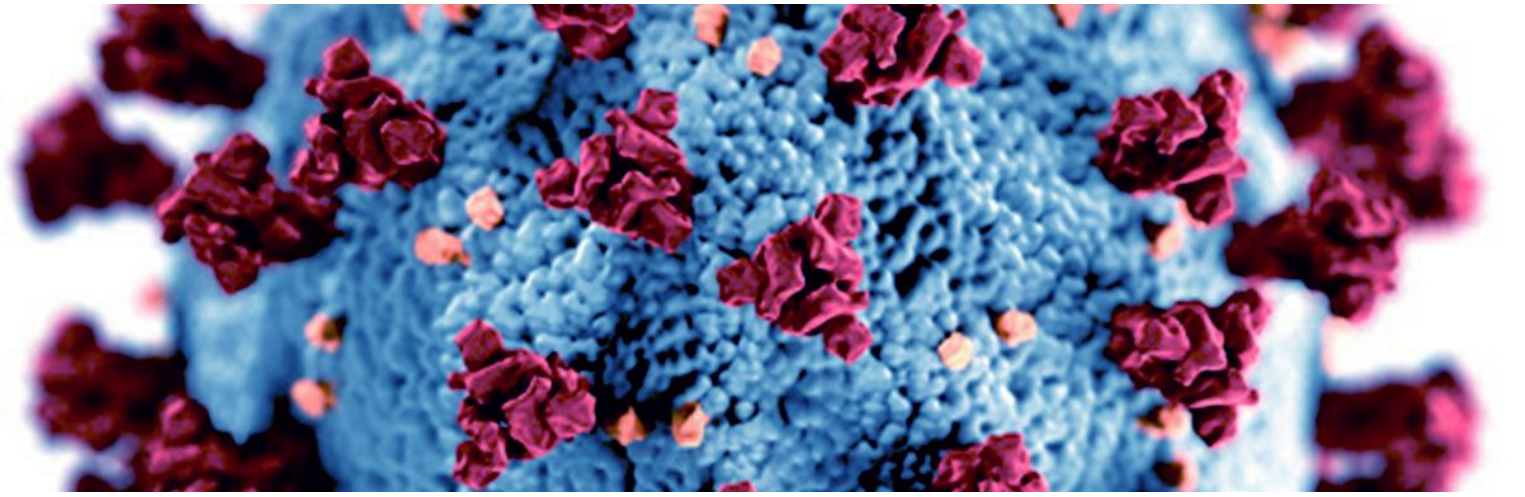
INgezim® COVID 19 CROM

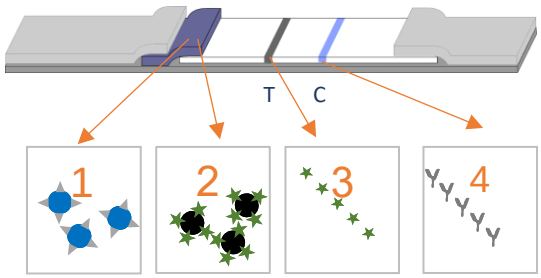
R.50.CoV.K41



The INgezim® COVID 19 CROM test is a dual-recognition immunochromatographic assay capable of detecting specific COVID-19 (SARS-CoV-2) antibodies in serum and blood samples.

Application

INgezim® COVID 19 CROM qualitatively determines the total antibodies (IgG, IgA, and IgM) specific to SARS-CoV-2 virus N in a single blood, serum, or plasma sample by using nucleoprotein (N protein) as an antigen for detection of antibodies to the virus. This rapid, point-of-care test delivers results in only 10 minutes and can be performed outside of the laboratory. The test is intended for use by healthcare professionals, not for self-diagnosis.



Technical Principles

The test uses coloured latex microspheres that bind to the proteins of interest. The black particles are covalently bound to the full-length recombinant SARS-CoV-2 N protein (2), while the blue particles are bound to a control protein (1), indicating the correct development of the immunochromatography.

The membrane contains a test line (T), in which the SARS-CoV-2 N protein (3) is immobilized, and a control line (C), formed by a specific monoclonal antibody (4) of the control protein. SARS-CoV-2 antibodies present in the sample react with the black latex particles coated and the latex/protein/antibody complex, migrate across the membrane, and bind to the protein contained within the test line, resulting in a coloured T line. If the sample has no SARS-CoV-2 antibodies, no colour will appear on the T line. The C line must always appear blue or the test is invalid.

Validation Data

The product has been validated with collections of previously characterized sera.

DIAGNOSTIC SENSITIVITY AND SPECIFICITY

Diagnostic sensitivity was determined in two ways:

1. **In comparison to the PCR technique (157 sera extracted on different days after the first day of symptoms onset from patients tested positive by PCR)**

   A relative sensitivity of 72.6% was obtained with respect to the PCR technique. The difference in the detection target between the two techniques should be taken into account. PCR detects the virus itself, while the INgezim® COVID 19 CROM assay detects the antibodies generated after infection. Antibodies take some days/weeks to appear in detectable quantities after infection while the virus is generally detectable earlier in the nasopharyngeal area.

2. **In comparison to other commercial serological tests (315 sera)**

   The relative sensitivity with respect to other commercial ELISA kits is 90.7%.

Results in comparison with PCR

	INgezim® COVID-19 CROM	PCR
POSITIVE	114	157
NEGATIVE	43	0

Results in comparison with serological tests

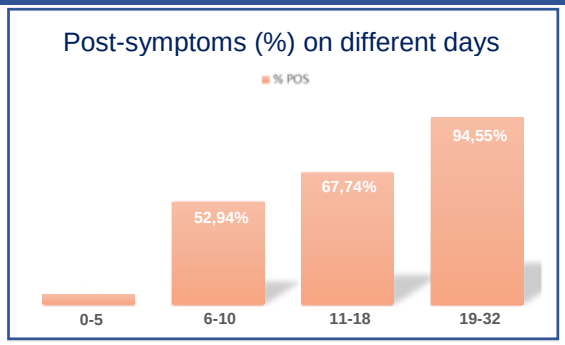
	INgezim® COVID-19 CROM	Other tests
POSITIVE	286	315
NEGATIVE	29	0

To determine diagnostic specificity, 146 sera previously classified as: (1) sera from patients tested positive by PCR and negative by serology, (2) sera from patients tested negative by PCR and negative by serology, or (3) sera from historically negative patients (blood donors prior to 2019) were analysed. Results showed **99.3% specificity**.

ANALYTICAL SENSITIVITY AND SPECIFICITY

Study of Analytical Sensitivity

To determine the ability of the assay to detect antibodies during an infection, 153 human sera were tested, extracted on different days after the first day symptoms appeared. The table shows the data grouped by post-symptom periods and the percentage of positives detected. In 68% of cases, the assay was able to detect antibodies from day 11 after the onset of first symptoms, and in **94.5% of cases from day 19.**



Study of Analytical Specificity

To determine the analytical specificity of the assay, samples were analysed from people affected by other respiratory coronaviruses (229E, NL63, OC43, and HKU1) and people with respiratory infections caused by other agents, such as RSV, enteroviruses, Bordetella pertussis, Mycoplasma pneumoniae, Influenza A and B, and adenoviruses.

The results obtained indicate **no cross-reactivity** with antibodies specific to other coronaviruses or agents related to human respiratory illnesses. As a result, the specificity was established higher than 99%.

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EXPIRATION 12 months
Keep at 4ºC-25ºC