

## Cross-reactivity study confirms high analytical specificity of the SERION ELISA *agile* SARS-CoV-2 IgA / IgG / IgM

Category	SERION ELISA <i>agile</i> SARS-CoV-2 IgA		SERION ELISA <i>agile</i> SARS-CoV-2 IgG		SERION ELISA <i>agile</i> SARS-CoV-2 IgM	
	Number of samples tested	Equivocal or positive results	Number of samples tested	Equivocal or positive results	Number of samples tested	Equivocal or positive results
Other Coronaviruses	9	0	9	0	8	0
Epstein-Barr Virus VCA	10	0	10	0	10	0
Epstein-Barr Virus EA	-	-	10	0	-	-
Adenovirus	10	0	10	0	7	0
Influenza A Virus	10	0	10	0	7	0
<i>Plasmodium falciparum</i>	-	-	15	0	15	3
<i>Plasmodium ovale</i>	-	-	5	0	5	0
Dengue Virus (type 1-4)	-	-	10	0	10	1
HIV	10	0	10	0	10	0
ANA	10	0	10	0	10	0
RF	10	0	10	0	10	1

## Excellent study results in independent publications

Publication	Type and scope	Results
Strömer <i>et al.</i> , 2020	Comparative analysis of eight different anti-SARS-CoV-2 immunoassays  <b>Sample panel:</b> 26 SARS-CoV-2 RT-PCR samples 27 sera with neutralizing antibodies against SARS-CoV-2 (neutralization assay: PRNT) <sup>1</sup> 100 pre-pandemic sera	SERION ELISA <i>agile</i> SARS-CoV-2 IgG showed highest sensitivity and specificity values  <b>Sensitivity vs. PCR: 96.2%</b> <b>Sensitivity vs. PRNT: 96.3%</b> <b>Specificity: 100%</b>
Werner <i>et al.</i> , 2021	Comparative analysis of 16 ELISA/ECLIA-based and 16 LFA-based tests.  <b>Sample panel:</b> 101 SARS-CoV-2 RT-PCR sera with defined collection time after positive RT-PCR 60 SARS-CoV-2 negative sera 22 sera with defined SARS-CoV-2 virus-neutralization titers (Neutralization assay: IC50) <sup>2</sup>	SERION ELISA <i>agile</i> SARS-CoV-2 IgA und IgG tests showed very good sensitivities and specificities compared to other manufacturers.  <b>With an R<sup>2</sup> value of 0.87, the SERION ELISA <i>agile</i> SARS-CoV-2 IgG achieved the best correlation with SARS-CoV-2 virus neutralization titers</b>
Krone <i>et al.</i> , 2021	Comparative analysis of six anti-SARS-CoV-2 assays with a neutralization assay.  <b>Sample panel:</b> 63 samples that are positive in a neutralization assay (neutralization assay: PRNT) 50 SARS-CoV-2 negative sera	The SERION ELISA <i>agile</i> SARS-CoV-2 IgG showed the best performance: <b>Sensitivity: 98.3% Specificity: 100%</b>  The SERION ELISA <i>agile</i> SARS-CoV-2 IgA achieved very good results: <b>Sensitivity: 82.5% Specificity: 100%</b>  A combination of SERION ELISA <i>agile</i> SARS-CoV-2 IgA and IgG increases sensitivity without loss of specificity. <b>Sensitivity: 100% Specificity: 100%</b>
Perkmann <i>et al.</i> , 2021	Comparative analysis of five quantitative spike protein-based assays against a surrogate virus neutralization test (sVNT)  <b>Sample panel:</b> 69 sera from initially SARS-CoV-2 naive individuals after first vaccination with BNT162b2 (Pfizer/BioNTech)	<b>Overall, a very good correlation between SERION ELISA <i>agile</i> SARS-CoV-2 IgG and the sVNT was demonstrated.</b>

<sup>1</sup>PRNT = Plaque reduction neutralization assay    <sup>2</sup>IC50= half maximal inhibitory concentrations

### References:

Strömer A. et al, 2020, doi:10.3390/microorganisms8101572

Perkmann et al, 2021, doi: 10.1128/Spectrum.00247-21

Krone et. al, 2021, doi:10.1128/JCM.00319-21

Werner et al, 2021, doi:10.3390/jcm10081580

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Anti-SARS-CoV-2 ELISAs based on  
high quality antigens

SERION ELISA *agile*

SARS-CoV-2 IgA/IgG/IgM

## Highlights

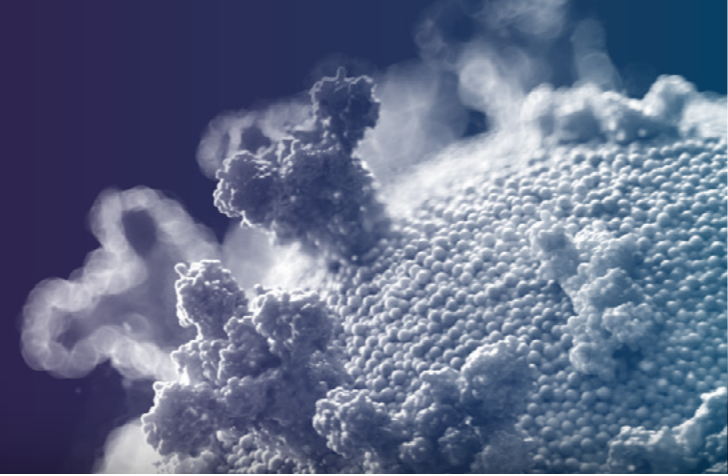
- The utilization of the **whole spike protein** ensures an early and sensitive detection of SARS-CoV-2 IgG
- **Quantitative IgG test** allows monitoring of immune response after infection or vaccination
- Expression of **SARS-CoV-2 IgG antibody activity** in standardized **BAU/ml** possible
- Detection of intrathecally synthesized IgG antibodies for **CSF diagnostics** NEW
- Excellent correlation of the IgG test with **neutralization assays**
- **Sensitive IgA and IgM antibody detection** with **high specificity** ideal for determination of acute infections as complement to direct pathogen detection
- **Quantitative evaluation** of IgA antibody activities
- In house produced antigens guarantee **reliable and reproducible results**

SARS-CoV-2 IgA/IgG/IgM EN V3 21/08

Product	Order No.	Product	Order No.
SERION ELISA <i>agile</i> SARS-CoV-2 IgA	ESR400A	SERION ELISA <i>control</i> SARS-CoV-2 IgA	BC400A
SERION ELISA <i>agile</i> SARS-CoV-2 IgG	ESR400G	SERION ELISA <i>control</i> SARS-CoV-2 IgG	BC400G
SERION ELISA <i>agile</i> SARS-CoV-2 IgM	ESR400M	SERION ELISA <i>control</i> SARS-CoV-2 IgM	BC400M

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# A global challenge



## Pathogen

SARS-CoV-2 (severe acute respiratory syndrome coronavirus type 2) belongs to the corona virus family. The virus first became apparent in 2019 and caused a worldwide pandemic. An infection with SARS-CoV-2 can cause the respiratory disease COVID-19.

## Disease

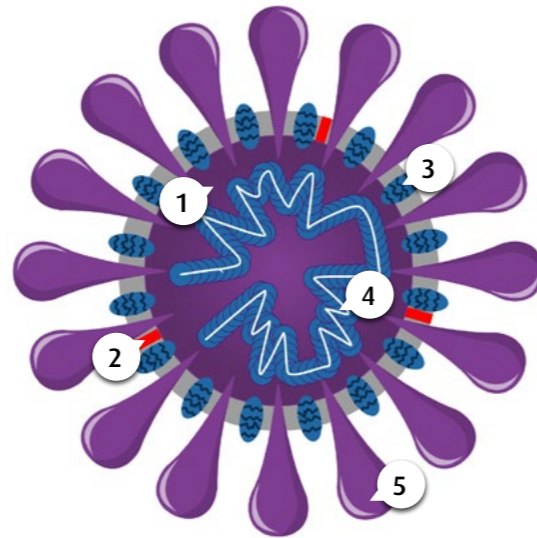
In COVID-19 patients, primarily the respiratory tract is affected. The infectious disease was first described at the end of 2019, before it expanded to a global pandemic in 2020. The infection usually occurs by droplets when coughing or sneezing or through close contact with sick people; in poorly ventilated rooms in closed areas a transmission via aerosols is also possible. The incubation time is 3 to maximum 14 days. The most common symptoms are fever, dry cough and fatigue as well as the loss of sense of smell and taste. Currently there are over 205 million documented cases of illness worldwide, over 4.3 millions with fatal outcome (data from August 2021). At the moment there are hardly any effective drugs available to fight SARS-CoV-2; couple of vaccines are available since December 2020.

## Diagnosis

Direct detection of pathogens by means of qRT-PCR is the most commonly used acute diagnostic method, supplemented by rapid antigen tests. However, recent publications show that the sensitivity of the qRT-PCR alone is not sufficient to adequately exclude false negative findings. A combination of antibody detection with qRT-PCR increases the diagnostic sensitivity compared to the sole detection of COVID-19 disease by qRT-PCR. Furthermore it is possible to perform antibody tests for epidemiological studies, e.g. to determine the immune status of the population and to investigate the development of the pandemic. Antibody tests are also used to determine and monitor the immune response after vaccination. Since the currently available vaccines mainly contain or encode the spike protein, a spike protein based immunoassay is required to analyze the immune response.

## Antigens

To achieve the best possible diagnostic properties, the IgA and IgM tests are based on a mixture of nucleocapsid protein and the whole spike protein (S1/S2 ectodomain) of SARS-CoV-2, recombinantly expressed in insect cells and highly purified. For the specific IgG test the whole spike protein is used solely. The nucleocapsid protein is associated with the RNA genome and part of the virus envelope. The S protein is a glycoprotein consisting of two domains, the S1 domain, which contains the receptor binding domain (RBD) and the S2 domain including transmembrane and endodomain. The antigens are produced in our own antigen production facility which guarantees a high availability and constant superb quality.



1) Nucleocapsidprotein 2) Envelope Protein 3) Membrane Protein 4) RNA 5) Spike Protein

## Diagnostic Efficiency

To determine the diagnostic performance of the SERION ELISA *agile* SARS-CoV-2 IgA/IgG/IgM immunoassays 138/136/143 blood donor sera, 134/134/120 sera from patients with suspected COVID-19 infection and 13/13/22 EQAs samples were evaluated against the corresponding commercially available ELISAs of a competitor.

Product	Sensitivity	Specificity
SERION ELISA <i>agile</i> SARS-CoV-2 IgA	96.3 %	> 99 %
SERION ELISA <i>agile</i> SARS-CoV-2 IgG	96.2 %	99.2 %
SERION ELISA <i>agile</i> SARS-CoV-2 IgM	96.2 %	> 99 %

## Precision

### SERION ELISA *agile* SARS-CoV-2 IgA

Sample	Mean Value (OD)	Intraassay (CV%)	Mean Value (OD)	Interassay (CV%)
Serum 1	0.234	2.7	0.238	4.7
Serum 2	0.441	3.2	0.418	7.6
Serum 3	1.052	2.3	0.758	13.4

### SERION ELISA *agile* SARS-CoV-2 IgG

Sample	Mean Value (OD)	Intraassay (CV%)	Mean Value (OD)	Interassay (CV%)
Serum 1	0.185	4.1	0.180	3.6
Serum 2	0.787	2.3	0.755	3.5
Serum 3	1.931	1.7	1.840	1.2

### SERION ELISA *agile* SARS-CoV-2 IgM

Sample	Mean Value (OD)	Intraassay (CV%)	Mean Value (OD)	Interassay (CV%)
Serum 1	0.122	4.1	0.113	10.8
Serum 2	0.233	3.6	0.221	8.3
Serum 3	2.463	2.6	2.801	6.3