between onset of symptoms and sample collection	Specimens	Nonreactive specimens	Total	%
≤7 days	5	1	6	83.33%
8-14 days	37	0	37	100%
15-21 days	12	0	12	100%
22-28 days	9	0	9	100%
≥29 days	16	0	16	100%
Total	**79**	**1**	**80**	**98.75%**