

SARS-CoV-2 S IgG ELISA

Specific and sensitive test for the detection of antibodies against SARS-CoV-2 virus

The **SARS-CoV-2 S IgG ELISA** is a semi-quantitative enzyme-linked immunosorbent assay (ELISA) for the detection of human IgG class antibodies to SARS-CoV-2 virus spike protein in blood serum or plasma with EDTA. This is a test to confirm COVID-19, to assess the immune response to SARS-CoV-2 virus or vaccines, and to provide information on acquired protective immunity.

- ✓ **High sensitivity**
- ✓ **High specificity**
- ✓ **High repeatability**

Note. *The test does not directly detect the virus. It detects antibodies specific for the virus or vaccine and provides information on the immune system's response to the virus infection or vaccine.*

Technical parameters

Format	indirect ELISA, antigen-coated 96-well plate
Method	semi-quantitative, colorimetric
Detected antibodies	IgG <i>Note. The test achieves the best results if the sample is taken for analysis no earlier than 14 days after the onset of symptoms</i>
Number of samples	90
Results	the results are given in relative values, which are calculated from the measured optical density
Antigen	recombinant SARS-CoV-2 S protein
Sample type	blood plasma or serum
Sample dilution, reaction volume	1:101 dilution (for example, dilute 10 µl of sample with 1 ml of diluent), reaction volume 100 µl
Incubation	with sample: 60 min +37 ° C, with enzyme conjugate: 60 min +37 ° C, with enzyme substrate solution: 10 min
Number of washes	2
Signal measurement	optical density at 450 nm and 620 nm reference wavelengths
Stability	6 month

Test description

- ✓ **94% sensitivity**
- ✓ **99,38% specificity**

The performance of the **SARS-CoV-2 S IgG ELISA** was compared to the serological tests with CE IVD markings:

- ELISA IgG test detects IgG antibodies specific for SARS-CoV-2 virus S1 fragment,
- The rapid IgG test detects IgG antibodies specific for SARS-CoV-2 virus S1 and N proteins.

The **SARS-CoV-2 S IgG ELISA** has a sensitivity of 94% and a specificity of 99.38%. It is more accurate than the CE IVD serological tests used in the analysis.

The sensitivity and specificity of the analyzed tests were evaluated according to the results of the RT-PCR (reverse transcription polymerase chain reaction) test:

Analyzed and other serological tests	SARS-CoV-2 S IgG ELISA	Rapid IgG test	ELISA IgG test
Sensitivity (n = 50), True positive, %	94,00	92,00	92,00
Specificity (n = 160), True negative, %	99,38	99,38	98,75
Accuracy *	99,11	99,01	98,41

* - assuming a COVID prevalence of 5%, this indicates the likelihood that the test will correctly classify samples as positive and negative.