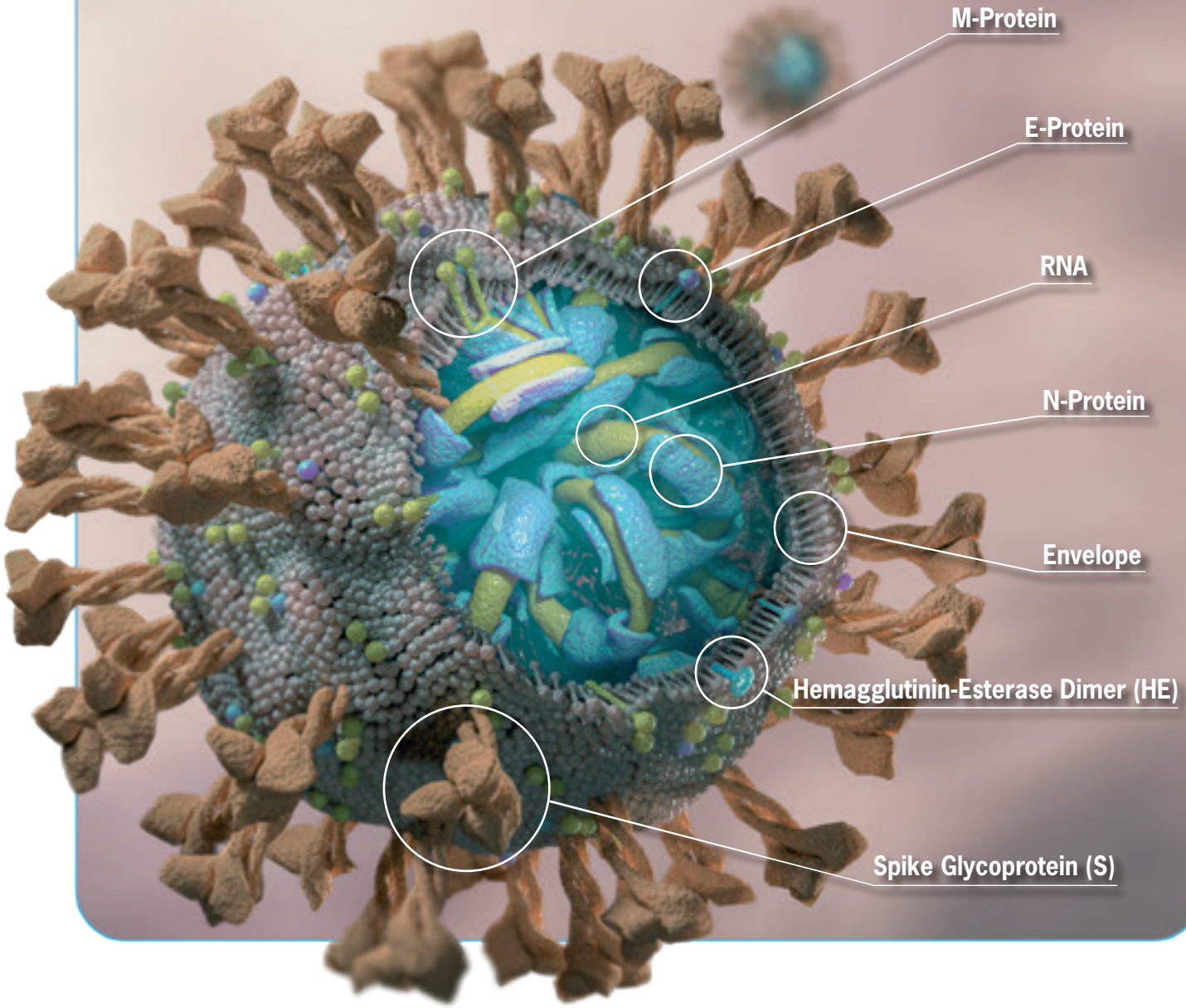
TRACING THE VIRUS



AESKULISA® SARS-CoV-2 NP IgA/IgG/IgM

AESKU.GROUP
WE TAKE CARE OF YOUR HEALTH

SARS-CoV-2 and COVID-19

Epidemiology

SARS-CoV-2 was first identified in December 2019 in Wuhan, China, as the causative agent of severe acute respiratory syndrome and has since spread globally, resulting in the COVID-19 pandemic.

SARS-CoV-2

SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2) is a human pathogenic, SARS-associated coronavirus and the causative agent of COVID-19 (corona virus disease 2019). A range of different membrane proteins such as the glycosylated spike protein (S), the envelope protein (E) and the matrix protein (M) are integrated in the virus envelope. The capsid inside of the virus with a diameter of 120 to 160 nm is composed of the nucleoprotein (N) and the (+)ssRNA. The spike protein (S) can be divided into the S1 and S2 domains. The S1 domain interacts with the ACE2 (angiotensin converting enzyme 2) receptor located on the surface of the host cell, whereas the S2 domain supports in the fusion of the virus with the cell membrane.

Transmission

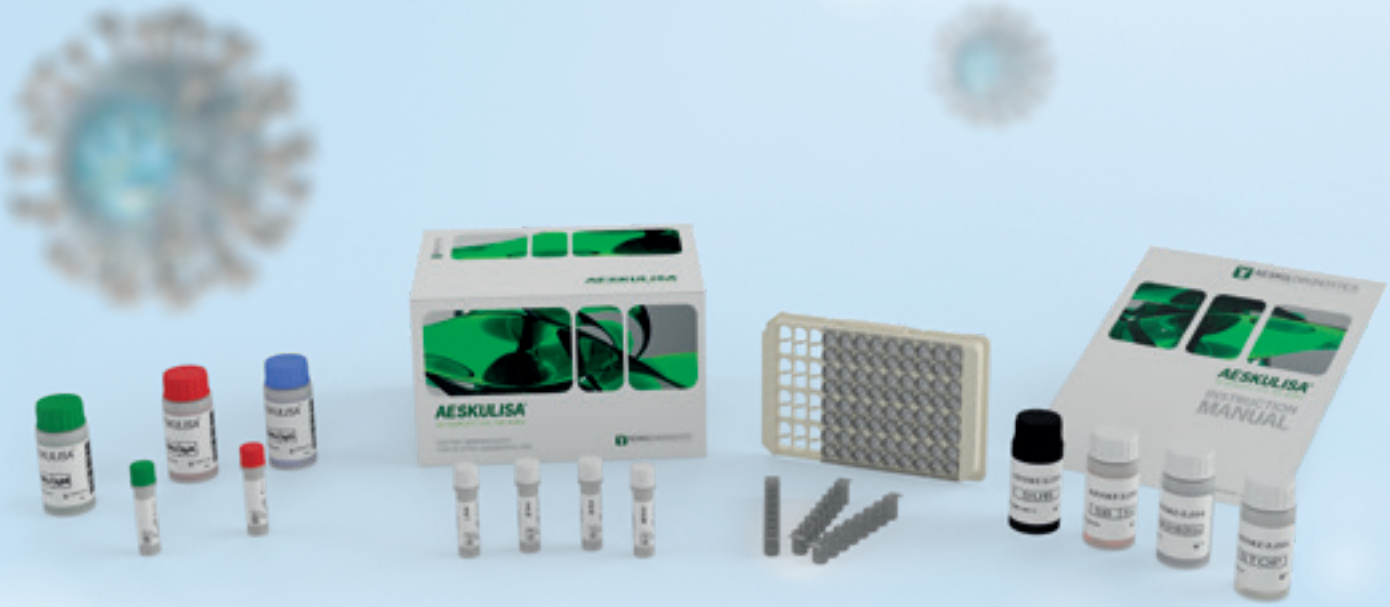
Transmission occurs primarily via aerosols and droplets. In general, infection via contaminated surfaces is also possible.

Disease and symptoms

The incubation period is usually five to six days, but may last up to 14 days. Infection of other people during the incubation period is possible despite a lack of clinical symptoms. The course of the disease is often unspecific and varies widely. In addition to clinically unapparent infections, predominantly mild to moderate illnesses with flu-like symptoms and dry cough have been described. The disease manifests in most cases with fever, sore throat, headache, body aches and pneumonia. In some cases, however, severe courses with acute respiratory syndromes have been described. Life-threatening pneumonia, which can sometimes be fatal, can occur particularly in high-risk patients with previous illnesses or in people above 60 years of age. In mild cases, the symptoms usually subside within two weeks. Serious disease courses can last three to six weeks.

Diagnosis

As the clinical symptoms of COVID-19 are very variable, laboratory diagnosis is of particular importance. Serological determination of IgA, IgG and IgM antibodies supplements the direct detection and supports in the diagnosis of COVID-19 in the course of the disease. In addition, the demonstration of antibodies serves for the determination of the immune status, the identification of individuals with previous contact to the pathogen as well as for epidemiological studies.



AESKULISA® SARS-CoV-2 NP IgA/IgG/IgM

The ***AESKULISA***® SARS-CoV-2 NP IgA, IgG and IgM tests are qualitative and quantitative immunoassays for the demonstration of human IgA, IgG and IgM antibodies in serum or plasma directed against the nucleocapsid protein of SARS-CoV-2. The ***AESKULISA***® SARS-CoV-2 NP IgA and IgM tests assist in the detection of acute infections. The ***AESKULISA***® SARS-CoV-2 NP IgG test serves for confirmation of a contact with the pathogen and supports in immune status determination.

Antigen

Antibody detection with ***AESKULISA***® SARS-CoV-2 NP IgA, IgG and IgM immunoassays is based on the nucleocapsid protein of SARS-CoV-2.

Sensitivity and Specificity

The sensitivity of the ***AESKULISA®*** SARS-CoV-2 NP IgA / IgG / IgM immunoassay was assessed by the analysis of 62 / 65 / 28 samples from patients with suspected SARS-CoV-2 infection. The specificity of the ***AESKULISA®*** SARS-CoV-2 NP IgA / IgG / IgM was determined by the analysis of 74 / 87 / 182 samples from healthy blood donors.

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

Precision

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

AESKULISA® SARS-CoV-2 NP IgA

Sample	Extinction (OD)	IgA Activity	Intraassay (U/ml) CV	Interassay (U/ml) CV	Lot-to-Lot (U/ml) CV
Serum 1	0.483	9.5 U/ml	4.4 %	12.8 %	12.8 %
Serum 2	0.933	22.9 U/ml	3.4 %	5.9 %	8.6 %
Serum 3	1.175	34.1 U/ml	2.4 %	4.3 %	9.8 %
Serum 4	1.350	42.9 U/ml	2.2 %	4.5 %	7.8 %
Serum 5	2.144	118.6 U/ml	5.5 %	11.3 %	9.0 %

AESKULISA® SARS-CoV-2 NP IgG

Sample	Extinction (OD)	IgG Activity	Intraassay (U/ml) CV	Interassay (U/ml) CV	Lot-to-Lot (U/ml) CV
Serum 1	0.479	5.8 U/ml	3.3 %	3.7 %	6.2 %
Serum 2	0.704	10.0 U/ml	2.8 %	3.7 %	9.7 %
Serum 3	0.942	16.1 U/ml	3.0 %	4.9 %	9.0 %
Serum 4	1.371	33.1 U/ml	3.5 %	7.1 %	14.1 %
Serum 5	1.810	70.8 U/ml	4.6 %	6.1 %	8.6 %

AESKULISA® SARS-CoV-2 NP IgM

Sample	Extinction (OD)	IgM Activity	Intraassay (U/ml) CV	Interassay (U/ml) CV	Lot-to-Lot (U/ml) CV
Serum 1	0.275	4.5 U/ml	3.7 %	5.2 %	9.1 %
Serum 2	0.423	7.7 U/ml	2.9 %	4.5 %	9.1 %
Serum 3	0.730	16.0 U/ml	3.8 %	6.1 %	5.0 %
Serum 4	1.433	45.3 U/ml	4.4 %	5.7 %	7.5 %
Serum 5	1.803	73.0 U/ml	4.1 %	15.5 %	6.6 %

ASSAY FEATURES	
Antigen	Nucleocapsid protein of SARS-CoV-2
Calibration	Quantitative (4 calibrators A-D) or qualitative (cut off calibrator B)
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 at room temperature, automatable
Analysis	450 nm, reference wavelength between 620 and 650 nm
Package format	96 (12x8) individually breakable wells; test kit contains all necessary reagents.

AESKULISA® SARS-CoV-2 NP IgA/IgG/IgM

Product Highlights	
Antigen	Use of the immunogenic nucleocapsid protein of SARS-CoV-2
Samples	Serum or plasma, 1 + 100
Calibration	Quantitative (4 calibrators A - D) or qualitative (cut off calibrator B)
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 and 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 IgA, IgG and IgM 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-certified
Compatibility	Application with conventional ELISA Washer and Reader Systems
Automation	Application with Triturus®, SQII and comparable instruments

Ordering information

REF.	Product Name:	Format:	Calibration:	Description:
REF. 6121	***AESKULISA***® SARS-CoV-2 NP IgA	96 (12x8) Cavities	qualitative/ quantitative	Immunoassay for the detection of human IgA antibodies in serum or plasma directed against the nucleocapsid protein of SARS-CoV-2
REF. 6122	***AESKULISA***® SARS-CoV-2 NP IgG	96 (12x8) Cavities	qualitative/ quantitative	Immunoassay for the detection of human IgG antibodies in serum or plasma directed against the nucleocapsid protein of SARS-CoV-2
REF. 6123	***AESKULISA***® SARS-CoV-2 NP IgM	96 (12x8) Cavities	qualitative/ quantitative	Immunoassay for the detection of human IgM antibodies in serum or plasma directed against the nucleocapsid protein of SARS-CoV-2

VERSION 002: 2020-07-22-EN

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