

# SARS-CoV-2 Diagnostic

## Serology-based Total Antibody Detection Rapid Tests

**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

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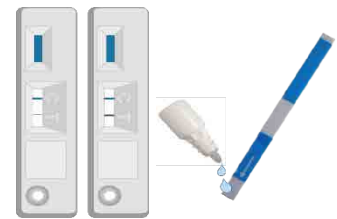
### Application

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.



### Assay Features

- 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 of 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 and a specificity of 99.3% was determined.

Product / Format	Article Number	Description
<b>INgezim® COVID-19 CROM</b>		
25 tests	HW/50.CoV.K.41	Immunochromatography for determination of total antibodies in blood and serum samples
<b>INgezim® COVID-19 CROM easy</b>		
25 tests	HW/50.CoV.K.41/S	Immunochromatography strips for determination of total antibodies in blood and serum samples (Easy)

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