

## Product datasheet

# SARS-CoV-2 (COVID-19) IgM ELISA Kit ab277287

1 Image

### Overview

**Product name** SARS-CoV-2 (COVID-19) IgM ELISA Kit

**Detection method** Colorimetric

**Precision**

Intra-assay

Sample	n	Mean	SD	CV%
No.1	24			2.75%
No. 2	24			5.41%
No. 3	24			10.3%

Inter-assay

Sample	n	Mean	SD	CV%
No. 1	12			6%
No. 2	12			8.01%
No. 3	12			11.91%

**Sample type** Serum, Hep Plasma, Cit plasma

**Assay duration** Multiple steps standard assay

**Product overview**

SARS-CoV-2 (COVID-19) IgM ELISA Kit (ab277287) is intended for the qualitative determination of IgM class antibodies against SARS-CoV-2 in human serum or plasma (citrate, heparin) to support the diagnosis of COVID-19 disease and constitutes a supplement to direct pathogen detection. In addition, serology can be used to collect epidemiological information on the prevalence of SARS-CoV-2.

Microtiter plates are coated with specific antigens to bind corresponding antibodies of the sample. After washing the wells to remove all unbound sample material a horseradish peroxidase (HRP) labelled conjugate is added. This conjugate binds to the captured antibodies. In a second washing step unbound conjugate is removed. The immune complex formed by the bound conjugate is visualized by adding Tetramethylbenzidine (TMB) substrate which gives a blue

reaction product. The intensity of this product is proportional to the amount of specific antibodies in the sample. Sulfuric acid is added to stop the reaction. This produces a yellow endpoint color. Absorbance at 450/620 nm is read using an ELISA Microtiter plate reader.

## Notes

### Antibody Isotypes and State of Infection:

#### Serology Significance

IgM Characteristic of the primary antibody response.

High IgM titer: → suggests a current or very recent infection.

IgG Follows IgM production.

Characteristic of the secondary antibody response.

May persist for several years.

High IgG titer with low IgM titer: → may indicate past infection.

IgA Produced in mucosal linings throughout the body (□ protective barrier).

Usually produced early in the course of the infection.

### Diagnostic Specificity:

The diagnostic specificity is defined as the probability of the assay of scoring negative in the absence of the specific analyte. SARS-CoV-2 infections emerged in December 2019 in Wuhan, China. The expected prevalence values for German and US blood donor panels from before December 2019 therefore amount to 0 %. The determined positive results correspond to a specificity of 100 % (95 %-confidence interval: 97.26 % - 100 %).

Sample panel	No. patients (n)	Positive	Equivocal	Negative	Specificity	95% CI
Blood donors Germany	83	0	0	83	100%	
Blood donors US	50	0	0	50	100%	
Total	133	0	0	133	100%	97.26%-100%

### Diagnostic Sensitivity:

The diagnostic sensitivity is defined as the probability of the assay of scoring positive in the presence of the specific analyte. 42 samples from 25 patients tested positive for SARS-CoV-2 RNA by RT-PCR were tested.

Days post symptom onset	No. samples (n)	Positive	Equivocal	Negative	Sensitivity (Eqv excluded)
0-5	13	0	0	13	0%
6-8	10	2	0	8	20%
9-11	10	3	0	7	30%
greater than 12	9	4	2	3	57.14%

### Interferences:

Three clinical samples exhibiting differing reactivities were tested for interference with each substance listed in the Table below: a positive, a negative, and an equivocal sample. All samples exhibited a change of signal less than 15 % when tested with each potential interferant.

Interferent	Conc. tested
Albumin	60 mg/mL
Bilirubin conjugated	0.4 mg/mL
Bilirubin unconjugated	0.4 mg/mL
Cholesterol	4 mg/mL
Hemoglobin	10 mg/mL
Triglycerides	15 mg/mL

### Cross Reactivity:

131 samples with antibody activities to potentially cross reacting parameters (including

antibodies to several respiratory pathogens) were tested to evaluate the cross reactivity of the assay.

Samples +ve to antibodies to	No. of samples (n)	Positive	Equivocal	Negative
Adenovirus	10	0	0	10
Parainfluenzavirus	9	0	0	9
Candida albicans	8	0	0	8
Bordetella pertussis	9	0	0	9
Influenzavirus A	9	0	0	9
Influenzavirus B	10	0	0	10
Enterovirus	10	0	0	10
Respiratory syncytial virus	10	1	1	8
Chlamydia pneumoniae	9	0	0	9
Legionella pneumoniae	8	0	0	8
Mycoplasma pneumoniae	9	0	0	9
Haemophilus influenzae	3	0	0	3
Other Coronavirus	1	0	0	1
Rheumatoid Factor positive	26	0	0	26

Cross reactions with antibodies to respiratory syncytial virus cannot be excluded. Cross reactivity with other human coronaviruses should be considered for result interpretation.

**Platform** Pre-coated microplate (12 x 8 well strips)

### Properties

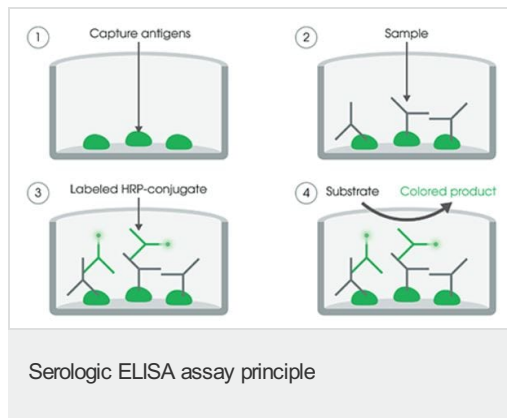
**Storage instructions** Store at +4°C. Please refer to protocols.

Components	1 x 96 tests
SARS-CoV-2 coated microplate	1 unit
IgM Sample Dilution Buffer	1 x 100ml
Stop Solution	1 x 15ml
20X Wash Buffer	1 x 50ml
HRP-human IgM antibody	1 x 20ml
TMB Substrate Solution	1 x 15ml
Positive control	1 x 2ml
Cut-off control	1 x 3ml
Negative control	1 x 2ml

**Relevance** Nucleocapsid protein is a most abundant protein of coronavirus on the helical nucleocapsid of coronaviruses. N protein of SARS CoV-2 [ab273530](#) is a structural protein required for RNA synthesis, and has RNA chaperone activity that may be involved in template switch. N protein enters the host cell with the viral RNA to facilitate its replication and process the virus particle assembly and release. N protein is a highly immunogenic phosphoprotein also implicated in modulating cell signalling pathways. Coronavirus nucleocapsid proteins localize to the cytoplasm

and the nucleolus, a subnuclear structure, in both virus-infected primary cells and in cells transfected with plasmids that express N protein.

## Images



Specific antigens are coated on the 96-well plate, controls or test samples are added to the well and incubated. The wells are washed to remove any unbound Human anti-antigen antibodies (Ig). A horseradish peroxidase (HRP) labelled anti-Human Ig conjugate is added to the wells. TMB is then catalyzed by the HRP to produce a blue color product that changes to yellow after adding an acidic stop solution. The intensity of yellow coloration is directly proportional to the amount of Human anti-antigen Ig captured on the plate.

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