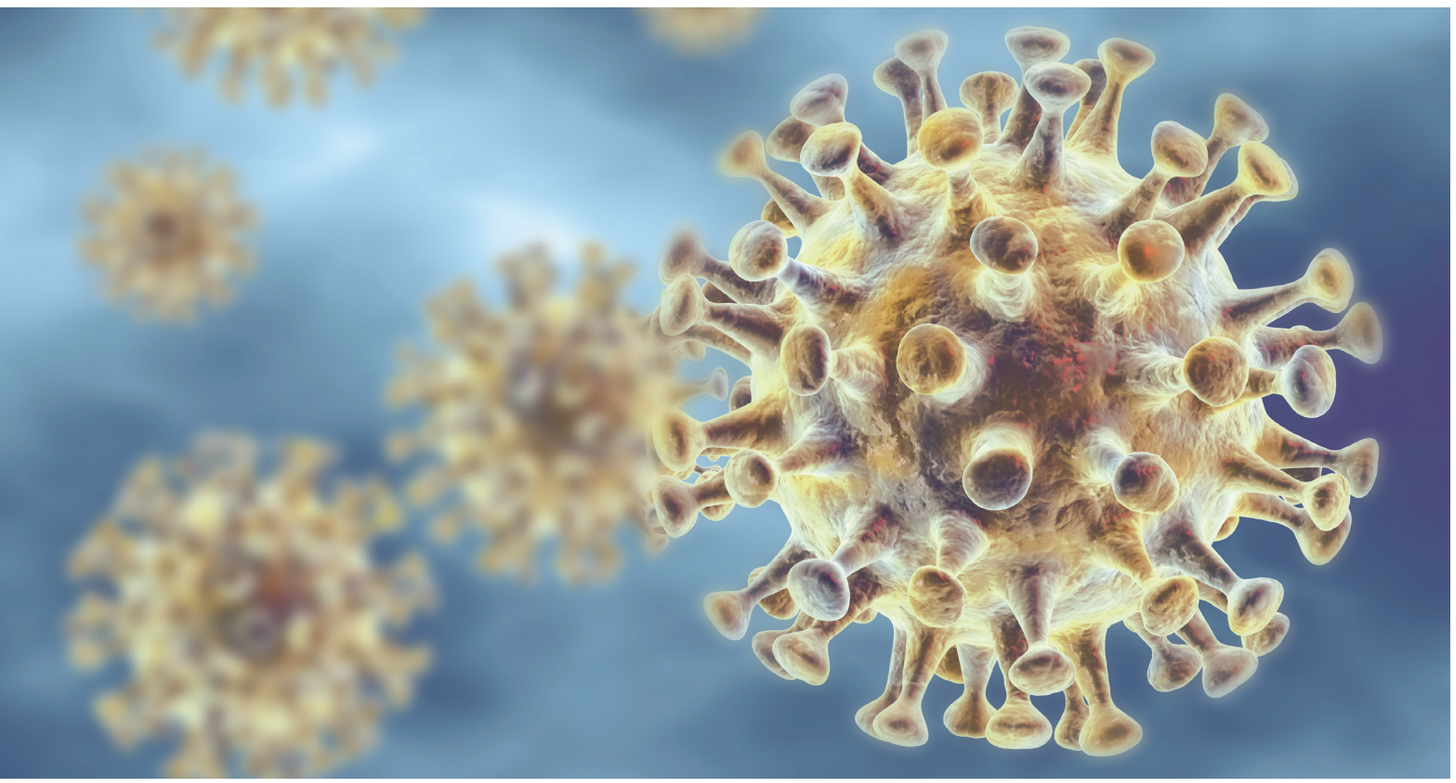

SARS-CoV-2 IgG ELISA Kit

The SARS-CoV-2 virus was discovered in 2019 in Wuhan, China and is the cause of the COVID-19 disease in humans. This virus is a single-stranded-RNA coronavirus. SARS-CoV-2 may cause severe respiratory infection and breathing problems in humans. Human to human transition of coronaviruses is believed to occur via close contact by respiratory droplets generated by coughing and sneezing of infected individuals.

The RT-PCR test is considered as primary test for the clinical diagnosis of SARS-CoV-2. However, it can be used for diagnose from the naso-pharynx samples within the first 7 days from the beginning of the symptoms and then its diagnostic value decreases. Antibody tests are used for the clinical diagnosis of SARS-CoV-2 after this period. The presence of Anti-SARS-CoV2 IgM indicates the acute phase of infection while the presence of Anti-SARS-CoV2 IgG indicates a long-term immune response.

Trimaris SARS-CoV-2 IgG ELISA kit determines the presence of SARS-CoV-2 IgG antibodies in the patient's serum/plasma samples in a qualitative way. The main uses of this test are listed below.

- It is stated that IgG and IgM antibodies may contribute to the diagnosis after the 14th day from the beginning of the infection. The test results can be used as an aid to diagnosis together with clinical findings and other tests.
- Anti-SARS-CoV2 IgG antibodies are seen in the blood for a long time after being produced in the body. Therefore, information can be obtained about whether the person has previously been exposed to the SARS-CoV-2 virus by measuring the IgG antibodies. Thus, the number of individuals exposed to infection can be determined through surveillance studies to be conducted in selected groups such as healthcare professionals, frontline persons and people with low immunity.
- Since the individuals who have had the disease asymptomatically can also be identified with this test, it is also possible to have information about the total population rate exposed to the SARS-CoV-2 virus.

Analytical Performance

Sensitivity

34 positive serum samples collected from individuals who had clinical finding, lung RT-CT positive sign and a positive RT-PCR test. Samples collected two weeks after onset of clinical manifestations. 32 samples showed positive results. Trimaris SARS-CoV-2 IgG ELISA kit had positive percent agreement of 94.1 %.

Specifity

The total number of 111 negative serum samples collected one year prior to January 2019 that store in -20 degree was tested with our kit. 109 samples showed negative results. Trimaris SARS-CoV-2 IgG ELISA kit had Negative percent agreement of 98.3%.

Test Precision

Intra-assay and Inter-assay precision, carried out by negative, positive and weakly positive sera was performed, and its results were shown below in Table 1 and Table 2. Qualitatively 100% reproducibility was observed in all negative, low positive and positive samples. CV values were found below 10% in the samples around cut-off value and above.

Table 1. Intra-assay precision

Sample	Test Number	Result
Negative	10	-
Weakly Positive	10	+
Positive	10	+

Table 2. Inter-assay precision

Sample	Test Number	Result
Negative	10	-
Weakly Positive	10	+
Positive	10	+

Interference

Positive and negative serum samples were added in a known amount of the potential endogenous interfering agents such as hemoglobin, bilirubin and triglycerides. Spiked samples were tested and no significant interference detected from the tested interfering agents.

Ordering Information:

Cat. No:	Product Name	Test Number
BR150010	SARS-CoV-2 IgG ELISA Kit	96 Tests

Assay Procedure

Dilute 10 µL of serum samples are with 1000 µL of sample diluent and transfer to the microplate well. Kit control sera are ready to use and must be transferred directly to the well without dilution.

Step 1:

Reagent	Blank	Control Serum	Diluted Sample
Control Serum	-	100 µL	-
Diluted Sample	-	-	100 µL

Cover the microplate wells with sealer tightly and incubate them for 30 minutes at 37 °C.

Step 2:

Remove plate cover and discard contents of the wells. Wash the microplate wells for 5 times according to test manual. Automated washing can also be applied.

Step 3:

Ready to use-HRP conjugate	-	100 µL	100 µL

Cover the microplate wells with sealer tightly and incubate them for 30 minutes at 37 °C.

Step 4:

Remove plate cover and discard contents of the wells. Wash the microplate wells for 5 times according to test manual. Automated washing can also be applied.

Step 5:

Chromogenic substrate solution	100 µL	100 µL	100 µL

Incubate wells for 15 minutes at room temperature and dark.

Step 6:

Stop Solution	100 µL	100 µL	100 µL

Read absorbance at 450 nm wavelenght. It is suggested to use 630 nm filter as reference filter if it's available.

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Bome Trivitron Sanayi Ürünleri Dış Tic. A.Ş.
Sokullu Mehmet Paşa Mah. 1361. Sokak, No: 6/A, Sokullu, Çankaya, Ankara, Turkey
T. +90 312 479 33 30 | F. +90 312 478 37 18 | info@bometrivitron.com.tr
www.bometrivitron.com.tr