Frequently Asked Questions

WHAT IS THE DIFFERENCE BETWEEN COVID19Ab Rapid Test AND OTHER TESTS?

Currently, there are two main types of tests for SARS-CoV-2 infection detection available on the market: molecular tests that detect the presence of the virus in bodily fluids and serological tests that detect antibodies to the virus in human blood.

Molecular tests are based on RT-PCR technique to transcribe, multiply and detect viral RNA. Molecular tests use nasopharyngeal andoropharyngeal *swabs* that are sent to laboratories for analysis. Molecular tests can take hours to days or even weeks to perform depending on laboratory location and testing capacity.

Serological tests are based on immunoassay technique and detect the presence of antibodies to new coronavirus in whole blood, plasma or serum. Serological tests are faster than molecular tests and can be an instant point of care tests or can be performed in a laboratory. Serological tests can be qualitative and quantitative.

COVID19AbRapid Test is an instant qualitative serological test. It detects the presence of IgM and IgG antibodies specific to the novel coronavirus.

	COVID19AbRapid Test	**Molecular Test**
What does it detect	Antibodies to the virus	Viral genetic material
Specimen type	Whole blood/Plasma/Serum	Nasopharyngeal/Oropharyngeal *swabs*
Detection Window	IgM: 3-5 days post symptom onset up to two months	At symptom onset - throughout the duration of acute infection

	IgG: 21 days post symptom onset-up to many months later (not determined yet)	
Time to get result	10 min	Hours to Days
Technology	Immunoassay	RT-PCR
Relative Sensitivity	85% (IgM), 100% (IgG)	96.6% – 100%*
Relative Specificity	96% (IgM), 98% (IgG)	94.7% – 100%*
Positive Result Interpretation	Positive IgM -current or recent SARS-CoV-2 infection; Positive IgG - past SARS-CoV-2 infection	SARS-CoV-2 infection present
Negative Result Interpretation	Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with other clinical observations, patient history, and epidemiological information.	

IS COVID19Ab RAPID TEST REGISTERED WITH FDA?

The test has been registered with the FDA. The FDA allows the commercial distribution of the test for use by health care providers and laboratories in

accordance with the FDA policy on March 16, 2020, relating to COVID-19 testing.

WHAT IS THE DETECTION WINDOW FOR THE COVID19AbRAPIDTEST?

Detection Window for IgM:

Symptomatic patients - 3-5 days post symptom onset up to 2 months

Asymptomatic patients - 7 days up to 2 months

3-5 days post symptom onset up to 2 months

Detection Window for IgG:

All patients - 21 days post-infection to many months later (not determined yet)

IS THE TEST SPECIFIC TO COVID-19?

SARS-CoV-2 virus particle contains four proteins: Spike, Envelope, Membrane, and Nucleocapsid.

COVID19Ab Rapid Test Cassette utilizes nucleocapsid protein (N-protein) as the binding antigen, and it is very specific.

N-protein is the most abundant protein in coronavirus. The N-protein is a highly immunogenic phosphoprotein, and its structure is conserved. The N protein of coronavirus is often used as a marker in other diagnostic assays.

COVID19Ab Rapid Test does not show cross-reactivity with antibodies to Influenza A, B, and other viruses (see Clinical Performance Characteristics of the Test).

WHAT DOES THE RESULT MEAN?

IgM positive result indicates current or recent infection with the SARS-CoV-2 virus. IgM antibodies are usually detected 3-5 days post symptom onset in symptomatic patients and around 7 days post-infection in asymptomatic patients.

IgG positive result indicates past exposure to SARS-CoV-2. IgG antibodies are usually produced 21 days post-infection and can be detected for months

to years later. The duration of human immunity to SARS-CoV-2 remains to be determined.

Both IgM and IgG positive result indicate recent SARS-CoV-2 infection that occurred between one to two months prior to performed test.

Negative result does not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with other clinical observations, patient history, and epidemiological information.

If the test result is negative and clinical symptoms, additional follow-up testing using other clinical methods is suggested. A negative result at any time does not preclude the possibility of COVID19 infections.

WHAT ARE COVID19Ab RAPID TEST LIMITATIONS?

-The COVID19 Ab test is for in vitro diagnostic use only. This test should be used for the detection of IgG and IgM antibody to SARS-CoV-2 in whole blood, serum or plasma specimens. Neither the quantitative value nor the rate of increase in the concentration of IgG or IgM antibodies to SARS-CoV-2 can be determined by this qualitative test.

-The COVID19 Ab test will only indicate the presence of IgG and IgM antibodies to the SARS-CoV-2 virus in the specimen and should NOT be used as the sole criteria for the diagnosis of COVID19infections.

- A negative result for an individual subject indicates the absence of detectable anti-COVID-19 antibodies. However, a negative test result does not preclude the possibility of exposure to or infection with COVID-19. A negative result can occur if the quantity of the anti-COVID-19 antibodies present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.

- The hematocrit level of the whole blood can affect the test results. Hematocrit level needs to be between 25% and 65% for accurate results.

- As with all diagnostic tests, all results must be considered with other clinical information available to the physician.

HOW DOES THE COVID19 Ab RAPID TEST WORK?

The COVID19Ab test is an instant serological test. It detects the presence of IgG and IgM antibodies to 2019-nCoV by lateral flow immunoassay method. The specimen used can be whole blood, serum or plasma. The test consists of two components, an IgG component, and an IgM component. The test cassette also includes test Control component, indicating that the proper volume of specimen has been added and membrane wicking has occurred and the test has been activated correctly. The test consists of three simple steps: 1) Putting one drop of specimen to test sample well, 2) Adding two drops of buffer to the test sample well, 3) Reading results in 10 min.