COVID-19 IgG/IgM RAPID TEST

Rapid test for the qualitative detection of IgG and IgM antibodies against SARS-CoV-2 in human whole blood, serum or plasma specimens. For professional in vitro diagnostic use only.

PRIMA® PROFESSIONAL

Result in 10 minutes

Test your health

CE

COVID-19 and SARS-CoV-2

Coronavirus Disease 2019 (COVID-19) is an infectious respiratory disease caused by SARS-CoV-2 (Severe Acute Respiratory Syndrome Coronavirus 2), an infectious agent only recently discovered.
The virus was first reported in December 2019 in Wuhan (Hubei Province, China), from where it spread to almost all over the world. For this reason, on 11 March 2020, the General Director of the World Health Organization declared the pandemic status.

PRINCIPLE OF THE TEST

COVID-19 IgG/IgM Rapid Test is a qualitative membrane based lateral flow immunochromatographic assay for the detection of Immunoglobulin G (IgG) and Immunoglobulin M (IgM) against SARS-CoV-2 in whole blood, serum or plasma specimens.
Immunoglobulins, or antibodies, are proteins produced by specific immune cells in response to bacteria, viruses, microorganisms and other substances recognized by the body as foreign antigens.
There are five classes of immunoglobulins, of which IgM are generally produced as the body's first response to a new infection, providing short-term protection. The concentration of these antibodies increases for a few weeks and then decreases at the end of the infection. IgG, on the other hand, account for about 70-80% of immunoglobulins in the blood and they are generally produced later than the IgM. IgG levels usually tend to increase for a few weeks and then stabilise. The body is able to remember the different IgG levels, which can then be reproduced at each exposure to the same antigen.

WHO ARE THE INTENDED USERS

COVID-19 IgG/IgM Rapid Test is intended to be used by healthcare professionals in supporting the diagnosis of COVID-19.

TECH SPEC

COVID-19 IgG/IgM Rapid Test was evaluated as a serological device in multiple hospitals and research centers, in comparison with commercial reference PCR test. The results, when tested with specimens collected from individuals positive to PCR test at ≥ 11 days post-symptom onset, show high Sensitivity and Specificity reaching up to: 100% of Sensitivity and 99.2 % of Specificity for IgG (as expressed in Valenti *et al.*[3] study).
Combined results for IgG and IgM on 551 samples are shown in the table below.

METHOD		PCR	
	RESULTS	POSITIVE	NEGATIVE
COVID-19 IgG/IgM RAPID TEST (≥ 11 days post-symptom onset)	Positive (IgG and/or IgM)	133	9
	Negative	6	403
	Total Results	139	412

COMBINED DATA (IgG/IgM)
Sensibility: 95.7% (95% CI: 92.3%-99.1%)
Specificity: 97.8% (95% CI: 96.4%-99.2%)
Accuracy: 97.3% (95% CI: 95.9%-98.6%)

BIBLIOGRAPHY

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2. Su S, Wong G, Shi W, et al. Epidemiology, genetic recombination, and pathogenesis of coronaviruses. Trends Microbiol 2016; 24:490-502. PMID:27012512 DOI: 10.1016/j.tim.2016.03.003
3. Valenti L et al. SARS-CoV-2 seroprevalence trends in healthy blood donors during the COVID-19 Milan outbreak. Submitted to Eurosurveillance, 2020, medRxiv preprint doi: https://www.medrxiv.org/content/10.1101/2020.05.11.20098442v2
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WHY THE NEED FOR A COVID-19 SEROLOGICAL TEST?

The use of a serological test allows to identify individuals possibly exposed to the virus and to take initial precautionary isolation measures in order to reduce further spread of the virus itself.
In infected individuals the incubation period can vary between 1 and 14 days, with a prevalence of 3 to 7 days, after which the first symptoms begin to appear. Sethuraman *et al.* show the trend over time in the detection of diagnostic tests for SARS-CoV-2. In case of nasopharyngeal swab, the detection increases after the onset of the first symptoms (Figure 1) reaching a peak of detection in the first week after the onset of symptoms and then decreases steadily. IgM and IgG antibodies to SARS-CoV-2 appear in the blood of infected individuals from a few days up to 2 weeks after these symptoms and, while IgM levels decrease after the end of the infection, IgG levels remain high and detectable.
For this reason, these tests are useful for: (1) help the diagnosis of late symptomatic cases, as a support for molecular testing (nasopharyngeal swabs followed by PCR tests); (2) screen asymptomatic individuals who may have recently been exposed to the virus; (3) assist in seroprevalence investigations to define population exposure levels.

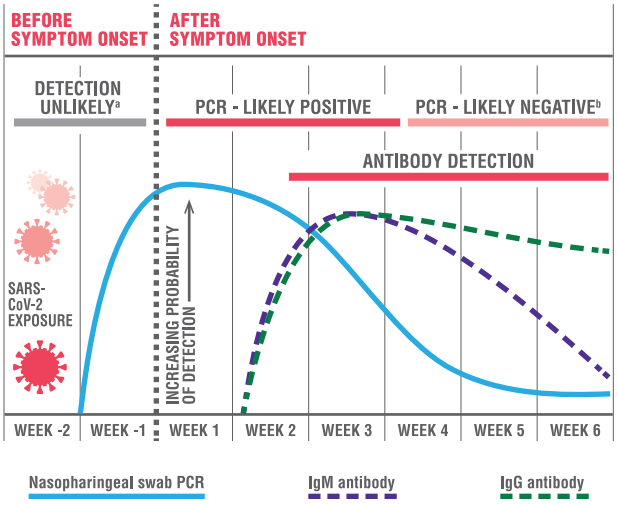


Figure 1
Graph related to COVID-19 detection with PCR and serological rapid tests. Image adapted from Sethuraman et al.

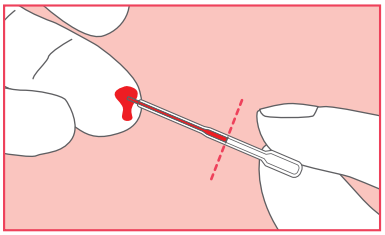
CONTENT

The box contains:
1* hermetically sealed aluminum pouch, containing:
- 1 COVID-19 IgG/IgM Rapid Test cassette
- 1 dessicant bag

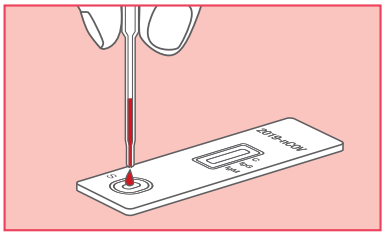
1* vial with dropper tip containing COVID-19 IgG/IgM Rapid Test diluent sufficient for 1* test
1 instructions for use leaflet
OPTIONAL*: Transparent plastic bag containing 1* 10-20 µL pipette or 20 µL capillary pipette for blood collection; 1*Sterile Lancet; 1*antiseptic cleanser gauze.
**The number of the testing devices of the kit may vary.*

HOW DOES THE TEST WORK?

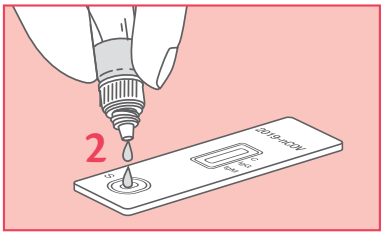
1) Take 20 µL of the whole blood sample after pricking the finger with the sterile lancet, taking care not to squeeze the pipette bulb. Alternatively, a laboratory micropipette can be used. For serum and plasma: add 10 µL of sample.



2) Deposit the blood sample into the sample well (S) of the cassette.



3) Add 2 drops of diluent (approx. 80 µL). Wait 5 seconds between the first and second drop of buffer.
Wait 10 minutes and read the results.



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