COVID-19
Coronavirus (SARS-CoV-2)

MIKROGEN
DIAGNOSTIK

NEW

Automatische Streifen-Auswertung recomScan

*recom*Line SARS-CoV-2 IgG

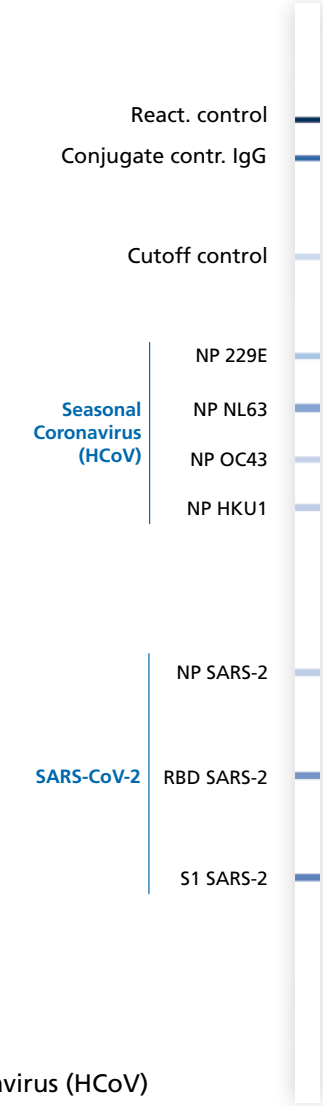
Line immunoassay with antigens produced by recombinant techniques for the detection of IgG antibodies against the coronavirus SARS-CoV-2 in human serum or plasma.

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 by transmission 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.

In commercial screening tests for antibody detection, the nucleocapsid protein (NP) and/or the spike protein (S) or corresponding subunits are usually used as immunodominant antigens. The *recom*Line SARS-CoV-2 IgG immunoassay combines these diagnostic markers and allows the identification of specific antibodies against the individual antigens. In addition, reactivities against the seasonally occurring coronaviruses (HCoV) are detected. The test can be used for screening or for confirmation of unclear SARS-CoV-2 results.



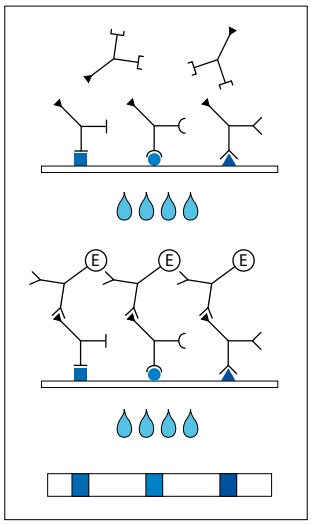
Product advantages for your benefit

- **Very high sensitivity and specificity** by using different, recombinant SARS-CoV-2 specific antigens
- Suitable as **screening and confirmatory test** for the detection of IgG antibodies against SARS-CoV-2
- **Additional information** through the detection of antibodies against seasonal coronavirus (HCoV)
- **Simple and flexible handling**, since manual, semi- or fully automated processing and evaluation is possible
- **Same workflow** as well as uniform and interchangeable reagents for all tests from the *recom*Line product line
- **CE label:** The *recom*Line SARS-CoV-2 IgG meet the high standards of the EC directive 98/79/EC on in vitro diagnostic medical devices

Coronavirus-specific antigens

Pathogen	Antigen	Description
SARS-CoV-2	**NP**	Nucleocapsid – antigen with the strongest immunogenicity among coronaviruses. As a structural protein, it primarily serves to package the viral genetic information and also fulfils regulatory functions.
	RBD	Units of the spike surface protein – main target antigen for neutralizing antibodies. The S1 subunit with integrated receptor binding domain (RBD) is responsible for binding to the host cell.
	S1	
Seasonal coronaviruses HCoV (229E, NL63, OC43, HKU1)	**NP**	Nucleocapsid – similar to the nucleocapsid of SARS-CoV-2, from seasonally occurring human pathogenic α- and β- coronaviruses (229E, NL63 and OC43, HKU1 respectively).

Test principle and procedure



1st Incubation A test strip loaded with specific antigens is incubated with diluted serum or plasma in a dish for **1 hour**.

wash 3 times

2nd Incubation Peroxidase conjugated anti-human antibodies (IgG specific) are added. Incubate for **45 minutes**.

wash 3 times

Color reaction **8 minutes** after addition of the coloring solution, insoluble colored bands develop at the sites on the test strips adhered by antibodies.

Evaluation

Diagnostic Specificity

*recom*Line SARS-CoV-2 IgG	Blood donors (n = 300)	Potentially cross-reactive samples* (n = 191)	Potentially interfering samples** (n = 80)
Positive	1	4	2
Negative	299	187	78
Specificity	**99.7%**	**97.9%**	**97.5%**
	98.8%		

Diagnostic Specificity – Stepwise Diagnostics***

*recom*Well SARS-CoV-2 IgG in combination with *recom*Line SARS-CoV-2 IgG	Blood donors (n = 300)	Potentially cross-reactive samples* (n = 191)	Potentially interfering samples** (n = 80)
Positive	0	1	0
Negative	300	190	80
Specificity Stepwise Diagnostics	**100%**	**99.5%**	**100%**
	99.8%		

* Samples positive for seasonal coronaviruses, influenza A/B virus, RSV, adenoviruses, *Mycoplasma pn.*, *Chlamydia pn.*, EBV, CMV, autoantibodies, and from pregnant women.
** Lipemic, hemolytic and icteric samples, RF-positive samples.
*** Positive and borderline samples from screening with *recom*Well SARS-CoV-2 IgG were additionally tested with *recom*Line SARS-CoV-2 IgG. Samples were considered positive if confirmed positive with *recom*Line SARS-CoV-IgG.

Diagnostic Sensitivity*

*recom*Line SARS-CoV-2 IgG	Days after the onset of symptoms		
	Early < 12 Days	Medium 12-23 Days	Late > 23 Days
Positive	6	20	26
Negative	1	1	0
Sensitivity	**85.7%**	**95.2%**	**100%**
	96.3%		

* 54 samples from RT-PCR-confirmed SARS-CoV-2 infected individuals.

Cross-reactivity

Sample set (n = 271)	*recom*Line SARS-CoV-2 IgG
	Positive
Seasonal coronaviruses (HCoV) (n = 9)	0
Influenza A virus (n = 9)	0
Influenza B virus (n = 5)	0
Respiratory syncytial virus (RSV) (n = 10)	0
Adenoviruses (n = 6)	0
Mycoplasma pneumoniae (n = 10)	0
Chlamydia pneumoniae (n = 25)	0
Epstein-Barr virus (EBV) (n = 31)	2
Cytomegalovirus (CMV) (n = 11)	0
Autoantibodies positive (n = 15)	0
Pregnant women (n = 60)	2
Rheumatoid factor positive (n = 50)	1
Haemolytic samples (n = 10)	0
Lipaemic samples (n = 10)	1
Icteric samples (n = 10)	0

Article-No.

7374 *recom*Line SARS-CoV-2 IgG
Reagents for 20 determinations

Storage

At +2°C to +8°C

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