

# AllCheck COVID-19 IgG/IgM

## One-step COVID-19 IgG/IgM test

### Allcheck COVID-19 IgG/IgM

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 mucous membranes of the eyes, nose and mouth.

After infection, after 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.

AllCheck COVID-19 IgG/IgM is a rapid immunochromatography test for the qualitative detection of IgG and IgM antibodies 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
- Material provided : Device, Sample diluent



### Test Procedure

#### 1. Sample loading

10µl of serum, plasma or whole Blood



#### 2. Run

3 drops of sample diluent

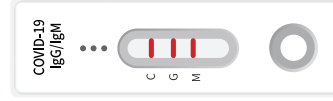
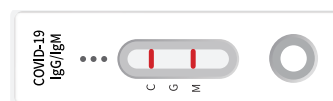


### Result Interpretation

#### Negative



#### Positive



#### Invalid



# Clinical Evaluation

## For the Clinical sensitivity

218 positive serum samples were collected from individuals who tested positive with a RT-PCR method for SARS-CoV-2 infection. 204 of 218 were found to be reactive with AllCheck COVID-19 IgG/IgM. The day of collection relative to the onset of illness was recorded for 31 samples.

Time post Symptoms onset	Date of Symptoms onset	Confirmation test date	Specimen collection date	Days after onset	All Check 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
15-21 days	Mar. 14, 2020	Feb. 24, 2020	Mar. 24, 2020	10	POS	POS	POS
	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
20-40 days	Mar. 14, 2020	Feb. 24, 2020	Apr. 01, 2020	18	POS	POS	POS
	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	

Sensitivity(%)=(204/218)=93.58%

### 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 Specificity

220 negative serum samples were collected from individuals who tested negative with a RT-PCR method for SARS-CoV-2 infection. 205 of 220 were found to be non-reactive with AllCheck COVID-19 IgG/IgM.

Specificity	All Check COVID-19 IgG/IgM	
	IgM	IgG
PT-PCR SARS-CoV-2 negative sample	94.55%(208/220)	98.64%(217/220)
<b>Total</b>	<b>93.18%(205/220)</b>	

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 <sup>nd</sup> test date	2 <sup>nd</sup> test results	Blood Confirmation date	All Check 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

## Ordering Information

Cat.No	Product	Type	Pack Size	Sample type	Stability	Shelf Life
CHR09E	AllCheck COVID-19 IgG/IgM	Device	25T/Box	Serum / Plasma / Whole Blood	1~30°C	18 months



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