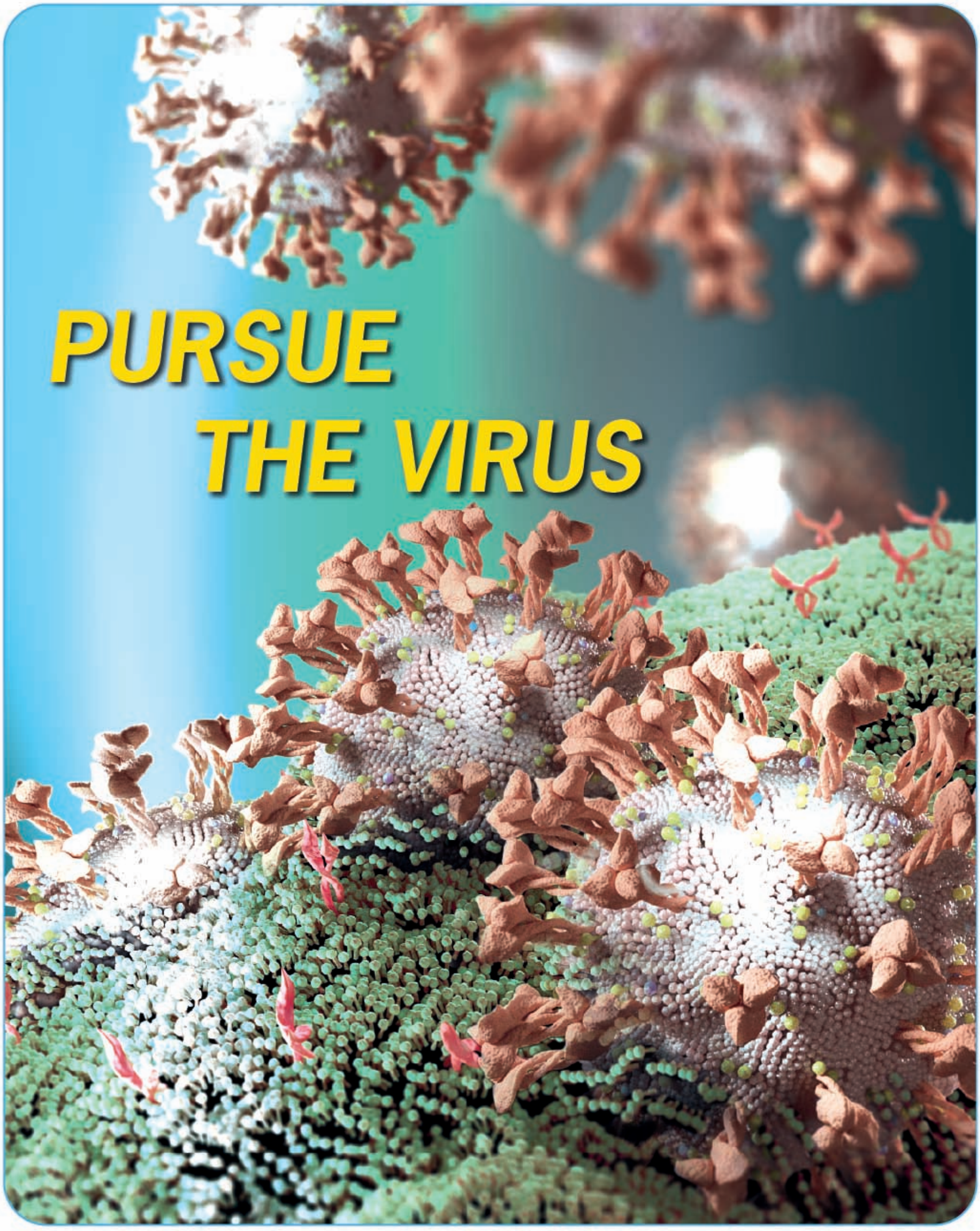

AESKULISA® SARS-CoV-2 S1 IgA / IgG / IgM

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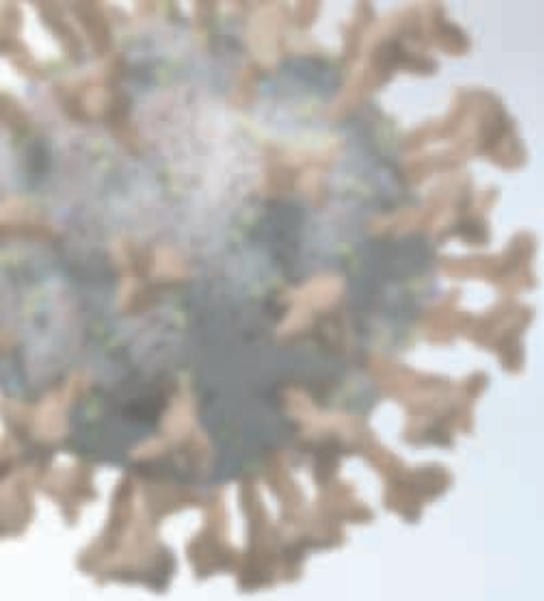


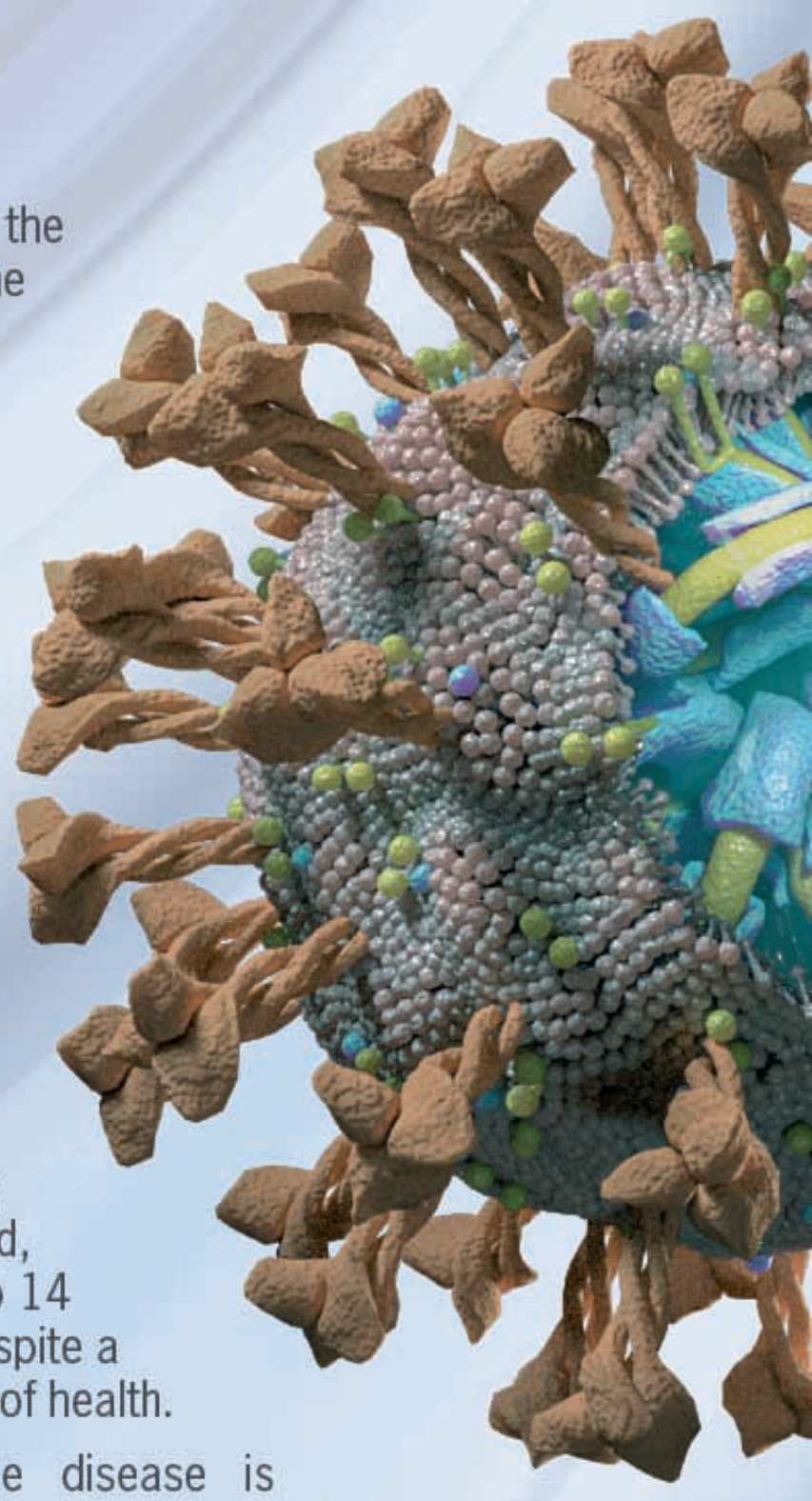
The ***AESKULISA®*** SARS-CoV-2 S1 IgA / IgG / IgM tests are quantitative immunoassays for the demonstration of human IgA, IgG or IgM antibodies in serum or plasma directed against the S1 domain of the Spike protein of SARS-CoV-2, and serve for confirmation of a contact with the pathogen and support in immune status determination.

Epidemiology

The Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) first appeared in December 2019 in the Chinese city of Wuhan as the pathogen and spread worldwide.

Severe Acute Respiratory Syndrome Coronavirus 2

SARS-CoV-2 is the causative agent of Coronavirus Disease 2019 (COVID-19). The virus envelope of the up to 160 nm large virus contains membrane proteins such as the glycosylated Spike protein (S), the Envelope protein (E), and the Matrix protein (M). Inside the virus is the capsid, which is formed from the nucleocapsid protein (N). The SARS-CoV-2 Spike (S) protein consists of the domains S1 and S2. The S1 subunit recognizes and binds to angiotensin-converting enzyme 2 (ACE2) receptors on the target cells via the receptor binding domain (RBD) portion, and subsequent conformational changes in S2 enable fusion between the virus envelope and the host cell. In contrast to the highly conserved nucleocapsid protein (NP) in the coronavirus family, the S1 domain of the spike protein is more specific for SARS-CoV-2. The development of vaccines and therapeutics targets parts of the spike protein.



Symptoms

The infection of other people during the incubation period, which can last up to 14 days, is possible despite a symptom-free state of health.

The course of the disease is unspecific, diverse and varies greatly. In addition to clinically unremarkable infections, mild to moderate disease progressions with flu-like symptoms and dry cough has been described. The disease manifests itself in most patients with fever, sore throat, headache, aching limbs, and pneumonia. In some cases, severe courses of the disease have been described with respiratory distress. Particularly in high-risk patients with previous illnesses or in people over 60 years of age, life-threatening pneumonia can occur, sometimes with a fatal outcome. In mild cases, the symptoms usually subside within two weeks. Severe courses of the disease can last three to six weeks. Permanent damage has also been observed.

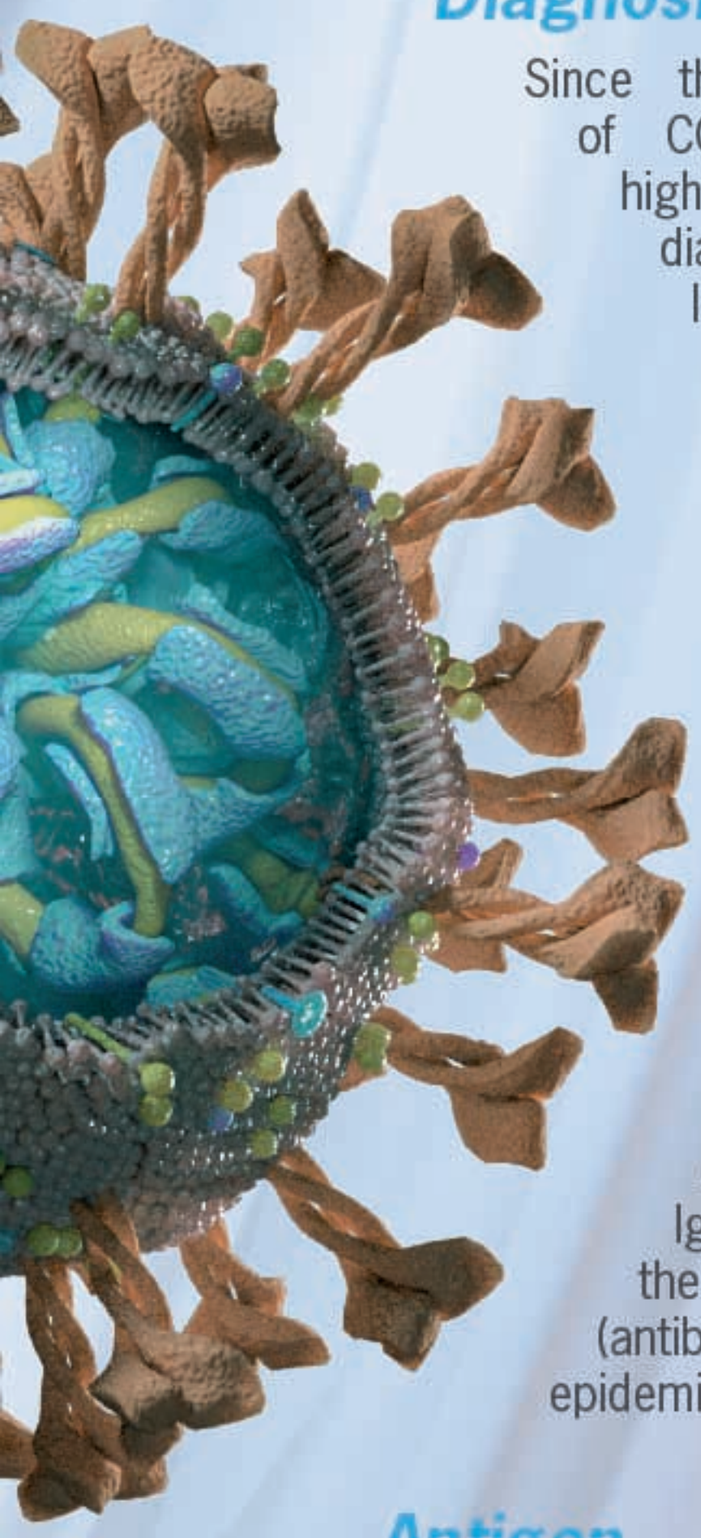
ASSAY FEATURES	
Antigen	S1 domain of the Spike protein of SARS-CoV-2
Calibration	Quantitative (4 calibrators A-D)
Sample dilution	Serum or plasma 1+100
Reagents	Ready for use, coloured, barcoded; Exception: sample buffer (5x) and wash buffer (50x)
Processing	30 min / 30 min / 30 min incubation time, room temperature incubation, automatable
Analysis	450 nm, reference wavelength between 620 and 650 nm
Package format	96 (12 x 8) individually breakable wells; test kit contains all necessary reagents

AESKULISA® SARS-CoV-2 S1 IgA / IgG / IgM

Transmission

The transmission is mainly through droplets (aerosols) and via contaminated surfaces.

Diagnosis



Since the clinical symptoms of COVID-19 disease are highly variable, laboratory diagnostics are of particular importance. The serological determination of IgA and IgM antibodies supports the diagnosis of COVID-19 during the infection. IgG antibodies react against the receptor-binding domain (RBD) on the spike proteins and are therefore considered neutralizing.

Also, the detection of IgG serves to determine the immune status (antibody titer) and to collect epidemiological data.

Antigen

Antibody detection with ***AESKULISA®*** SARS-CoV-2 IgA / IgG / IgM immunoassays are based on the S1 domain of the Spike protein of SARS-CoV-2.

Sensitivity and Specifity

The sensitivity of the ***AESKULISA®*** SARS-CoV-2 S1 IgA / IgG / IgM immunoassays was assessed by the analysis of 39 / 69 / 16 samples from patients with suspected SARS-CoV-2 infection. The specifity of the ***AESKULISA®*** SARS-CoV-2 S1 IgA / IgG / IgM was determined by the analysis of 99 / 110 / 96 samples from healthy blood donors.

The results of the ***AESKULISA®*** SARS-CoV-2 IgA / IgG / IgM were compared using SARS-CoV-2 S1 IgA / IgG / IgM immunoassays from a European manufacturer as a reference.

	Sensitivity	Specifity
SARS-CoV-2 S1 IgA	94.6%	>99.0%
SARS-CoV-2 S1 IgG	98.6%	>99.0%
SARS-CoV-2 S1 IgM	>99.0%	>99.0%

Precision

Precision and reproducibility of test results obtained with ***AESKULISA®*** SARS-CoV-2 IgA / IgG / IgM were assessed by the determination of the intra- and interassay precision as well as the lot-to-lot coefficient of variation (CV) by the analysis of multiple samples of different antibody activities.

AESKULISA® SARS-CoV-2 S1 IgG

Sample	Extinction (OD)	IgG Activity	Intraassay (U/ml) CV	Interassay (U/ml) CV	Lot-to-Lot (U/ml) CV
Serum 1	0.176	3.0 U/ml	4.1 %	7.5 %	12.7 %
Serum 2	0.733	17.9 U/ml	2.6 %	8.3 %	13.1 %
Serum 3	0.937	24.9 U/ml	3.3 %	6.3 %	12.3 %
Serum 4	1.421	46.9 U/ml	2.7 %	6.5 %	10.2 %
Serum 5	1.891	76.0 U/ml	3.8 %	4.4 %	5.4%

AESKULISA® SARS-CoV-2 S1 IgA

Sample	Extinction (OD)	IgA Activity	Intraassay (U/ml) CV	Interassay (U/ml) CV	Lot-to-Lot (U/ml) CV
Serum 1	0.165	3.5 U/ml	4.1 %	5.2 %	5.5 %
Serum 2	0.352	8.7 U/ml	2.7 %	3.4 %	3.2 %
Serum 3	0.774	22.5 U/ml	2.9 %	2.9 %	5.7 %
Serum 4	0.997	31.0 U/ml	2.7 %	5.1 %	6.5 %
Serum 5	1.611	60.3 U/ml	4.8 %	7.5 %	7.0 %

AESKULISA® SARS-CoV-2 S1 IgM

Sample	Extinction (OD)	IgM Activity	Intraassay (U/ml) CV	Interassay (U/ml) CV	Lot-to-Lot (U/ml) CV
Serum 1	0.199	4.5 U/ml	5.3 %	6.9 %	18.4 %
Serum 2	0.392	10.0 U/ml	3.0 %	7.2 %	4.4 %
Serum 3	0.672	19.0 U/ml	3.3 %	6.9 %	10.1 %
Serum 4	1.029	32.6 U/ml	3.3 %	5.9 %	9.1 %
Serum 5	1.538	59.7 U/ml	2.6 %	3.9 %	5.6 %

AESKULISA® SARS-CoV-2 S1 IgA / IgG / IgM

Product Highlights	
Antigen	Use of the immunogenic Spike protein S1 of SARS-CoV-2
Samples	Serum or plasma, 1 + 100
Calibration	Quantitative (4 calibrators A - D)
Quality assured application	Ready to use, coloured, barcoded and exchangeable reagents; *Exception:* sample buffer (5x) and wash buffer (50x)
	Positive and negative controls according to modern quality management guidelines
	Use of CAL B as cut off calibrator
Processing	Standardized application of ***AESKULISA***® IgA / IgG / IgM immunoassays at room temperature with short incubation times (30 min / 30 min / 30 min) for combination of different ***AESKULISA***® in one test run
Analysis	Measurement at 450 nm, reference wavelength between 620 nm and 650 nm
Quantification	Use of the precise 4-parameter logistic (4 PL) function for the quantification of pathogen-specific antibody activity
Reproducibility	High precision and linearity in wide measuring ranges
Package format	96 (12 x 8) individually breakable wells; test kit contains all necessary reagents.
Certification	CE-marked
Compatibility	Application with conventional ELISA Washer and Reader Systems
Automation	Application with Triturus®, SQII and comparable instruments

Ordering information

REF. 6124	**Product Name:** ***AESKULISA***® SARS-CoV-2 S1 IgA	**Format:** 96 (12x8) Cavities	**Calibration:** quantitative	**Description:** Immunoassay for the detection of human IgA antibodies in serum or plasma directed against the Spike protein S1 domain.
REF. 6125	**Product Name:** ***AESKULISA***® SARS-CoV-2 S1 IgG	**Format:** 96 (12x8) Cavities	**Calibration:** quantitative	**Description:** Immunoassay for the detection of human IgG antibodies in serum or plasma directed against the Spike protein S1 domain.
REF. 6126	**Product Name:** ***AESKULISA***® SARS-CoV-2 S1 IgM	**Format:** 96 (12x8) Cavities	**Calibration:** quantitative	**Description:** Immunoassay for the detection of human IgM antibodies in serum or plasma directed against the Spike protein S1 domain.

VERSION 003: 2020-10-16-EN

DIAGNOSTICS MADE IN GERMANY

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