

Serology-based Total Antibody Detection Rapid Tests COVID-19 (Lateral Flow Devices)

Rapid, point-of-care antibody testing is an essential component of the tools portfolio used for addressing the COVID-19 (SARS-CoV-2) global pandemic by helping to prevent the spread of infection and acting as a complementary tool for direct detection methods.

The INgezim[®] COVID 19 CROM total antibody detection lateral flow devices, or rapid tests, determine past exposure to the virus in just 10 minutes. The serology-based, finger-prick tests are dual-recognition immunochromatographic assays that determine the presence of total antibodies (IgG, IgA, and IgM) specific to SARS-CoV-2 in a single blood, serum, or plasma sample, with high sensitivity and specificity.

Key Benefits of the INgezim[®] COVID 19 CROM

- Results in only 10 minutes
- Detects antibodies in 94.5% of cases from 19 days post-symptom onset and features a diagnostic specificity of 99.3%*
- No cross-reactivity with antibodies specific to other coronaviruses or agents related to human respiratory illnesses
- CE-IVD marked

Double recognition ELISA kits (INgezim COVID 19 DR) for the determination of total antibodies to SARS-CoV-2 in blood and serum samples are also available.

Serology-based Total Antibody Detection Rapid Tests COVID-19



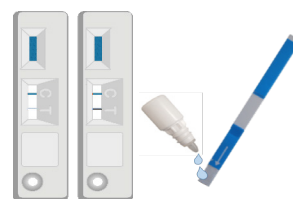
Application

The INgezim® COVID 19 CROM tests qualitatively determine total antibodies specific to the SARS-CoV-2 virus nucleoprotein (N protein) in human serum or blood samples.

These rapid, point-of-care tests can be performed outside of the laboratory and are intended for use by healthcare professionals only, not for self-diagnosis.

Principles of the Tests

The tests use coloured latex microspheres that bind to proteins of interest. The black particles are covalently bound to the N protein of SARS-CoV-2, while the blue particles are bound to a control protein, indicating the correct development of the immunochromatography. SARS-CoV-2 antibodies present in the sample react with the black latex particles coated with the N protein.



Key Benefits

- Results in only 10 minutes
- High sensitivity and specificity: Detects antibodies in **94.5% of cases from day 19 post-symptom onset** and features a diagnostic **specificity is 99.3%.***
- No cross-reactivity with antibodies specific to other coronaviruses or agents related to human respiratory illnesses
- Test kits include all materials required to perform the test (test strip, lancet, pipette and diluent).
- The test is facilitated through finger-prick blood extraction.
- CE-IVD marked

** Validation study, May 2020: Validation of the assays was determined with a panel of more than 400 well characterised sera samples. No cross-reactivity with other respiratory coronaviruses (229E, NL63, OC43 and HKU1) was detected.*

Art. No.	Product	No. of tests	Product description
50.CoV.K.41	INgezim COVID 19 CROM	25	Immunochromatography for determination of total antibodies in blood and serum samples
50.CoV.K.41/S	INgezim COVID 19 CROM Easy	25	Immunochromatography strips for determination of total antibodies in blood and serum samples (Easy)



ELISA Kit also available:

Eurofins Technologies also offers a double recognition ELISA kit, INgezim COVID 19 DR, for the determination of total antibodies to SARS-CoV-2 in blood and serum samples. Please contact us for further information on our ELISA assay portfolio.