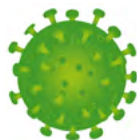


COVID-19 Coronavirus (SARS-CoV-2)



MIKROGEN
D I A G N O S T I K

Distributed by



recomWell SARS-CoV-2 IgG recomWell SARS-CoV-2 IgA

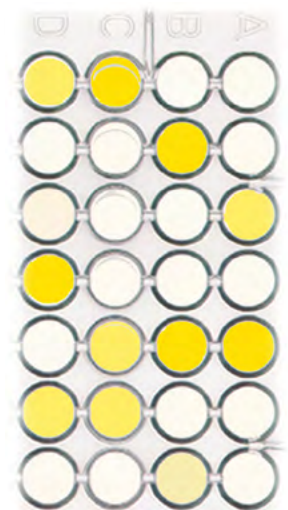
Enzyme immunoassay with antigens produced by recombinant techniques for the detection of IgG and IgA antibodies against the coronavirus SARS-CoV-2 in human serum or plasma.

In December 2019 began in the city of Wuhan, capital of Hubei in China, a pandemic spread of the disease caused by a new variant of the Severe Acute Respiratory Syndrome Coronavirus (SARS-CoV). The newly discovered variant is called SARS-CoV-2 and is closely related to SARS-CoV(-1). SARS coronaviruses spread primarily via droplets in exhaled air to transmit from person to person.

Symptoms range from fever, cough and dyspnoea to pneumonia and acute respiratory distress syndrome and ultimately death in persons with comorbidities. There is currently no medication or vaccine available that can prevent a SARS-CoV-2 associated illness.

According to the German Robert Koch Institute, infected persons usually develop detectable antibodies in the second week after the onset of symptoms. A seroconversion or a significant increase in titer for IgG antibodies in the same test system can indicate an acute infection, especially in combination with corresponding symptoms. Thus, serological detection of antibodies serves as an ideal addition to molecular detection, which is recommended for acute diagnostics. Furthermore, the detection of IgG antibodies is a clear indication of pathogen contact and can detect a past infection and can be used for epidemiological studies.

Whether detected antibodies are accompanied by a corresponding immunity is currently the decisive scientific question to be clarified, which can have a great influence on health medicine and society. In this context, antibody tests could, for example, be used in the monitoring of vaccination studies, the donor screening of convalescent plasma for therapeutic use, or in decisions on the work and operational capability of systemically relevant personnel.



Product advantages for your benefit

- **Very high sensitivity and specificity** due to the use of highly purified recombinant nucleocapsid antigen
- **Easy test procedure** in the automatable ELISA screening format; quantitative results
- **Identical processing** as well as uniform and interchangeable reagents for all MIKROGEN *recomWell* ELISA
- **Break-aparts:** single sample examination possible
- **CE label:** The *recomWell* SARS-CoV-2 IgG, IgA tests meet the high standards of the European directive 98/79/EC on in vitro diagnostic medical devices

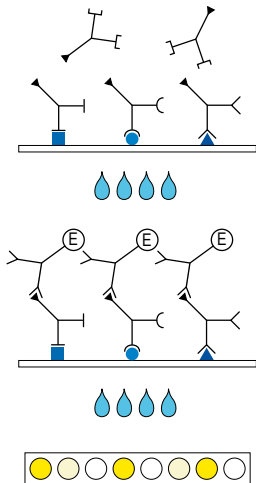
Antigen specification

Antigen	Description
Nukleokapsid	Antigen with the strongest immunogenicity in the coronaviruses. As a structural protein, it primarily serves to package viral genetic information and also fulfils regulatory functions.

Test principle and procedure

Indirect sandwich test.

Recombinant antigens are bound to the solid phase.



1st Incubation

Add patient samples diluted 1:101 (sample 10 µl of serum or plasma), incubate for **1 h**.

wash 4 times

2nd Incubation

Add peroxidase conjugated anti-human IgG or IgA antibodies, incubate **30 min** at **37 °C**.

wash 4 times

Color reaction

Add ready-to-use TMB solution and incubate **30 min** at room temperature. **Stop the substrate solution with H₃PO₄** and measure the absorbance at 450 nm.

Evaluation

Diagnostic Sensitivity*

recomWell SARS-CoV-2 IgG	Days after the onset of symptoms		
	Early < 12 days	Medium 12-23 days	Late > 23 days
Positive	6	23	28
Borderline	0	1	0
Negative	1	0	0
Sensitivity	86%	100%	100%
	98%		

recomWell SARS-CoV-2 IgA	Days after the onset of symptoms		
	Early < 12 days	Medium 12-23 days	Late > 23 days
Positive	2	16	21
Borderline	1	2	7
Negative	3	1	14
Sensitivity	50%	95%	67%
	73%		

* determined with samples from RT-PCR-confirmed SARS-CoV-2 infected individuals

Diagnostic Specificity

Blood donor (n = 300)	recomWell SARS-CoV-2	
	IgG	IgA
Positive	3	2
Borderline	1	0
Negative	296	298
Specificity	98.7%	99.3%

Cross-reactivity

Sample set (n = 241)	Positive / borderline with recomWell SARS-CoV-2	
	IgG	IgA
Seasonal coronaviruses (HCoV) (n = 9)	0/1	0/0
Influenza A virus (n = 9)	1/0	0/0
Influenza B virus (n = 5)	0/0	0/0
Respiratory syncytial virus (RSV) (n = 10)	0/0	0/0
Adenoviruses (n = 6)	1/1	0/0
<i>Mycoplasma pneumoniae</i> (n = 10)	0/0	0/0
<i>Chlamydia pneumoniae</i> (n = 25)	1/0	1/1
Epstein-Barr virus (EBV) (n = 31)	2/0	1/1
Cytomegalovirus (CMV) (n = 11)	2/0	2/0
Autoantibodies positive (n = 15)	0/0	0/0
Pregnant women (n = 60)	0/1	0/0
Rheumatoid factor positive (n = 50)	2/0	1/0

Article-No.

7304 **recomWell SARS-CoV-2 IgG**
Reagents for 96 determinations

7305 **recomWell SARS-CoV-2 IgA**
Reagents for 96 determinations

Storage

At +2°C to +8°C