



COVID-19 IgG/IgM

One-step COVID-19 IgG/IgM test



COVID-19 IgG/IgM Rapid Test

It is a respiratory infection caused by a new type of coronavirus (SARS-CoV-2) that has spread worldwide since its first occurrence in December 2019. Covid-19 is transmitted when the droplets of an infected person penetrate the respiratory tract or mucus membranes of the eyes, nose and mouth. After infection, about 2 to 14 days (estimation), the respiratory symptoms such as fever (37.5 degrees) and cough or dyspnea appear as the main symptoms, but asymptomatic infection cases are rare.

COVID-19 IgG/IgM is a rapid immunochromatography test for the qualitative presumptive detection of specific IgG and IgM to SARS-CoV-2 in human serum, plasma, venous or Capillary whole blood.

- Rapid testing for SARS-CoV-2 antibodies within 10 minutes
- Just 10 uL of specimen : whole blood, serum, plasma
- Suitable for Point-of-Care testing : No need for extra equipment

Features

- ✓ Rapid testing for SARS-CoV-2 antibodies within 10 minutes
- ✓ Just 10µl of specimen : serum, plasma or whole blood
- ✓ Suitable for Point-of-Care testing
- ✓ No need for extra equipment

Includes:


25 each- Test Cartridges
1 each - Bottle Buffer
Instructions



Test Procedure


1. Sample loading

10µl of serum, plasma or whole Blood




2. Run

3 drops of sample diluent




Result Interpretation

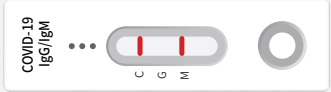
Negative

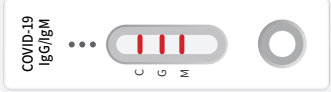



Invalid

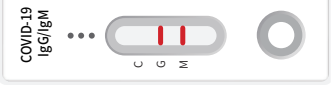



Positive














Clinical Evaluation

For the Clinical sensitivity

31 positive serum samples were collected from individuals who tested positive with a RT- PCR method for SARS-CoV-2 infection and were collected within 8-40 days after onset of symptoms. 29 of 31 were found be reactive with COVID-19 IgG/IgM.

The day of collection relative to the onset of illness was recorded.

Time post Symptoms onset	Date of Symptoms onset	Confirmation test date	Specimen collection date	Days after onset	COVID-19 IgG/IgM		
					IgM	IgG	Result
8-14 days	Apr. 09, 2020	Apr. 14, 2020	Apr. 22, 2020	11	POS	POS	POS
	Apr. 12, 2020	Apr. 19, 2020	Apr. 19, 2020	8	NEG	NEG	NEG
	Apr. 09, 2020	Apr. 11, 2020	Apr. 21, 2020	11	NEG	POS	POS
	No symptom	Apr. 12, 2020	Apr. 19, 2020	8	NEG	POS	POS
	Mar. 14, 2020	Feb. 24, 2020	Mar. 24, 2020	10	POS	POS	POS
15-21 days	Apr. 09, 2020	Apr. 12, 2020	Apr. 28, 2020	19	POS	POS	POS
	No symptom	Apr. 16, 2020	May. 04, 2020	18	POS	POS	POS
	Apr. 04, 2020	Mar. 20, 2020	Apr. 28, 2020	16	POS	POS	POS
	Apr. 14, 2020	Apr. 13, 2020	Apr. 28, 2020	14	POS	POS	POS
	Apr. 04, 2020	Apr. 07, 2020	Apr. 20, 2020	16	NEG	POS	POS
	Mar. 06, 2020	Mar. 09, 2020	Mar. 25, 2020	19	POS	POS	POS
	Feb. 24, 2020	Feb. 27, 2020	Mar. 15, 2020	20	NEG	POS	POS
	Mar. 14, 2020	Feb. 24, 2020	Apr. 01, 2020	18	POS	POS	POS
20-40 days	Apr. 06, 2020	Apr. 08, 2020	May. 01, 2020	25	POS	POS	POS
	Mar. 30, 2020	Apr. 02, 2020	May. 02, 2020	33	NEG	POS	POS
	Mar. 30, 2020	Apr. 02, 2020	May. 02, 2020	33	POS	POS	POS
	Apr. 12, 2020	Apr. 12, 2020	May. 04, 2020	22	NEG	POS	POS
	Apr. 08, 2020	Apr. 13, 2020	May. 04, 2020	26	NEG	POS	POS
	Mar. 27, 2020	Apr. 28, 2020	May. 04, 2020	38	POS	POS	POS
	No symptom	Apr. 01, 2020	May. 04, 2020	33	NEG	POS	POS
	Mar. 19, 2020	Mar. 19, 2020	Apr. 20, 2020	32	POS	POS	POS
	No symptom	Apr. 02, 2020	May. 04, 2020	32	POS	POS	POS
	Mar. 27, 2020	Mar. 28, 2020	Apr. 20, 2020	24	NEG	POS	POS
	Mar. 18, 2020	Apr. 01, 2020	Apr. 20, 2020	33	POS	POS	POS
	No symptom	Mar. 27, 2020	May. 06, 2020	40	NEG	NEG	NEG
	No symptom	Mar. 28, 2020	May. 06, 2020	39	NEG	POS	POS
	Mar. 14, 2020	Mar. 28, 2020	Apr. 20, 2020	37	NEG	POS	POS
	No symptom	Mar. 29, 2020	Apr. 20, 2020	22	POS	POS	POS
	Mar. 27, 2020	Mar. 31, 2020	Apr. 20, 2020	24	POS	POS	POS
	Mar. 28, 2020	Apr. 05, 2020	Apr. 20, 2020	23	POS	POS	POS
	Feb. 14, 2020	Feb. 24, 2020	Mar. 15, 2020	30	POS	POS	POS
Sensutivity(%)=(29/31)=93.5%							

Note

- Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered.
- Positive results may be due to past or present infection with SARS-CoV-2
- A negative or non-reactive results can occur if the quantity of antibodies of the SARS-CoV-2 virus present in the specimen is below the detection limit of assay.
- This test detects the presence of SARS-CoV-2 IgG/IgM in the specimen and should not be used as the sole criteria for the diagnosis of SARS-CoV-2 infection

For the Clinical sensitivity

40 negative serum samples were collected from individuals who tested negative with a RT-PCR method for SARS-CoV-2 infection, 37 were found to be non-reactive with COVID-19 IgG/IgM

sensitivity	COVID-19 IgG/IgM	
	IgM	IgG
PT-PCR SARS-CoV-2 negative sample	95.0%(38/40)	97.5%(39/40)
Total	92.5%(37/40)	

7 positive serum samples collected from asymptomatic patients, which were tested twice with a RT-PCR at early infection and before blood collection.

	Confirmation test date	2 nd test date	2 nd test results	Blood Confirmation date	COVID-19 IgG/IgM		
					IgM	IgG	Result
Asymptomatic patients	Apr. 12, 2020	Apr. 19, 2020	POS	Apr. 20, 2020	NEG	POS	POS
	Apr. 16, 2020	May. 04, 2020	NEG	May. 04, 2020	POS	POS	POS
	Apr. 01, 2020	May. 04, 2020	NEG	May. 04, 2020	NEG	POS	POS
	Apr. 02, 2020	May. 04, 2020	POS	May. 04, 2020	POS	POS	POS
	Mar. 27, 2020	Apr. 18, 2020	NEG	May. 06, 2020	NEG	NEG	NEG
	Mar. 28, 2020	May. 05, 2020	POS	May. 06, 2020	POS	NEG	POS
	Mar. 29, 2020	Apr. 21, 2020	POS	Apr. 20, 2020	POS	POS	POS

Cat.No	Product	Type	Pack Size	Sample type	Stability	Shelf Life
IMS-CHR09E	COVID-19 IgG/IgM	Device	25T/Box	Serum / Plasma / Whole Blood	1~30°C	12 months

