MIKROGEN DIAGNOSTIK

*recom*Well SARS-CoV-2 IgG
*recom*Well 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. Since the end of 2020, several vaccines against SARS-CoV-2 have been approved, most of which target the spike protein of the virus that mediates contact with the host cell.

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.

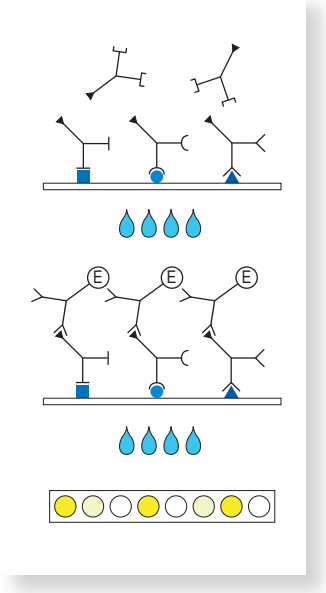
Product advantages for your benefit

- **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 *recom*Well ELISA
- **Break-aparts:** single sample examination possible
- **CE label:** The *recom*Well 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
Nucleocapsid	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 ELISA 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** H_3PO_4 and measure the absorbance at 450 nm.

Evaluation

Diagnostic Sensitivity*

***recom*Well 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%		

***recom*Well 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 donors (n = 300)	***recom*Well 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 *recom*Well 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
***Mycoplasma pneumoniae* (n = 10)**	0/0	0/0
***Chlamydia pneumoniae* (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 ***recom*Well SARS-CoV-2 IgG**
Reagents for 96 determinations

7305 ***recom*Well SARS-CoV-2 IgA**
Reagents for 96 determinations

Storage

At +2°C to +8°C

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