REVOLUTION COVID-19 TEST

ONLY FOR PROFESSIONAL USE

Rapid Antigenic Test for SARS-CoV-2

LATEST GENERATION TEST

CE IVD

What is

The Revolution Covid-19 – Rapid Antigenic Test for Sars-Cov-2 is an immunochromatographic test to detect the presence of the Sars-CoV-2 virus in nasal swab sample.

Features

- CE-IVD certifications and notified to the italian ministry of health
- Latest generation test: reliable, high performance
- Test for professional use
- 5-20 minute quick response diagnostic kit
- Stable at 4-30 ° C for 12 month
- Including all accessories for sampling
- Format of 25 tests

The test is useful because

- Prelievo minimamente invasivo
- It does not require any other technological equipment to perform the analysis
- Ability to perform the analysis directly on the sampling point
- It reduces contact with the operator, thus decreasing the risk of contagion
- Result comparable to classic molecular swabs

Main applications

- Fast screening in critical environments (health workers, law enforcement, public and private transport, public offices, logistics centers, companies)
- Systematic screening of the population in the “outbreak areas” (easy identification of asymptomatic patients). Patients who tested positive for the Revolution Covid-19 Test must be confirmed with the reference test (molecular PCR test)
- Mass screening at the entrance of large transit facilities (airports, ports, stadiums, theaters, schools, stations, ships, etc.)

Natrix S.r.l.
VAT N. 01917350355
Via F.Cavallotti, 16 42122 Reggio Emilia
Tel.+39 0522 232606 Fax.+39 0522 506136 Email. info@natrixlab.it

QUALITY SYSTEM CERTIFICATION DNV·GL ISO 9001

QUALITY SYSTEM CERTIFICATION DNV·GL ISO 13485

REVOLUTION COVID-19 TEST

ONLY FOR PROFESSIONAL USE

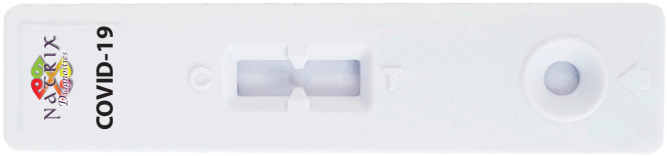
Rapid Antigenic Test for SARS-CoV-2

LATEST GENERATION TEST

CE IVD

Test principle

The Rapid Antigenic Test contains a test strip on which a monoclonal antibody has been immobilized, at the test line (T), and a polyclonal anti-rabbit-IgG antibody at the control line (C). A further monoclonal antibody, conjugated to colloidal gold nanospheres, is also already present in the strip. This conjugate, during the execution of the test, chromatographically migrates together with the sample along the strip. In the presence of the specific viral antigen of SARS CoV 2, the conjugate reacts with it, forming a complex which in turn is "captured" by the monoclonal antibody immobilized on the T line, generating a black / green band. The excess of the conjugate continues its chromato-graphic run until it reaches the control line (C) with which it reacts by generating an additional black / green band, thus indicating the correct execution of the test.



Test procedure

1. Collect the sample through the nasal swab
2. Fill the extraction tube with 10 drops of diluent. Dip the swab into the tube and shake the swab 5-10 times while pressing the head against the bottom and side of the extraction tube.
3. Remove the swab by squeezing the walls of the tube.
4. Close the extraction tube tightly with the dropper cap.
5. Remove the device from the foil pouch and place it on a flat, dry surface.
6. Invert the extraction tube and squeeze it gently to put 3-4 drops (90-150 µL) into the test well (S).

* Make sure that an appropriate amount of sample and test diluent is used for the test. Too little or too much sample and / or assay diluent can lead to bias in results.

7. Read the result in 15-20 minutes. Do not interpret the result after 20 minutes.

Natrix S.r.l.
VAT N. 01917350355
Via F.Cavallotti, 16 42122 Reggio Emilia
Tel.+39 0522 232606 Fax.+39 0522 506136 Email. info@natrixlab.it

QUALITY SYSTEM CERTIFICATION DNV·GL ISO 9001

QUALITY SYSTEM CERTIFICATION DNV·GL ISO 13485

REVOLUTION COVID-19 TEST

ONLY FOR PROFESSIONAL USE

Rapid Antigenic Test for SARS-CoV-2

LATEST GENERATION TEST

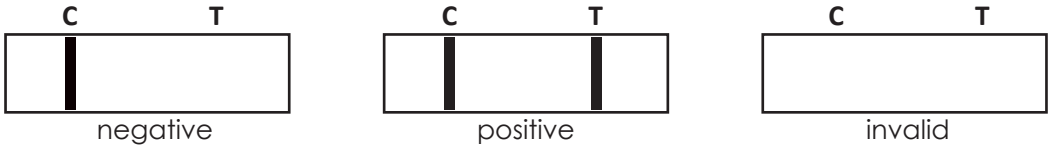
CE IVD

Interpretation of result

Negative result: A black / green line appears at the control line (C). There are no other bands.

Positive result: in addition to the black / green band corresponding to the control line (C), another band of the same color appears at the test line (T). Any line of black / green color (T), even if not very intense, must be considered an indication of a positive result.

Invalid result: the absence of a control line indicates an error in the test procedure. Repeat the test using a new cassette.



Test limits

The test is qualitative and therefore cannot be used to assess the amount of viral antigen that may be present in the sample. This is an acute phase screening test. Samples collected in the advanced stages of infection may contain antigenic titers below the sensitivity threshold of the test.

Comparison of the diagnostic methodology

	RAPID ANTIGENIC TEST	RT PCR
Sample	Nasopharyngeal swab	Nasopharyngeal swab
Diagnostic objective	Viral antigen	Nucleic acids (RNA)
Time to result	15-20 minutes	> 3 hours
Equipment needed	-	Nucleic Acid extraction, PCR
Laboratory requirements	no requirement	Specialized laboratory
Collection	performed by a specialized operator	performed by a specialized operator
Invasive collection	yes	yes
Comparison with the disease	evaluates the presence of the viral protein then gives the positive response when a person is infectious	can find small amounts of genetic viral material, so a test can be positive even when the person has stopped being infectious

Natrix S.r.l.
VAT N. 01917350355
Via F.Cavallotti, 16 42122 Reggio Emilia
Tel.+39 0522 232606 Fax.+39 0522 506136 Email. info@natrixlab.it

QUALITY SYSTEM CERTIFICATION DNV·GL ISO 9001

QUALITY SYSTEM CERTIFICATION DNV·GL ISO 13485

REVOLUTION COVID-19 TEST

ONLY FOR PROFESSIONAL USE

Rapid Antigenic Test for SARS-CoV-2

LATEST GENERATION TEST

CE IVD

Product data

Code	Description	Format	Technique	Certification
10400001	RAPID ANTIGENIC TEST FOR SARS-CoV-2	25 Test	IMMUNOCHROMATO-GRAPHY	CE-IVD

1 bottle with extraction liquid

25 extraction tubes

25 nasal swabs

25 strips packed in cassettes, sealed in heat-sealed bags with desiccant (1 pc / bag)

Natrix S.r.l.
VAT N. 01917350355
Via F.Cavallotti, 16 42122 Reggio Emilia
Tel.+39 0522 232606 Fax.+39 0522 506136 Email. info@natrixlab.it

REV 01 - 22/01/2021