

Product Info

PRODUCT NAME	SARS-CoV-2 Nucleocapsid protein (NP), Human IgM, ELISA assay
PRODUCT DESCRIPTION	<p>The SARS-CoV-2 NP IgM ELISA kit is a highly sensitive and specific enzyme-linked immunosorbent assay (ELISA) for the detection and qualitative measurement of IgM class antibodies against the nucleocapsid protein (NP) of SARS-CoV-2 virus (causing Covid-19) in human blood.</p> <p>The Biosensis SARS-CoV-2 NP IgM ELISA kit is a two-step incubation immunoassay kit. Recombinant nucleocapsid protein (NP) of SARS-CoV-2 pre-coated onto the polystyrene microwell strips can specifically recognize anti-NP antibodies in human serum or plasma specimens. After a 1 hour incubation, anti-NP antibodies are captured by immobilized NP protein while the unbound components are washed away. Afterwards, a detection solution containing HRP-conjugated anti-human IgM is added for another 1 hour incubation, wherein HRP-conjugated anti-human IgM binds to the IgM class antibodies previously bound to NP protein on the plate. After removal of nonspecific bindings, an HRP substrate solution containing 3,3',5,5'-Tetramethylbenzidine (TMB) is added, resulting in the formation of a blue color. Color reaction is stopped by 2M H₂SO₄, transforming the blue color to yellow, which is quantified by an absorbance microplate reader at 450 nm. Microplate wells with increased color intensity indicate presence of higher amount of anti-NP antibodies in the tested samples.</p> <p>This product is intended for use by professional persons only. For research use only. Not for use in clinical & diagnostic procedures. In line with FDA guidelines, test reports must include the following statements:</p> <p>(1) This test has not been reviewed by the FDA. (2) Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. (3) Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals. (4) Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status. (5) Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.</p>
CATALOG NUMBER(S)	BEK-1001-1P, BEK-1001-4P
UNIT SIZE(S)	1 Plate Kit, 4 Plate Kit
BATCH NUMBER	Please see item label.
SPECIFICITY	Clinical validation study of Biosensis SARS-CoV-2 NP IgM ELISA was conducted in 2020 in Shenzhen, China. Samples were collected from COVID-19 confirmed cases with clinical symptoms, laboratory abnormalities or pulmonary imaging manifestations. No tests have been performed on specimens from latent infections or patients in the incubation period. The kit showed higher positive detection rate in specimens from patients with delayed onset. Therefore, the interpretation of the test results should consider the specimen s collection time. It is highly recommended that each laboratory establishes its own normal and pathological reference range for anti-NP IgM level. Furthermore, it is also recommended that each laboratory includes its own panel of control samples in the assay.
APPLICATION(S)	ELISA
SAMPLE TYPE	Plasma (Citrate), Plasma (EDTA), Plasma (Heparin), Serum
APPLICATION DETAILS	<p>ELISA. For the detection of SARS-CoV-2 Nucleocapsid protein, Human IgM (NP) in Serum, Plasma (Citrate), Plasma (EDTA), Plasma (Heparin). Please download the detailed product insert for complete instructions for the successful use of this ELISA. Use only as directed.</p> <p>This product is intended for use by professional persons only. For research use only. Not for use in clinical & diagnostic procedures. In line with FDA guidelines, test reports must include the following statements:</p> <p>(1) This test has not been reviewed by the FDA. (2) Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. (3) Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals. (4) Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status. (5) Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.</p>
TARGET	SARS-CoV-2 Nucleocapsid protein, Human IgM (NP)
ALTERNATIVE NAMES	Nucleocapsid phosphoprotein [Severe acute respiratory syndrome coronavirus 2]; SARS-CoV-2;
UNIPROT NUMBER AND NAME	P0DTC9 (NCAP_SARS2)
TARGET HOST SPECIES	Human

SPECIES REACTIVITY	Human																				
DETECTION METHOD	Colorimetric																				
KIT COMPONENTS	The ELISA kit box contains 96-well pre-coated strip plate(s), blank control sample, detection reagents, wash and sample buffers, substrate buffer and detailed protocols.																				
STORAGE INSTRUCTIONS	2-8°C. Product ships on ice packs and is stable from ambient to refrigerated temperatures for 1 week.																				
EXPIRATION DATE	The unopened kit is stable for 6 months from date of receipt when stored at 2-8°C. Once opened, store reagents at 2-8°C for up to 1 month.																				
MAIN IMAGE	<table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th colspan="2">Inter Assay Precision</th> </tr> <tr> <th>Samples</th> <th>CV</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>7.16%</td> </tr> <tr> <td>2</td> <td>5.35%</td> </tr> <tr> <td>3</td> <td>6.19%</td> </tr> <tr> <th colspan="2">Intra Assay Precision</th> </tr> <tr> <th>Samples</th> <th>CV</th> </tr> <tr> <td>1</td> <td>4.93%</td> </tr> <tr> <td>2</td> <td>6.77%</td> </tr> <tr> <td>3</td> <td>5.89%</td> </tr> </tbody> </table>	Inter Assay Precision		Samples	CV	1	7.16%	2	5.35%	3	6.19%	Intra Assay Precision		Samples	CV	1	4.93%	2	6.77%	3	5.89%
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MAIN IMAGE CAPTION	Performance Characteristics																				
ADDITIONAL IMAGES STATEMENT	Please refer to the Biosensis website for additional product images.																				
REFERENCES STATEMENT	Please refer to our website for product-specific references.																				
REGULATORY STATUS	For research use only.																				