FDA Emergency Use Authorized

SARS-CoV-2 IgM/IgG ANTIBODY TEST KIT

COLLOIDAL GOLD METHOD

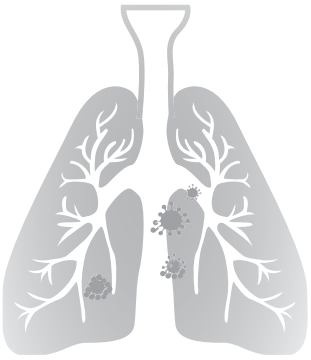
IVD

REF 11BH888889

CE

BACKGROUND

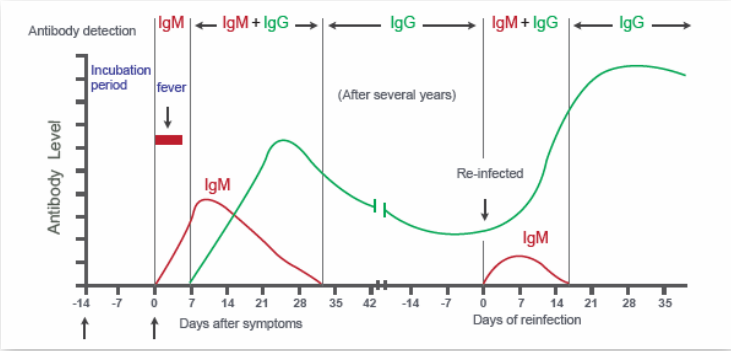
Coronaviruses are single-stranded, positive-sense RNA viruses with outer membranes that can cause acute and chronic diseases in humans and other vertebrates.



On February 1, 2020, the International Committee on the Taxonomy of Viruses named the new coronavirus as SARS-CoV-2. Infected individuals display acute and severe respiratory symptoms, accompanied by fever, cough, shortness of breath and dyspnea; severe cases may lead to renal failure and even death.

SARS-CoV-2 IgM/IgG ANTIBODY DETECTION

When the body is infected with a new coronavirus, the specific proteins of the virus stimulate the immune system and leads to an antibody response. The first antibody to appear is IgM, followed by the IgG antibody. During the general process of acute infection, IgG antibodies will begin to appear and their concentrations will gradually increase. This is accompanied by a reduction in IgM antibodies. The simultaneous dynamic monitoring of IgM and IgG antibody can be used in the auxiliary diagnosis of new coronavirus infection.



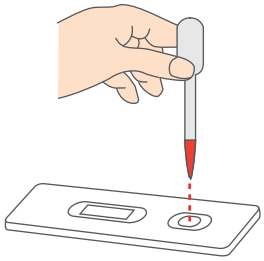
SARS-CoV-2 IgM/IgG ANTIBODY TEST KIT

Together, MP Biomedicals and Biohit Healthcare are now offering a SARS-CoV-2 IgM/IgG Antibody Test Kit. The kit has received Emergency Use Authorization (EUA) from the FDA for use as an aid in identifying individuals with recent or prior infections with SARS-CoV-2.

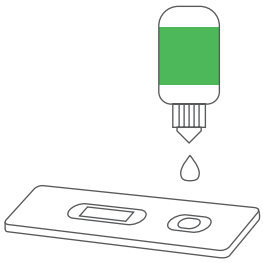
The qualitative test detects and differentiates both IgM and IgG antibodies against the virus that causes COVID-19 in human serum, plasma and venipuncture whole blood specimen samples.

Product Name	Sample Type	Storage Temperature	Packaging Size
SARS-CoV-2 IgM/IgG Antibody Test Kit	Serum, Plasma, Whole Blood	2 °C – 30 °C	25 tests/kit

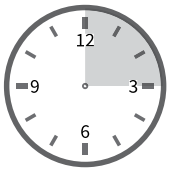
OPERATION PROCEDURE



1 Add 10 µL sample of serum, plasma or whole blood



2 Add 80 µL sample buffer

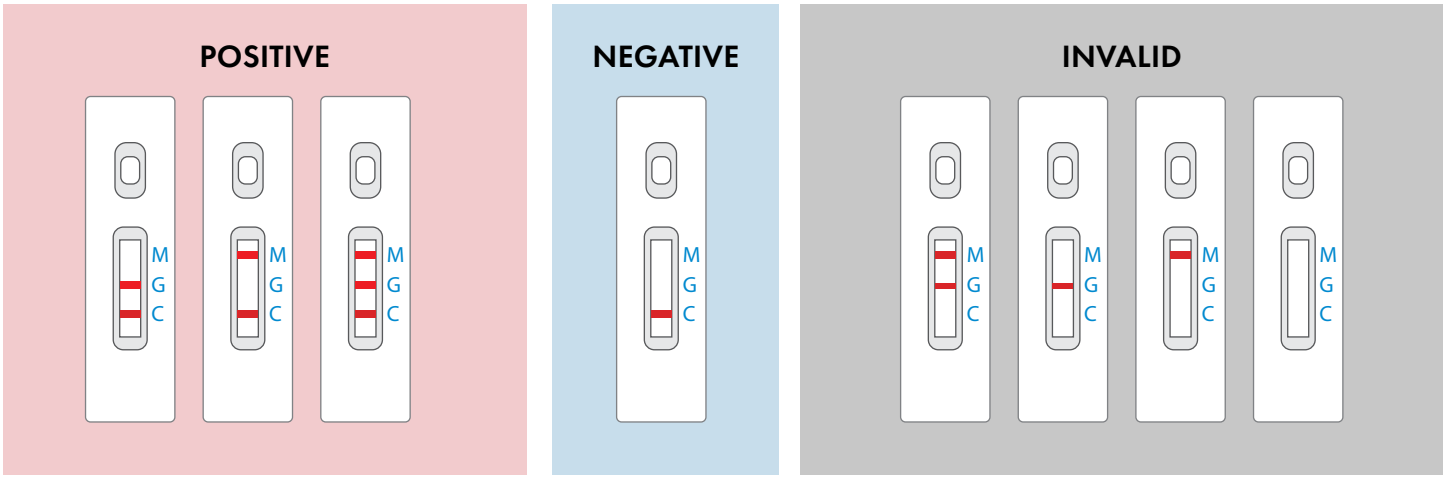


Within 1-15 Minutes

3 Interpret results within 15 minutes

RESULT INTERPRETATION

(C : Control M : IgM G : IgG)



PRODUCT FEATURES

Sample Flexibility

Test serum, plasma or whole blood

Low Risk

Antibody test reduces exposure risk from sampling

Simple and Rapid

Easy operation and only 15 minutes for test results

Sensitive

Combined IgM and IgG sensitivity of 96.7% and specificity of 95% (FDA-NCI Study)

CLINICAL EVALUATION

A retrospective study was carried out with 186 samples from a local hospital during the COVID-19 pandemic, including 78 samples of other (non SARS-CoV-2-mediated) respiratory tract infections (negative for SARS-CoV-2 infection by PCR) and 108 samples of healthy individuals (lacking respiratory symptoms by physical examination and negative for SARS-CoV-2 infection by PCR). All samples were tested with Biohit SARS-CoV-2 IgM/IgG Antibody Test Kit and negative percent agreement to PCR was evaluated.

Negative Percent Agreement (NPA) of IgM and IgG

All samples were tested with Biohit SARS-CoV-2 IgM/IgG Antibody Test Kit and negative percent agreement to PCR was evaluated.

	Reference method	NPA	95% Confidence Interval
SARS-CoV-2 IgM	SARS-CoV-2	99.46% (185/186)	97.04 - 99.99%
SARS-CoV-2 IgG	SARS-CoV-2	100% (186/186)	98.04% - 100%

To evaluate the performance of the Biohit SARS- CoV-2-IgM/IgG Antibody Test Kit over time with PCR positive patients, 197 serum samples were collected serially from 40 hospitalized SARS-CoV-2 PCR positive patients at different days following the onset of symptoms between 1-7, 8-14 and at least 15 days.

Positive Percent Agreement (PPA) (According to Days From Onset of Symptoms)

		IgG			IgM		
Days from onset of symptoms	PCR positive at any time	Samples with Positive results (Serum)	PPA	95% CI	Samples with Positive results (Serum)	PPA	95% CI
≤ 7	12	0	0		4	33.33%	13.81% - 60.93%
8-14	53	30	56.6%	43.26% - 69.05%	44	83.02%	70.78% - 90.80%
≥15	132	127	96.21%	91.43% - 98.37%	129	97.73%	93.53% - 99.22%
Total	197						

The Biohit SARS-CoV-2 IgM/IgG Antibody Test Kit has not been FDA cleared or approved; it has been authorized by the FDA under an EUA for use by authorized laboratories. Therefore, we cannot make any claims suggesting that the test is safe or effective for the detection of SARS-CoV-2. This test has been authorized only for the presence of IgM and IgG antibodies against SARS-CoV-2 and not for any other viruses or pathogens. This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

This test is authorized to be distributed by MP Biomedicals LLC., for Biohit Healthcare (Hefei) Co. Ltd.

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LEARN MORE
www.mpbio.com