COVID-19
Coronavirus (SARS-CoV-2)

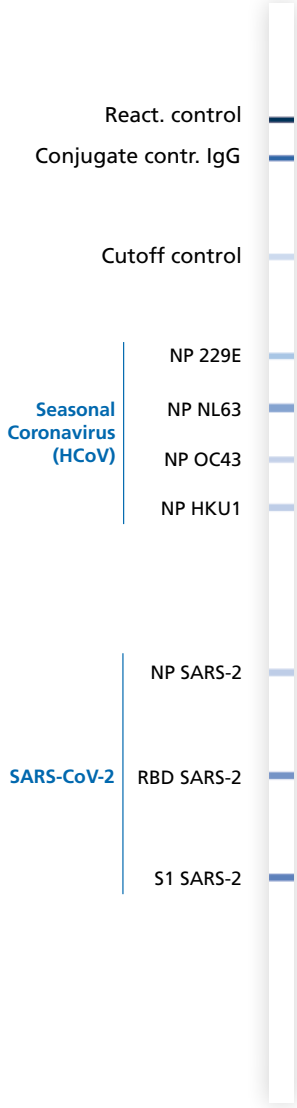
MIKROGEN
DIAGNOSTIK

NEW

Automatische Streifen-Auswertung RecomScan

*recom*Line SARS-CoV-2 IgG [Avidität]

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, a pandemic spread of the disease caused by a new variant of the Severe Acute Respiratory Syndrome Coronavirus (SARS-CoV) began in the city of Wuhan, capital of Hubei in China. The newly discovered variant is called SARS-CoV-2 and is closely related to SARS-CoV(-1). SARS coronaviruses spread primarily via droplets and airborne particles 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. Optimal vaccination with mRNA- or vector-based vaccines allows to reduce or prevent asymptomatic infections with the original SARS-CoV-2 virus strain and its variants (including the Delta variant), the spread of these viruses, symptomatic infection, as well as more severe disease. Optimal vaccination even has a preventive effect towards symptomatic or more severe disease caused by the immune-escape variant Omicron.

Persons infected with SARS-CoV-2 usually develop detectable antibodies 2-21 days after the onset of symptoms. But vaccination against COVID-19 leads also to the production of IgG antibodies after few days. Thus, serological detection of antibodies is a clear indication of a past SARS-CoV-2 infection if the time frame to detect a possible current infection by a PCR or antigen test was passed, or of a vaccination status. Antibody testing can be used for public and occupational health purposes, as well as epidemiological studies and treatment of patients suffering from long-term consequences of COVID-19 disease.

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 [Avidität] 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 allows the assessment of the adaptive immune response induced by SARS-CoV-2 infection and/or vaccination. Additional benefit can be derived from this test system when the quality of the antibodies is determined through avidity measurement.

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 after past infection or/and COVID-19 vaccination
- **Avidity determination** of SARS-CoV-2 specific IgG antibodies provides additional information about the quality of the antibodies
- **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 [Avidität] 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).

Evaluation

Diagnostic Specificity

*recom*Line SARS-CoV-2 IgG [Avidität]	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 [Avidität]	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 [Avidität]. Samples were considered positive if confirmed positive with *recom*Line SARS-CoV-IgG [Avidität].

Diagnostic Sensitivity*

*recom*Line SARS-CoV-2 IgG [Avidität]	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.

Avidity in SARS-CoV-2 infected individuals after onset of disease

SARS-CoV-2 infected individuals*	Days after onset of diseases					
	0-50 days (n = 52)			51-100 days (n = 32)		
Avidity**	l	i	h	l	i	h
NP [%]	98.1	-	1.9	87.4	6.3	6.3
RBD [%]	96.4	3.6	-	71.9	21.9	6.2
S1 [%]	96.4	3.6	-	78.1	12.5	9.4

* Serum samples from RT-PCR-confirmed SARS-CoV-2 infected individuals
** Avidity: l = low, i = intermediate, h = high

Avidity in SARS-CoV-2 infected individuals according to the severity of the disease

SARS-CoV-2 infected individuals*	Severity of diseases								
	Progression without hospitalisation (n = 14)			Progression with hospitalisation on normal ward (n = 24)			Progression with hospitalisation in ICU (n = 11)		
Avidity**	l	i	h	l	i	h	l	i	h
NP [%]	100	-	-	91.6	4.2	4.2	90.9	9.1	-
RBD [%]	92.9	7.1	-	70.8	16.7	12.5	81.8	-	18.2
S1 [%]	100	-	-	83.3	12.5	4.2	72.7	9.1	18.2

* Serum samples from RT-PCR-confirmed SARS-CoV-2 infected individuals
** Avidity: l = low, i = intermediate, h = high

Avidity in individuals vaccinated against SARS-CoV-2

SARS-CoV-2 vaccinated individuals*	Time after vaccination								
	1st dose (n = 28)			2nd dose (n = 40)			3rd dose (n = 20)		
Avidity**	l	i	h	l	i	h	l	i	h
NP [%]	-	-	-	-	-	-	-	-	-
RBD [%]	96.4	3.6	-	4.2	12.5	83.3	-	-	100
S1 [%]	96.4	3.6	-	4.2	12.5	83.3	-	-	100

* Serum samples were collected from individuals 10 to 50 days after their 1st, 2nd or 3rd vaccination against COVID-19. The group included vaccinees without prior infection with SARS-CoV-2 and following vaccine was used: BioNTech/Pfizer Comirnaty®
** Avidity: l = low, i = intermediate, h = high

Article No.

7374 ***recom*Line SARS-CoV-2 IgG [Avidität]***
Reagents for 20 determinations
*Avidity reagent optional available as additional reagent

11010 **Avidity reagent**
Reagents for 25 determinations

Storage

At +2°C to +8°C

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