REVOLUTION COVID-19 TEST

ONLY FOR PROFESSIONAL USE

Rapid Salivary Test for SARS-CoV-2 Ag

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
- 15-25 minute quick response diagnostic kit
- Stable at 4-30 ° C for 12 month
- Including all accessories for sampling
- Format of 25 tests
- Clinical specificity: 100%

Limit of detection:

Sample	TDCI50/ml In saliva	Replicates	Result		
			expected	obtained	percentage
1/40000 SARS-CoV-2	7.05×10^2 TCID50/mL	70	70	70	100 %
Sample NEG.	$TCID_{50}$/mL	70	70	70	100 %

The test is useful because:

- Non-invasive collection
- 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.)

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QUALITY SYSTEM CERTIFICATION DNV·GL ISO 9001
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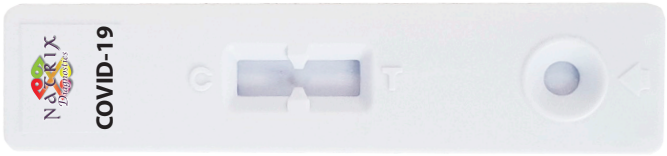
Test principle

The Rapid Salivary 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 chromatographic 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 saliva sample in the appropriate tube filling it at least to halfway
2. Insert the swab inside the saliva collection tube.
3. Dispense 15 drops (400 µl) from the Sample Lysis Buffer bottle directly into the conical extraction tube.
4. Remove the swab from the salivary collection tube, dip it into the extraction tube and shake the swab 5-10 times while pressing the head against the bottom and side of the extraction tube.
5. Remove the swab by squeezing the walls of the tube and dispose of it.
6. Close the extraction tube tightly with the dropper cap.
7. Remove the device from the foil pouch and place it on a flat, dry surface.
8. Invert the extraction tube and squeeze it gently to dispense 6 drops (approximately 150 µL) into the test well.

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

9. Read the result in 15-25 minutes. Do not interpret the result after 25 minutes.

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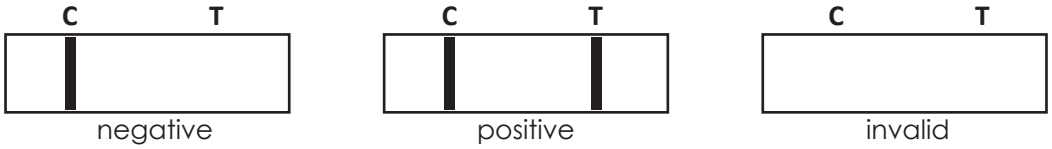
Interpretation of results

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

he 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.

Confronto della metodologia diagnostica

	REVOLUTION COVID-19	RAPID TEST AG SWAB	RT PCR
Sample	Saliva	Nasopharyngeal swab	Nasopharyngeal swab
Diagnostic objective	Viral antigen	Viral antigen	Nucleic acids (RNA)
Time to result	15-25 minutes	15-20 minutes	> 3 hours
Equipment needed	-	-	Nucleic Acid extraction, PCR
Laboratory requirements	no requirement	no requirement	Specialized laboratory
Collection	performed by the patient indepen-dently	performed by a specialized operator	performed by a specialized operator
Invasive collection	no	yes	yes
Comparison with the disease	evaluates the presence of the viral protein then gives the positive response when a person is infectious	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

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Product data

Code	Description	Format	Technique	Certification
10400000	REVOLUTION COVID-19 - RAPID SALIVARY TEST	25 Test	IMMUNOCHROMATO-GRAPHY	CE-IVD

1 Sample dilution buffer in a 15 mL bottle with dispenser cap

25 saliva sample collection tubes (25 pcs / bag)

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

25 collection swabs

25 extraction tubes

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