BIOHIT HealthCare
Innovating for Health

COVID-19 IgG/IgM

A Rapid Test for the Detection of IgG and IgM Against SARS-CoV-2

Colloidal Gold Method

High-Risk Population

Symptomatic Population

Potentially Exposed Population

<15 minute detection

CE-IVD

FDA Emergency Use Authorization Only

DialaneAG
the fast lane to the European IVD market

Background

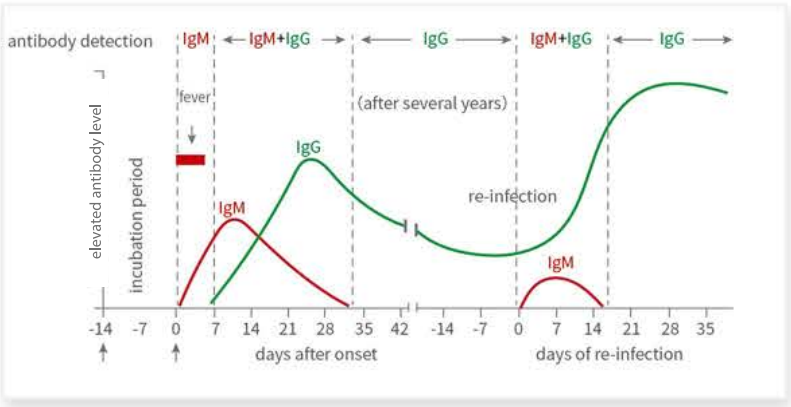
SARS-CoV-2

Coronaviruses are single-stranded, positive sense RNA-viruses. The virus contains 5 structural proteins, of which the S and N protein elicit the dominant response. It is those two proteins which are used in this test. The immunogold method used here is commonly accepted to be sensitive and the most robust of the lateral flow test.

On February 1, 2020, the International Committee on the Taxonomy of Viruses named the newest coro-navirus that causes COVID-19, SARS-CoV-2. Those infected may experience acute and severe respi-ratory diseases, accompanied by fever, cough, shortness of breath and dyspnea. Severe cases may lead to death.

SARS-CoV-2 IgG/IgM **Antibody Detection**

When the body is infected with coronavirus, the specific proteins on and within the virus stimulate a host immune response. The first antibody to appear is IgM, followed by IgG antibody. Following the acute infection and incubation period, subjects may become symptomatic with COVID-19. The IgG response increases and persists past the viremic phase, whereas the IgM response will decrease or even disappear entirely. The simultaneous dynamic monitoring of IgM and IgG can be used to better understand coronavirus exposure.



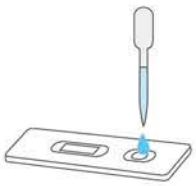
*Graph for illustrative purposes only

Specifications

- Sample volume: 10 µL
- Results in 10-15 minutes
- No cross-reactivity:
  Test Kit does not react with antibodies to the closely related coronaviruses (229E, OC43, HKU1 and NL63) or other pathogens (Influenza A viruses (H1N1, H3N2, H1N1-2009), Influ-enza B virus, Human adenovirus, Human metapneumovirus, Respiratory syncytial virus, Cytomegalovirus, Epstein-Barr virus, Hepatitis B, Hepatitis C, Haemophilius influenzae).

Product Name	Sample Type	Storage Temperature	Packaging Size
SARS-CoV-2 IgM/IgG ANTIBODY TEST KIT	Whole blood, Serum, Plasma	2°C - 30°C	25 tests/kit

Procedure

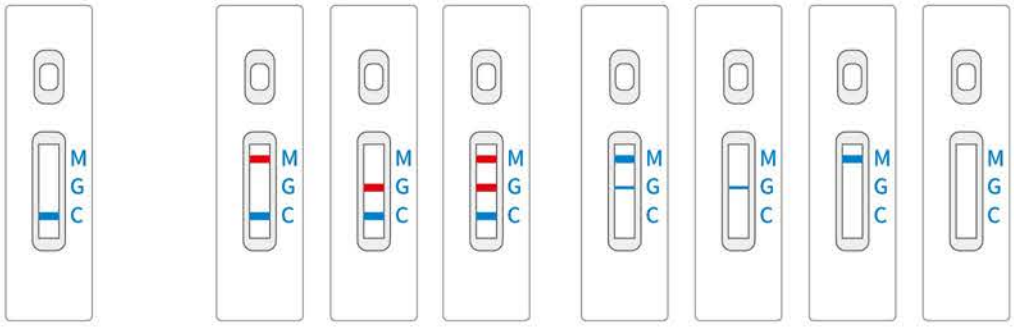


Within 10-15 Minutes

1. Add sample of whole blood, serum, or plasma
2. Add 2-3 drops sample dilution buffer
3. Read results in 10-15 minutes

Result Interpretation

A. Negative **B. Positive** **C. Invalid**



		Visible	Results	Action
Interpretation of Results	A	C (control band)	Negative	Negative result does not rule out infection.
	B	C + IgG + IgM	Positive	Positive result should be confirmed with a molecular method.*
		C + IgG		
		C + IgM		
	C	No C	Invalid	Result is not valid, repeat the test.
		No C + IgG + IgM		
		No C + IgG		
		No C + IgM		

* Please follow the guidelines of the national authorities, these may differ from FDA and CDC guidelines.

Yale University Performance Evaluation

Reference method: the COVID-19 antibody test was compared to real time PCR results by Yale University

No	Clinical diagnosis of patients	Sample Size
1	Healthy specimens	41
2	COVID-19 confirmed specimens	31

Analysis of Results >14 days post infection:

Detection	Reference method	Sensitivity	Specificity
SARS-CoV-2 IgG	RT-PCR	100%	100%
SARS-CoV-2 IgM	RT-PCR	100%	97.6%
SARS-CoV-2 IgG/IgM Total Antibody	RT-PCR	100%	97.6%

Target Population Group


High-Risk


Symptomatic


Potentially Exposed

Product Characteristics

1 **Flexibility**
Use Whole blood, Finger stick, Serum, or Plasma

2 **Safety**
Detect serum antibodies with reduced risk during sampling

3 **Cross-Reactivity**
Does not react with antibodies to the closely related coronaviruses (229E, OC43, HKU1 and NL63) or other pathogens (Influenza A viruses (H1N1, H3N2, H1N1-2009))

4 **Simplicity**
Perform the test and receive results in only 10-15 minutes

5 **Accuracy**
Excellent sensitivity and specificity provided with the detection of both IgG and IgM antibodies

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Order Test Kits Today:

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