

SARS-CoV-2 Antigen test

Rapid *in vitro* diagnosis test for professional use for the qualitative detection of specific antigens of the SARS-CoV-2 virus in humans from nasopharyngeal samples.



RAPID, PRECISE AND EASY TO USE TEST

biotical SARS-CoV-2 Ag card test is a very valuable tool in terms of cost and time compared to other diagnostic methods, with a much earlier detection window than a serological antibody test. It is able to identify an active infection in under 10 minutes and with no need for laboratory equipment.

Our test's monoclonal antibody has high specificity to the SARS-CoV-2 antigen, limiting the possibility of false positives.

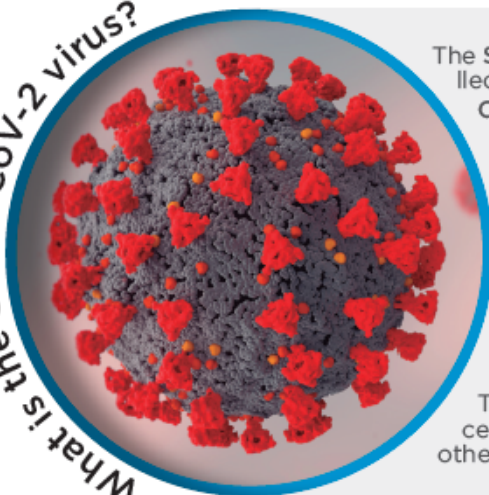
biotical SARS-CoV-2 Ag card test is manufactured in Spain by biotical health S.L.U, under European Regulation 98/79/EC on In Vitro Diagnostic Medical Devices, as well as the ISO13485 certification.



	IgG rapid test	IgM rapid test	Antigen rapid test	qPCR
Evidence of active infection	No	Yes	Yes	Yes
Detection time (from first symptoms)	> 15 days	> 5 days	Immediate	Immediate
Asymptomatic detection	Detectable	Detectable	Detectable	Detectable
Sensitivity	Low	Low	High*	Very high
Specificity	Average	Average	Very high	Very high
Time for result	Minutes	Minutes	Minutes	Hours/days
Cost	Low	Low	Low	Moderate
Equipment	No	No	No	Yes
Type of sample	Serological	Serological	Nasopharyngeal	Nasopharyngeal

*Results calculated according to the indications of the World Health Organization regarding the use of rapid antigen-detection tests for SARS-Cov-2 (Antigen-detection in the diagnosis of SARS-CoV-2 infection using rapid immunoassays, 11 September 2020), using nasopharyngeal samples with a high viral load.

What is the SARS-CoV-2 virus?



The SARS-CoV-2 virus is a new type of coronavirus responsible for the disease called COVID19.

COVID19 presents with a very wide picture of symptoms, among which are fever, fatigue, sore throat, headache, dyspnoea, diarrhoea, loss of taste and smell, as well as circulatory and organic complications of various types. SARS-CoV-2 is considered a respiratory virus that potentially causes pneumonia.

SARS-CoV-2 has demonstrated a high level of human-to-human transmission due to its long incubation period (from two to twelve days), the ability to occur asymptotically in certain individuals and to remain active on surfaces.

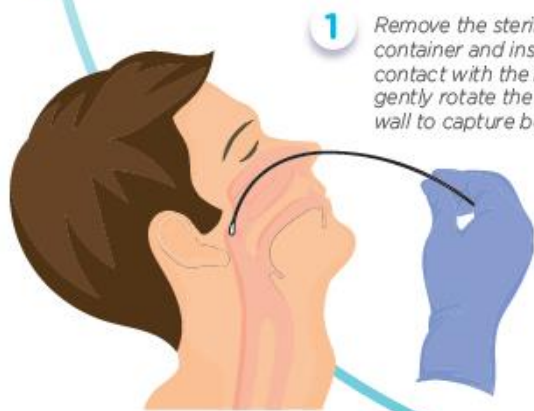
The virus is spread by drops of saliva when talking, coughing or sneezing over short distances and to a lesser extent by aerosols.

Other routes of transmission such as faecal contamination are possible.

The virus enters the nasopharyngeal cavity where it enters into the epithelial cells and shows its highest viral load in the first days, replicating and accessing other cells in the body with specific receptors as the disease progresses.



SARS-CoV-2 Ag card Procedure



1 Remove the sterile swab from its container and insert it until it makes contact with the nasopharynx, then gently rotate the swab against the nasal wall to capture both cells and snot.

2

- Add 15 drops of Reagent.
- Put the swab into the tube and rotate it for 1 minute to extract the liquid.

3

Add exactly 3 drops in the window "S".



4
Read the results after 10 minutes

10'



NEGATIVE



POSITIVE



INVALID



INVALID

biotical SARS-CoV-2 Ag card Vs qPCR technique

	Sensitivity	Specificity	PPV	NPV
Mean Value	92,9%*	99,6%	96,3%	99,1%
Intervalo de confianza	76,5 - 99,1%	97,6 - 100,0%	81,0 - 99,9%	97,0 - 99,9%

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SARS-CoV-2 biotical KIT	Test card in sealed container	Swab in sterile container	Test tubes and pipettes	Diluent	Extra quality control
Contenido del estuche	25 units	25 units	25 + 25 units	Included	Positive control included

Biomedical Diagnostics

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