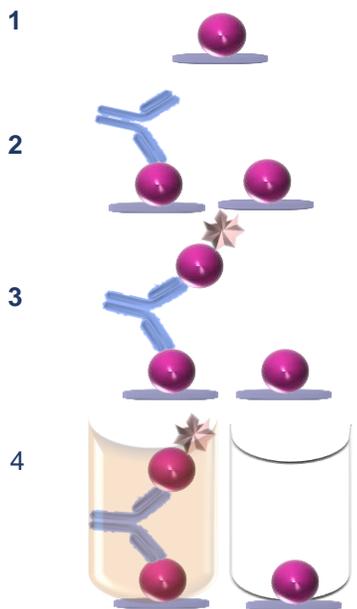INgezim® COVID-19 DR is an enzyme immunoassay to detect specific SARS-CoV-2 antibodies in serum or plasma samples.

Application

Detection of antibodies specific to the N protein of SARS-CoV-2. The test is valid for use with individual samples of serum or plasma. This assay is exclusively for laboratory use.

Technical Principles

The test uses SARS-CoV-2 recombinant N protein as a coating and conjugate.

1. Plates coated with SARS-CoV-2 antigen (recombinant N protein are used).

2. Serum samples are added to the wells and incubated.

3. If the sample contains antibodies specific to the N protein of SARS-CoV-2, these bind to the coated antigen.

4. When Peroxidase Conjugated N-Protein is added, this binds to antibodies in the serum if these antibodies are present (infected individuals). This bond is revealed by a colour reaction following the addition of the substrate.

Validation Data

This product has been validated using collections of sera which had previously been characterized.

DIAGNOSTIC SENSITIVITY AND SPECIFICITY

The diagnostic sensitivity has been determined in two ways:

1. **In comparison with the PCR technique (162 sera taken off at different days post first symptoms onset)**

   The **relative sensitivity** with respect to **PCR** is **92.5%**. 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 DR assay detects the antibodies that have been generated. Those can appear later in time.

2. **In comparison with some other commercial serological tests (116 sera).**

   The **relative sensitivity** for antibody detection compared to other serological tests on the market is **98.3%.**

Results in comparison with PCR

	INgezim® COVID-19 DR	PCR
POSITIVE	150	162
NEGATIVE	12	0

Results in comparison with other serological tests

	INgezim® COVID-19 DR	Other test
POSITIVE	114	116
NEGATIVE	2	0

To determine the diagnostic specificity 249 sera from healthy donors or samples from patients with other pathologies, but corresponding to years prior to the outbreak of COVID19 were analysed. The results showed **99.2% diagnostic specificity.**

ANALYTICAL SENSITIVITY AND SPECIFICITY

Study of Analytical Sensitivity

To determine how soon the assay is effective, the analytical sensitivity of the test was calculated by grouping the positive samples by the number of days since the onset of symptoms. A total of 99 samples were therefore segregated into corresponding groups. The assay is capable of detecting SARS-CoV-2-specific antibodies between 7 and 16 days after symptoms in 85% of cases, and in **100% of cases from day 17.**

analytical sensitivity

85,11% (7-16)   100,00% (17-32)

% positivive — days post symptoms (1-6, 7-16, 17-32)
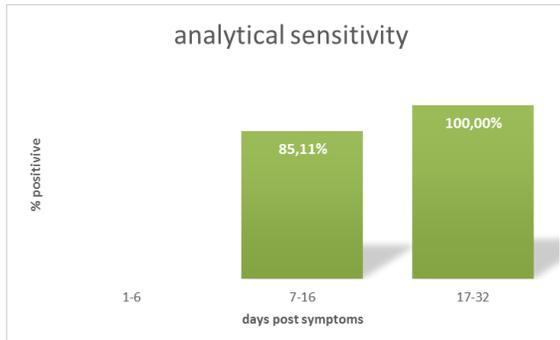
Study of Analytical Specificity

To determine the analytical specificity of the assay, samples were included from patients infected with other coronaviruses (229E, NL63, OC43 and HKU1) or other agents causing respiratory diseases. A total of 121 samples with these characteristics were analysed. The results indicate that there was **no cross-reactivity** with antibodies specific for other coronaviruses or other agents related to human respiratory illnesses.

PRODUCT MANUFACTURED BY INGENASA
IVD medical devices manufacturer licence:
7709-PS

CE

EXPIRATION: 12 months
Keep at 4ºC-8ºC