COVID-19 IgM/IgG Antibody Test

For In Vitro Diagnostic Use Only

Made in the USA

Easy, Efficient & Accurate Screening Device for COVID-19

- COVID-19 Positive/Negative Results in 15 Minutes
- Works with Fingerstick, Whole Blood, Serum or Plasma
- Increased Screening with IgM and IgG Antibody Detection
- Ideal High-Volume Screening Device to Complement Nucleic Acid Tests

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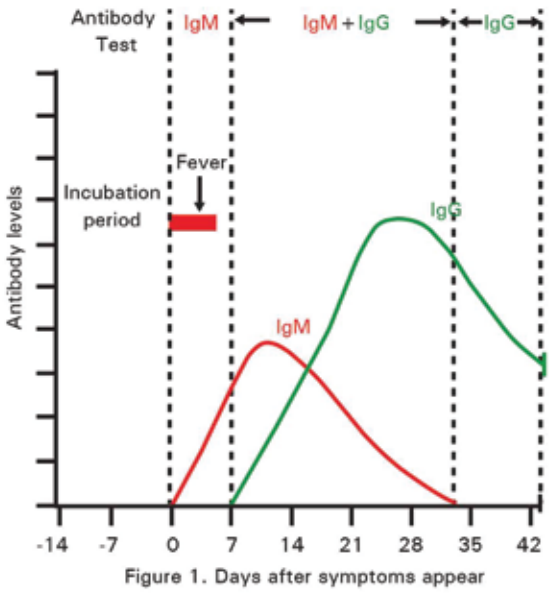


Figure 1. Days after symptoms appear

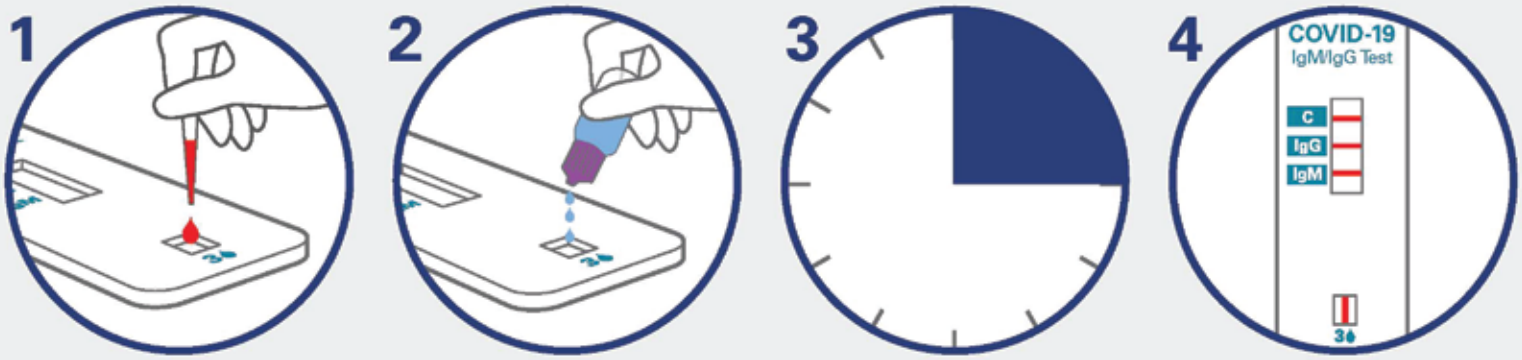
Testing for Antibodies

The human immune system is an incredibly effective defense mechanism in fighting and protecting the body against disease. When a patient is infected by the SARS-CoV-2 virus, the immune system will begin to form IgM antibodies as the first line of defense. While IgM antibodies are effective in the fight against infection, as the immune system mounts a more direct defense against the infection the body will begin to form specialized IgG antibodies.

- The IgM antibody can be detected in patient specimen 3-6 days after infection
- Positive result indicate a presumptive infection
- Negative results are a presumptive indication of no infection

COVID-19 IgM/IgG Antibody Test	
Clinical Sensitivity	93.5%
Clinical Specificity	100%
Relative Accuracy	97.9%

Finger Stick/Whole Blood Testing Procedure



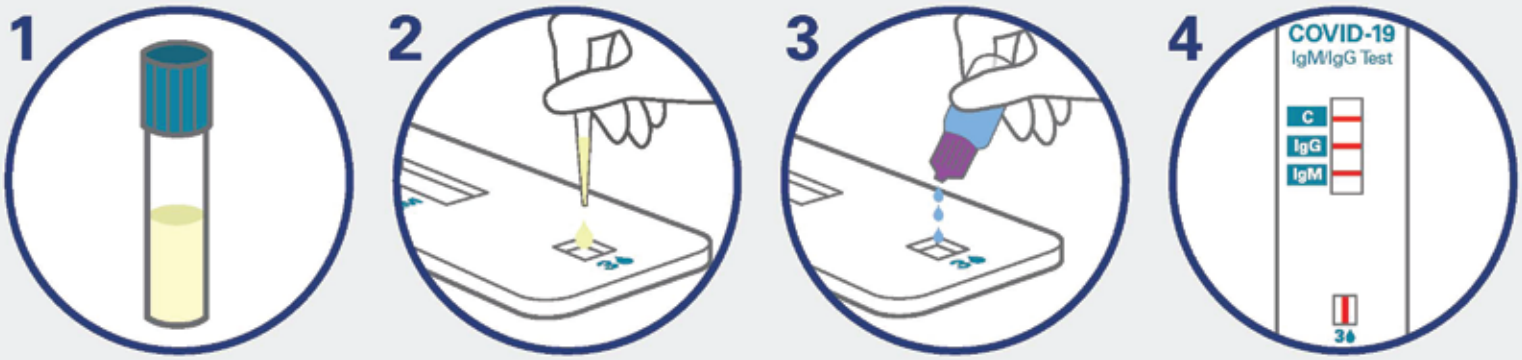
Collect 20ul whole blood and add sample to the sample well on the test.

Place 2-3 drops of buffer into the sample well.

Wait 15 minutes.

Read results.

Serum/Plasma Testing Procedure



Collect 10ul of serum/plasma.

Add serum/plasma sample to sample well.

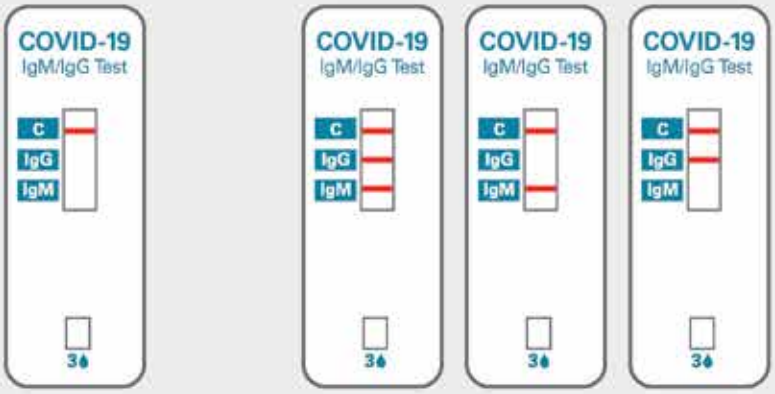
Place 2-3 drops of buffer in sample well.

Read results after 15 minutes.

IgG antibodies are highly specific to the disease in question, they will appear in a later stage of the infection and remain in the body for some time after the infection has been defeated. The COVID-19 IgM/IgG Antibody Test is designed to quickly detect and differentiate both the IgM and IgG antibodies produced by the immune system during a COVID-19 infection.

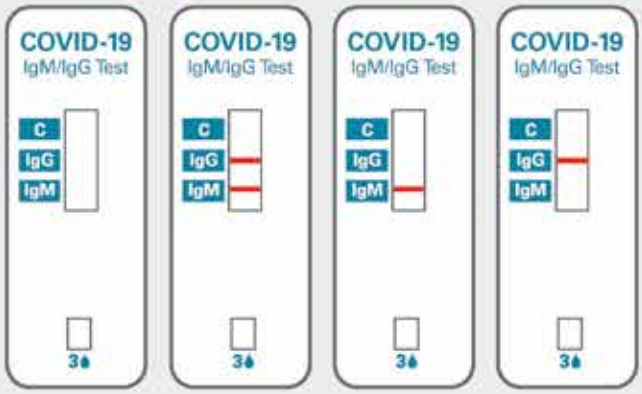
Test Results	Colloidal Gold	Fluorescence-PCR
Test Time	15 minutes	3-4 hours
Operation Method	Simple without supporting equipment required	Complex with supporting equipment required
Portability	Highly portable and stable test device at room temperature. Testing can be conducted at point of care including certified small labs, clinics or patient	Requires highly complex equipment only available in large hospitals

Results Interpretation



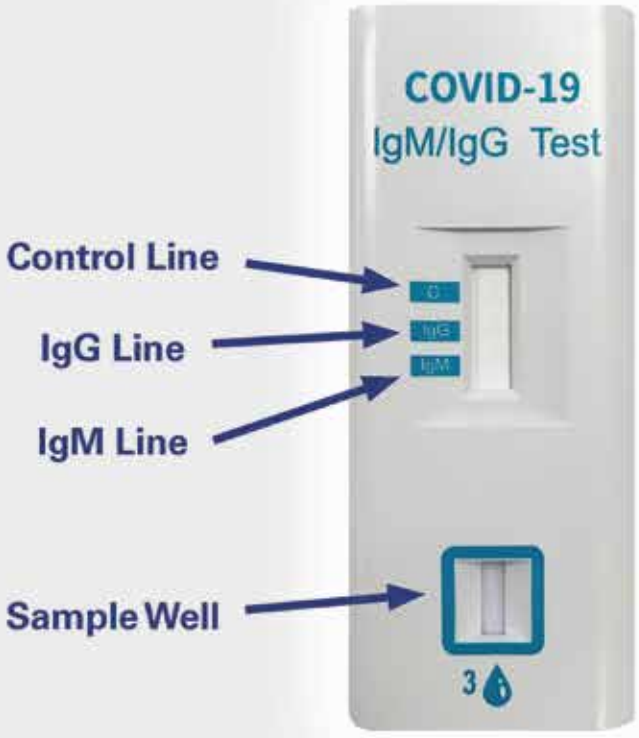
NEGATIVE

POSITIVE



INVALID

NOTE: On this device any line, no matter how faint, is considered a line. Do NOT compare test line intensity to control line.



SARS-COV-2 Antigen and IgG/IgM Antibody Test Results & Clinic Significance

Test Results			Clinical Implications
+	–	–	Patients may be in the "window period" of SARS-COV-2 infection.
+	+	–	Patient may be in the early stage of infection, and the body's immune response first produced the antibody IgM, but no IgG was produced or the IgG content did not reach the detection limit of the diagnostic reagent.
+	–	+	Patients may be in late or recurrent stage of infection
+	+	+	Patient is in the active phase of infection, but the human body has developed some immunity to SARS-COV-2 (the persistent antibody IgG has been produced).
–	+	–	Patient may be in the acute phase of SARS-COV-2 infection. At this time, nucleic acid test result need to be considered (PCR may be false negative).
–	–	+	Patient may have been infected with SARS-COV-2 in the past, but the patient has been recovered or the virus in body has been cleared.
–	+	+	Patient has recently been infected with SARS-COV-2 and is in the recovery stage. Or the nucleic acid test result is false negative and the patient is in the active infection stage.

COVID-19 IgM/IgG Antibody Test		Known Healthy Individuals		
		Positive	Negative	Total
IgM	Positive	0	0	0
	Negative	0	100	100
IgG	Positive	0	0	0
	Negative	0	100	100
Total		0	200	200

Seroconversion Timeline Evaluation		Confirmed COVID-19 Positive Specimens		
		4-10 Days	11-24 Days	Total
Confirmed Positives		10	36	46
COVID-19 IgM/ IgG Rapid Test	IgM Positive	7	34	41
	IgG Positive	2	36	38

COVID-19 IgM/IgG Antibody Test		Confirmed COVID-19 Patient Specimens & Healthy Individual Specimens		
		Positive	Negative	Total
IgM/IgG	Positive	43	0	43
	Negative	3	100	103
Total		46	100	146

PROFESSIONAL LAB KIT INCLUDES:

25 Cassettes • 1 Buffer Tube (5mL) • 25 Pipettes (20uL)

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