



PRIMACOVID[®] COVID-19 NEUTRALISING IgG SEROLOGICAL TEST

Rapid self-test for the qualitative detection of COVID-19 antibodies produced after vaccination in human whole blood samples



SPIKE PROTEIN

One of the most important proteins involved in the virus infection process is the Spike protein, which covers the whole virus' surface. It is divided into two portions: the first one contains a region known as RBD (Receptor Binding Domain) that allows the virus to bind to the host cell by adhering to the ACE2 receptor; while the second one allows the virus to enter the cell in a following phase.

This evidence allows us to assume that an antibody capable of inhibiting the interaction between the Spike protein and the ACE2 receptor would potentially prevent coronavirus infection and the associated disease.

WHO ARE THE INTENDED USERS

COVID-19 NEUTRALISING IgG SEROLOGICAL TEST is intended for anyone who wants to test their immune response following vaccination. It is advisable to do the test starting from 14 days after the end of the vaccination cycle.

WHY - BENEFITS

It is very important to support the ongoing vaccination campaigns, by checking the immune response post-vaccination.

TEST PRINCIPLE

COVID-19 NEUTRALISING IgG SEROLOGICAL 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 to the host cell.

TECH SPECS

SEROCONV. PFIZER	SEROCONV. MODERNA	SEROCONV. AZSTRAZENECA	BOOSTER DOSE POSITIVITY RATE
98.3%	95.2%	98.5%	100%*

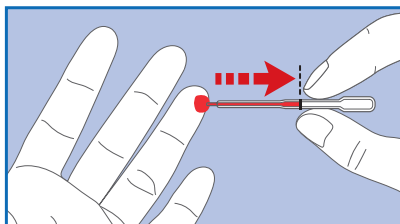
*Data obtained from subjects vaccinated with Pfizer BioNTech and Moderna booster dose.

CLINICAL EVIDENCES

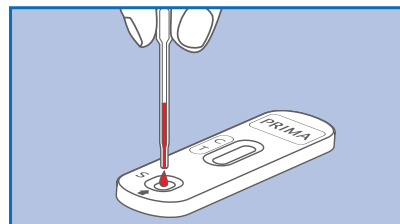
1. European Centre for Disease Prevention and Control, Disease background of COVID-19 (<https://www.ecdc.europa.eu/en/2019-ncov-background-disease>)
2. <https://www.who.int/emergencies/diseases/novel-coronavirus-2019>
3. HUANG, Yuan, et al. Structural and functional properties of SARS-CoV-2 Spike protein: 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.

HOW TO USE IT

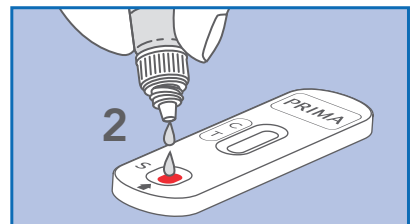
1) Take a blood sample after pricking the finger.



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



3) Add 2 drops into the well and wait 10 minutes before reading the result.



CONTENT: 1 sealed aluminium pouch containing: 1 test device and 1 desiccant bag; 1 transparent plastic bag containing a pipette for blood collecting; 1 vial with dropper containing the diluent; 2 sterile lancets for blood sampling; 1 alcohol swab and 1 instructions for use leaflet.



REF	DESCRIPTION	NUMBER OF TESTS
800165-1	COVID-19 NEUTRALISING IgG SEROLOGICAL TEST	1 TEST