PRIMACOVID®

COVID-19 NEUTRALISING Ab RAPID TEST

Rapid test for the qualitative detection of IgG antibodies directed against the SARS-CoV-2 Spike protein in human serum, blood, plasma samples

For professional in-vitro diagnostic use only

CONTENT

1. Pipette for sample collection
2. Test cassette
3. Vial containing the diluent
4. Sterile lancet

Cleanser gauze

Instructions for use leaflet

TECH SPECS

Accuracy: 96.5%
(95% CI: 94.9-98.13%)

Sensitivity: 98.1%
(95% CI: 96.0%-99.1%)

Specificity: 97.4%
(95% CI: 95.9-99.0%)

SEROCONV. PFIZER 98.3%
(95% C.I.: 95.6%-99.3%)

SEROCONV. MODERNA 95.2%
(95% C.I.: 77.3%-99.2%)

SEROCONV. ASTRAZENECA 98.5%
(95% C.I.: 92.1%-99.7%)

A recent investigation has shown a 100% positivity rate (95% Wilson C.I.: 87.1 - 100%)* after the booster dose - the study is still ongoing

**Data obtained from subjects vaccinated with Pfizer BioNTech and Moderna booster dose.*

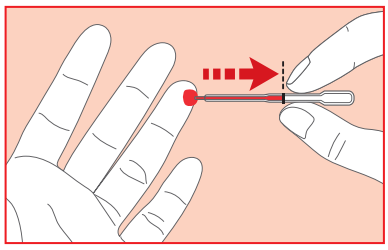
PRINCIPLE OF THE TEST

COVID-19 NEUTRALISING AB RAPID TEST is a rapid immunochromatographic assay, whose target analyte are IgG antibodies against the RBD (*Receptor Binding Domain*) portion of the SARS-CoV-2 Spike protein. This portion allows the virus to bind it to specific membrane receptors and to penetrate into the guest cell.

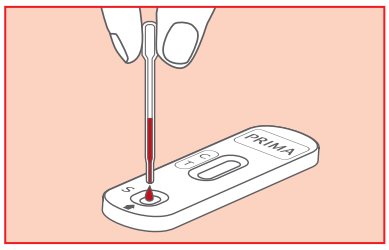
WHO ARE THE INTENDED USERS

The device is intended to be used by healthcare professionals in order to check the immune response of those who have been vaccinated or those who have previously contracted the disease. It is recommended to take the test starting from 14 days following the end of the vaccination cycle.

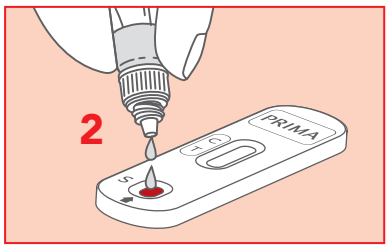
HOW DOES THE TEST WORK?



1. Take a blood sample after pricking the finger, using the provided pipette.



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



3. Add 2 drops of diluent and wait 10 minutes before reading the result.

BIBLIOGRAPHY

1. European Centre for Disease Prevention and Control, Disease background of COVID-19 (https://www.ecdc.europa.eu/en/2019-ncov-background-disease)
2. https://www.who.int/emergencies/diseases/novel-coronavirus-2019
3.HUANG, Yuan, et al. Structural and functional properties of SARS-CoV-2 Spike protein: potential antivirus drug development for COVID-19. Acta Pharmacologica Sinica, 2020, 41.9: 1141-1149.
4.SHANG, Jian, et al. Structural basis of receptor recognition by SARS-CoV-2. Nature, 2020, 581.7807: 221-224
5. Pfizer Seroconversion 98.3% (95% CI: 95.6-99.3%) - Data on file. Q8R318 Study Report. Italian National Cancer Institute (Milan, Italy), Interuniversity Center for Research on Influenza and other Transmissible infections (Genova, Italy), Pharmacological Research Institute Mario Negri (Bergamo, Italy) and PRIMA Lab SA (Balerna, Switzerland); May 2021.
6. Moderna Seroconversion 95.2% (95% CI: 77.3-99.2%) - Data on file. Q8R334 Study Report. PRIMA Lab SA (Balerna, Switzerland); June 2021.
7. AstraZeneca Seroconversion 98.5% (95% CI: 92.1-99.7%) - Data on file. Q8R335 Study Report. PRIMA Lab SA (Balerna, Switzerland); June 2021.
8. Performance Validation Post Booster Dose 100% positivity rate (95% Wilson C.I.: 87.1 - 100%) - Data on file. Q8R348 Study Report. PRIMA Lab SA (Balerna, Switzerland); January 2022.

REF	DESCRIPTION	NUMBER OF TESTS
800065-20P	COVID-19 NEUTRALISING Ab RAPID TEST	20 tests

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