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NATRIX SRL IS A RESELLER OF THIS PRODUCT

RAPID TEST

CE IVD

ONLY FOR PROFESSIONAL USE

COVID-19 IgM/IgG Antibody detection

What is

The Rapid Test COVID-19 IgM/IgG is an immunochromatographic test for the qualitative determination of IgM and IgG class antibodies against COVID-19 in serum, plasma and human whole blood samples.

Features

- Diagnostic kit with quick response in 15 minutes
- Simplicity and speed of use compared to other diagnostic tests
- Can be used with serum, plasma and human whole blood
- Single test for IgM and IgG antibodies against COVID-19
- Including all accessories for picking (lancing device)
- Simplicity of sample collection, reduction of contagion risks
- Stable at 4-30 ° C for 24 months
- Formed by 25 tests
- CE-IVD
- Sensitivity 90% and specificity 96%

Main applications

- Fast screening in critical environments (health workers, law enforcement, public and private transport, public offices, logistics, production and sale of primary goods, etc.)
- Systematic screening of the population in the “outbreak areas” (easy identification of asymptomatic patients. Patients tested positive for the Rapid Test can be confirmed with the reference test (buffer + RT-PCR)

SARS-CoV-2: deepening

Coronaviruses are a large family of positive-stranded RNA viruses, with a crown-like appearance under an electron microscope.

A new Coronavirus (nCoV) is a new coronavirus strain that has never been identified in humans previously. In particular, the one called SARS-CoV-2 (previously 2019-nCoV), has been identified as the causative agent of a very aggressive viral pneumonia called COVID-19

The virus causing the current coronavirus pandemic has been called SARS-CoV-2 “Acute severe coronavirus 2 respiratory syndrome”. SARS-CoV-2 belongs to the β-coronavirus genus and is similar to that of SARS in 2003 and MERS in 2012.

The Coronavirus genome encodes 4 structural proteins that comprise the Spike protein (S), the envelope proteins or Envelope (E), the Membrane protein (M) and the Nucleocapside (N).

The human immune system produces specific antibodies from the first days of the first infection with the new coronavirus 2019.

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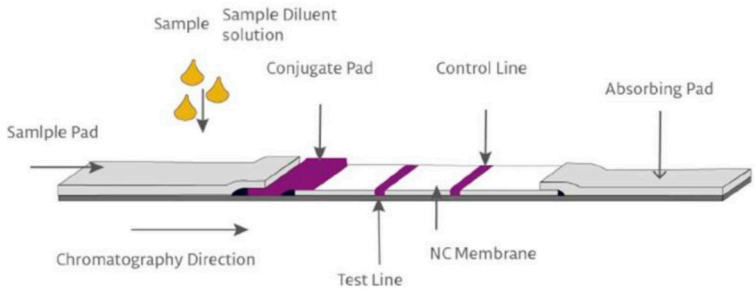
Test principle

The COVID-19 IgM / IgG Rapid Test uses colloidal gold chromatography technology as a solid phase for the qualitative determination of SARS-COV-2 IgM / IgG antibodies in human serum, plasma or whole blood.



The SARS-CoV-2 antigen and chicken IgY are conjugated with colloidal gold and coat the membrane

Test line T1 (IgM antibodies), test line T2 (SPA Protein A) and control line C (Chicken IgY antibodies) are pre-absorbed on the surface of the cellulose membrane (NC).

When the sample is added to the sample housing, it migrates through the conjugate present on the membrane:

Test Procedure

Dispense 10 µL of the sample of plasma or serum or 20 µL of the whole blood sample into the sample area

Slowly add 3 drops of sample diluent (120 µL) in the same area.

Incubate and read the result after 15 minutes

- In the presence of IgM antibodies the T1 line will be visible since the SARS-CoV-2 antigen complex conjugated with gold – IgM antibodies against SARS-CoV-2- antibodies against human IgM will be formed
- In the presence of IgG antibodies the T2 line will be visible since the SARS-CoV-2 antigen complex conjugated with gold – IgG antibodies against SARS-CoV-2-SPA will be formed
- If the specific antibodies of the IgM / IgG classes are absent, no test line appears (Negative Result)

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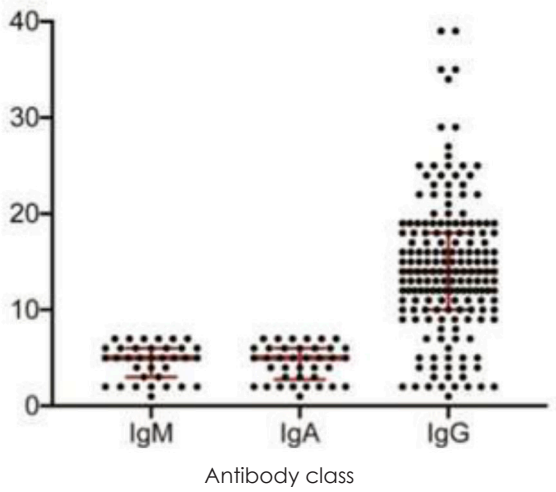
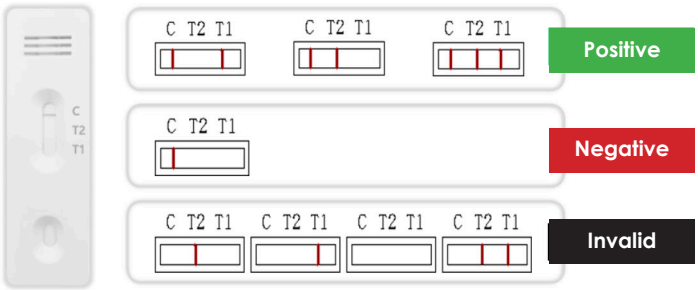
Interpretation of results

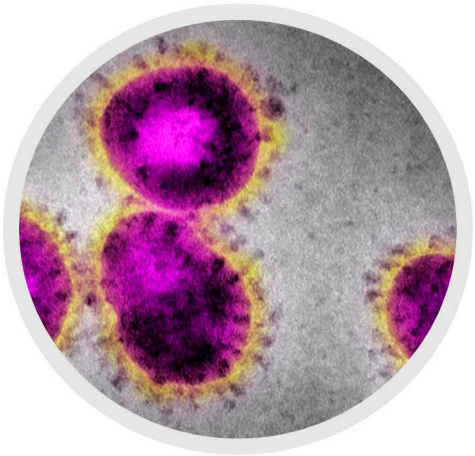
If the patient has contracted the virus, after a "window period", he begins to develop IgM class antibodies (active phase) and to follow IgG class antibodies.

With the passage of time the IgG rise while the IgM drop, with times and kinetics currently under study. This means that an individual with positive IgG has already been in contact with the virus, therefore either he has recovered or has passed the infection asymptomatically.

A patient with positive IgM has an ongoing COVID-19 infection.







- When the test result is "negative" but still associated with the patient's symptoms, the diagnosis must be confirmed with other methodologies or the Rapid Test repeated later.
- When the test result is "positive", it is suggested to deepen the diagnosis.

Test limits

- The presence of false positives, essentially attributable to possible cross reactions with other coronaviruses, is resolved by directing all the positives to the confirmatory test (RT-PCR).
- The presence of false negatives, inevitable in the window phase, can be resolved by means of a program of close re-tests of the negative individuals, in order to detect or exclude a possible seroconversion.

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Comparison of the diagnostic methodology

Rapid Test		PCR
Serum, Plasma or Whole Blood	Sample	Nasopharyngeal swab, sputum, lower respiratory tract, blood, stool
Antibodies	Diagnostic goal	Nucleic acids
15 minutes	Time to the result	> 3 hours
-	Equipment needed	Nucleic Acid extraction, PCR
No requirement	Laboratory requirements	Specialized laboratory
No requirement	Operator requirements	Qualified

Registry

Codice	Descrizione	Formato	Tecnica	Certificazione
	SARS-CoV-2 IgM/IgG GOLD	25 Test	Rapid Test	CE-IVD

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