COVID-19 Ab S/P/W Rapid Test
Frequently Asked Questions (FAQ)

Q: What is Coronavirus?
A: Coronaviruses are a large family of viruses which may cause illness in animals or humans. In humans, several coronaviruses are known to cause respiratory infections ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS). The most recently discovered coronavirus causes coronavirus disease COVID-19.

Q: What is COVID-19?
A: COVID-19 is the infectious disease caused by the most recently discovered coronavirus. This new virus and disease were unknown before. COVID-19 is now a pandemic affecting many countries globally.

Q: What are the known symptoms to COVID-19?
A: COVID-19 symptoms can range from mild (or no symptoms) to severe illness. The most common symptoms of COVID-19 are fever, dry cough, and tiredness. Some people may have aches and pains, nasal congestion, sore throat, or diarrhea. These symptoms are usually mild and begin gradually. Most people (about 80%) recover from the disease without needing hospital treatment. Around 1 out of every 6 people who gets COVID-19 becomes seriously ill and develops difficulty breathing. Older people, and those with underlying medical problems like high blood pressure, heart and lung problems, diabetes, or cancer, are at higher risk of developing serious illness. However, anyone can catch COVID-19 and become seriously ill. The virus most often spreads through people who have symptoms, but it is possible for people without any symptoms to pass on the virus. People of all ages who experience fever, cough and difficulty breathing should seek medical attention.

Q: How does the ACON SARS-Cov2 IgG/IgM rapid test work?
A: The SARS-COV-2 IgG/IgM Rapid Test is a qualitative membrane-based immunoassay for the detection of IgG and IgM antibodies to SARS-COV-2 in human serum, plasma, or whole blood. The membrane is pre-coated with anti-human IgM antibody and anti-human IgG antibody.
During testing, SARS-COV-2 antibodies, if present in the specimen, will react with the SARS-COV-2 antigen-coated particles, which have been pre-coated on the test strip.
The mixture then migrates upward on the membrane by capillary action, reacting with anti-human IgM antibody on the IgM Test Line region (M) and/or with anti-human IgG antibody on the IgG Test Line region (G), forming a colored line in IgM line region (M) and/or IgG line region (G).
The absence of the colored lines in IgM line region (M) and IgG line region (G) indicates that the specimen does not have any SARS-COV-2 antibodies. To serve as a procedure control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

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Q: Why does the test use the IgG and IgM antibodies?

A: Immunoglobulin detection tests are based on the qualitative detection of IgM and IgG that are specifically generated by the body in response to SARS-CoV-2 infection.
IgM is usually the first, specific antibody type generated by the body in response to exposure to an infection. When IgM antibodies are present, they can indicate that a patient has an active or recent infection with SARS CoV-2.
IgG antibodies develop later following infection, and generally do not begin to appear until 7 – 10 days after infection. When IgG antibodies are present it often indicates a past infection but does not exclude recently infected patients who are still contagious, especially if detected with IgM antibodies.
It is unknown how long IgM or IgG antibodies to SARS-CoV-2 will remain present in the body after infection and if they confer immunity to infection.
IgM and IgG fight infections by targeting specific antigens on the surface of the SARS-nCoV-2 virus.

Q: What do the test results mean?

A: Immunoglobulin tests for COVID-19 cannot confirm the presence of the virus in your system. It can only tell whether you have been exposed in the past or if you have never been exposed to SARS-CoV-2. Since the test will only indicate the presence of SARS-COV-2 IgM and IgG antibodies in the blood specimen it should not be used as the sole criteria for the diagnosis of SARS-COV-2 infection.

Q: What are the known limitations of the test?

A: The SARS-COV-2 IgG/IgM Rapid Test is for in vitro diagnostic use only. The test should be used for the detection of SARS-COV-2 antibodies in serum, plasma, or whole blood specimens only. Neither the quantitative value nor the rate of increase in SARS-COV-2 antibody concentration can be determined by this qualitative test.

- The test will only indicate the presence of SARS-COV-2 IgM and IgG antibodies in the specimen and should not be used as the sole criteria for the diagnosis of SARS-COV-2 infection.
- The results obtained from this test are intended to be an aid to diagnosis only. Each physician must interpret the results in conjunction with the patient's history, physical findings, and other diagnostic procedures.
- Results from immunosuppressed patients should be interpreted with caution.
- False positive results for IgG and IgM may occur due to cross reactivity from some pre-existing antibodies or other possible causes.
- A negative result may occur if the quantity of antibodies to SARS-CoV-2 is below the detection limit of the assay.
- If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of SARS-COV-2 infection.

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