

Distributie Nederland:



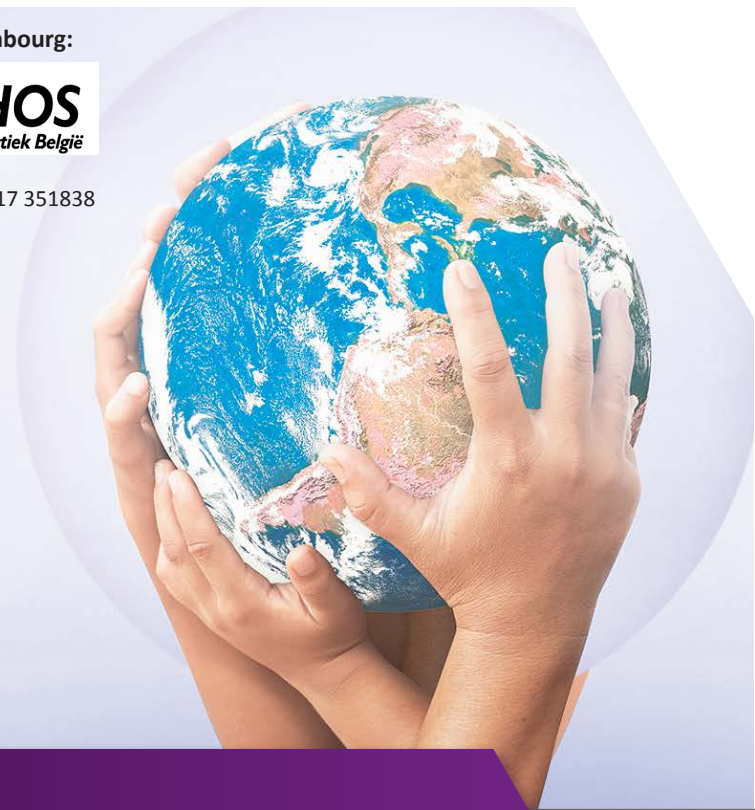
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# Now available!

Fully automatable 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
- **Sensitive IgA and IgM antibody detection** with **high specificity** ideal for determination of acute infections as complement to direct pathogen detection
- **Specific IgG test** for epidemiological studies, determination of the immune status and to analyze pandemic progression
- Quantitative evaluation of IgA and IgG antibody titers
- **Free from cross-reactions** against other pathogens, also from the corona virus family
- In house produced antigens guarantee **reliable and reproducible results** as well as sufficient production quantities
- **CE**-marked assays

serion\diagnostics

# 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

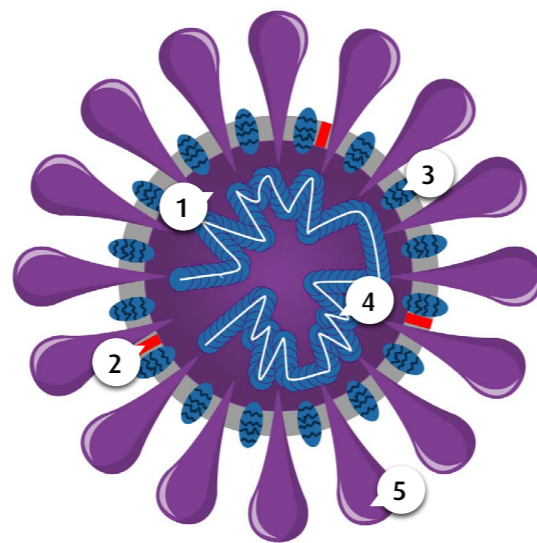
In COVID-19 patients, primarily the respiratory tract is affected. The infectious disease was first described at the end of 2019, before it expanded to a global pandemic in 2020. The infection usually occurs by droplets when coughing or sneezing or through close contact with sick people; in poorly ventilated 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 67 million documented cases of illness worldwide, over 1.5 millions with fatal outcome (Data from December 2020). At the moment there are hardly any effective drugs available to fight SARS-CoV-2; first vaccines will be approved in December 2020.

## Diagnosis

Currently, the 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 can also help to clarify infection chains. The knowledge obtained from this provides an important contribution to the decision making process regarding the application, enforcement or relaxation of containment measures.

## 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.



## Schematic illustration of a coronavirus

1) Nucleocapsid protein 2) Envelope Protein 3) Membrane Protein 4) RNA 5) Spike Protein



## SERION ELISA agile SARS-CoV-2 IgA antibody profile

The combined use of nucleocapsid and whole spike protein ensures high sensitivity and high specificity.

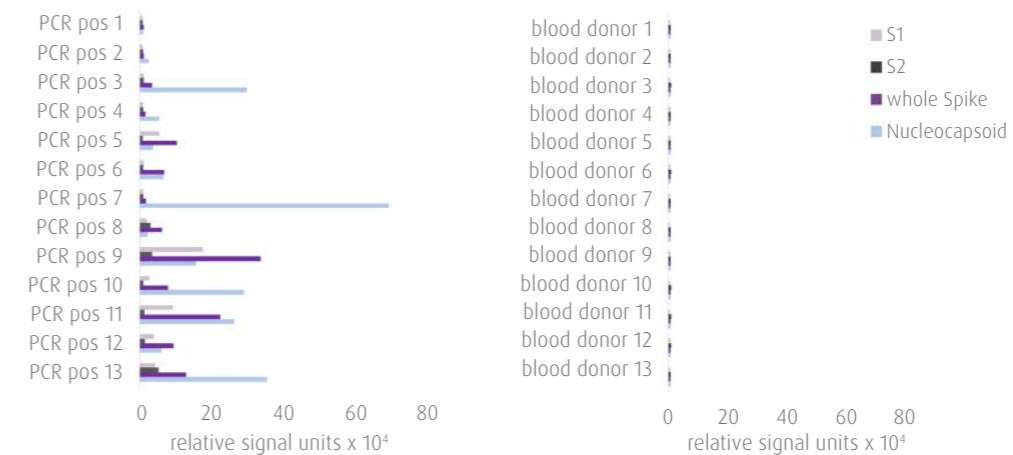


Figure 1:

By using a microparticle-based test system for the detection of SARS-CoV-2 IgA antibodies, the antigens S1, S2, whole spike protein and nucleocapsid protein were coated and analyzed with a total of 337 sera (including PCR positive patient sera, sera from patients with suspected infection, blood donor sera and potentially cross-reactive sera). The data reveal an increased sensitivity with very good specificity when nucleocapsid protein and whole spike protein are used in combination.

Analogous data (not shown here) also for SERION ELISA agile SARS-CoV-2 IgM

## SERION ELISA agile SARS-CoV-2 IgG antibody profile

The adoption of the whole spike protein guarantees a very high sensitivity and a high specificity compared to S1 and S2.

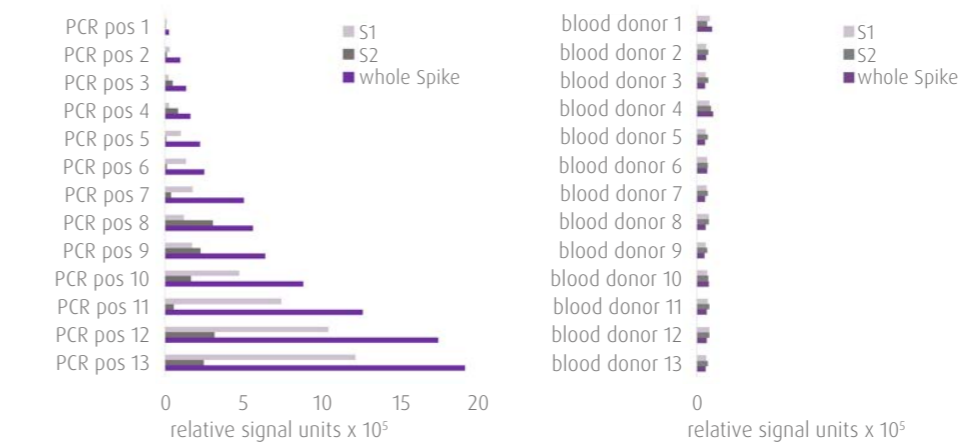


Figure 2:

By using a microparticle-based test system for the detection of SARS-CoV-2 IgG antibodies, the antigens S1, S2 and whole spike protein were coated and analyzed with a total of 337 sera (including PCR positive patient sera, sera from patients with suspected infection, blood donor sera and potentially cross-reactive sera). The data reveal an increased sensitivity at the same specificity when using the whole 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

### Cross-reactivity of SERION ELISA *agile* SARS-CoV-2 IgA

The cross-reactivity of SERION ELISA *agile* SARS-CoV-2 IgA was evaluated in a study with 9 resp. 10 sera each containing potentially cross-reactive antibodies and therefore tested positive for other Corona Viruses, Epstein-Barr Virus VCA IgM, Adenovirus IgA and Influenza A Virus IgA. No cross reactivity could be detected for the SERION ELISA *agile* SARS-CoV-2 IgA.

### Cross-reactivity of SERION ELISA *agile* SARS-CoV-2 IgG

The cross reactivity of SERION ELISA *agile* SARS-CoV-2 IgG was evaluated in a study with 9 resp. 10 sera each containing potentially cross-reactive antibodies and therefore tested positive for other Corona Viruses, Epstein-Barr Virus VCA IgG, Adenovirus IgG, Influenza A Virus IgG and Epstein-Barr Virus EA IgG. No cross reactivity could be detected for the SERION ELISA *agile* SARS-CoV-2 IgG.

### Cross-reactivity of SERION ELISA *agile* SARS-CoV-2 IgM

The cross reactivity of SERION ELISA *agile* SARS-CoV-2 IgM was evaluated in a study with 7 - 10 sera each containing potentially cross-reactive antibodies and therefore tested positive for other Corona Viruses, Epstein-Barr Virus VCA IgM, Adenovirus IgM, Influenza A Virus IgM, Cytomegalovirus IgM and Chlamydia pneumoniae IgM. No cross reactivity could be detected for the SERION ELISA *agile* SARS-CoV-2 IgM.

Product	Ig	Order No.
SARS-CoV-2	IgA	ESR400A

Product	Ig	Order No.
SARS-CoV-2	IgG	ESR400G

Product	Ig	Order No.
SARS-CoV-2	IgM	ESR400M <b>NEW!</b>

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