Anti-SARS-CoV-2 NCP ELISA (IgM)

- **Sensitive detection of IgM against SARS-CoV-2 using the nucleocapsid protein**
- **Antigen with the strongest immune dominance in the coronavirus family**
- **Optimised specificity of the ELISA due to the use of a modified nucleocapsid protein (NCP) that only contains diagnostically relevant epitopes**
- **Fully automated processing and evaluation possible**

Technical data

Antigen	Modified nucleocapsid protein (NCP)
Calibration	Semiquantitative; calculation of a ratio from the extinction of the sample and that of the calibrator
Result interpretation	EUROIMMUN recommends interpreting results as follows: Ratio < 0.8: negative Ratio ≥ 0.8 to < 1.1: borderline Ratio ≥ 1.1: positive
Sample dilution	Serum or plasma, 1 : 101 in sample buffer
Reagents	Ready for use, with the exception of the wash buffer (10x); colour-coded solutions, in most cases exchangeable with those in other EUROIMMUN ELISA kits
Test procedure	60 min (37 °C) / 30 min (RT) / 15 min (RT) (sample/conjugate/substrate incubations), fully automatable
Measurement	450 nm, reference wavelength between 620 nm and 650 nm
Test kit format	96 break-off wells; kit includes all necessary reagents
Stability	6 months
Order number	**EI 2606-9601-2 M**

Clinical significance

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2, previously called 2019-nCoV) belongs to the family of coronaviruses and, like SARS-CoV, is classified in the genus *Betacoronavirus*. The new coronavirus originated in China, in the city of Wuhan, Hubei province. At the end of 2019 it caused an infection wave that has spread rapidly over the country and worldwide. Just a few days after the first report about patients with pneumonia of unclear origin, SARS-CoV-2 was identified as the causative pathogen.

SARS-CoV-2 is mainly transmitted via aerosols during coughing or sneezing or at close contact with an infected person. Health care personnel and family members are especially at risk. The zoonotic reservoir of the virus appears to be bats. The incubation time of SARS-CoV-2 is three to seven, maximally 14 days. The symptoms of SARS-CoV-2 infection are fever, coughing, breathing difficulties and fatigue. In most patients the infection manifests with symptoms of a mild febrile illness with irregular lung infiltrates. Some patients, especially elderly or chronically ill patients, develop acute respiratory distress syndrome (ARDS). The fatality rate is between 0.6 and 7.2%, depending on the country. In February 2020, the disease caused by SARS-CoV-2 was named COVID-19 by the WHO.

Suitable methods for the diagnosis of SARS-CoV-2 infections are the detection of viral RNA by reverse transcriptase polymerase chain reaction (RT-PCR) or of virus protein by means of ELISA primarily in sample material from the upper (nasopharyngeal or oropharyngeal swab) or lower respiratory tract (bronchoalveolar lavage fluid, tracheal secretion, sputum, etc.). The determination of antibodies enables confirmation of SARS-CoV-2 infection in patients with typical symptoms and in suspected cases. It also contributes to monitoring and outbreak control. For significant serological results, two patient samples should be investigated, one from the acute phase (week 1 of the illness) and one from the convalescent phase (3 to 4 weeks later).

Cross reactions with antibodies within the genus *Betacoronavirus* have been described. Currently, there is no medication or vaccine available against infection with this new virus.

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Diagnostic sensitivity (prevalence)

The sensitivity was determined by investigating 102 samples from 79 European patients using the Anti-SARS-CoV-2 NCP ELISA (IgM). In these patients, infections with SARS-CoV-2 had been confirmed by RT-PCR[1] based on a sample taken at the early phase of infection. The serological examination was based on samples collected during the further course of the infection. In samples taken until day 10 (time point after symptom onset or positive direct detection), the Anti-SARS-CoV-2 NCP ELISA (IgM) showed a sensitivity of 88.2 %. The sensitivity of the Anti-SARS-CoV-2 ELISA (IgM) in samples collected between day 11 and 15 was 70.6 %. Further data on the sensitivity of the Anti-SARS-CoV-2 NCP ELISA (IgM) in samples taken after day 16 are given in the adjacent table.

Days after symptom onset or positive direct detection	EUROIMMUN-Anti-SARS-CoV-2 NCP ELISA (IgM)		
	Positive	Negative	Sensitivity (prevalence) *
< 10	15	2	**88.2 %**
11–15	12	5	**70.6 %**
16–25	15	13	**53.6 %**
26–35	5	6	**45.5 %**
36–45	3	3	**50.0 %**
> 46	2	15	**11.8 %**

* Borderline results (n = 6) were not included. The sensitivity depends on the prevalence of specific IgM antibodies in persons with COVID-19 infection.

Specificity

The specificity of the Anti-SARS-CoV-2 NCP ELISA (IgM) was determined by investigating 199 patient sera that were positive, for instance, for antibodies against other pathogens or for rheumatoid factors. Additionally, 622 samples from blood donors, children and pregnant women were analysed. The specificity of the Anti-SARS-CoV-2 NCP ELISA (IgM) thus amounted to 98.6 %.

Panel	EUROIMMUN Anti-SARS-CoV-2 NCP ELISA (IgM)	
	n	Specificity *
Blood donors	449	99.1 %
Pregnant women	99	96.9 %
Children	74	100 %
Elderly patients	97	100 %
Influenza (freshly vaccinated, incl. courses	40	100 %
Acute EBV infection & heterophilic antibodies	22	81.8 %
Rheumatoid factors	40	100 %
Total	**821**	**98.6 %**

* Borderline results (n = 7) were not included.

Literature

1. Corman VM, et al. **Detection of 2019 novel coronavirus (2019-nCoV) by real-time RT-PCR.** Euro Surveill 25(3): pii=2000045 (2020-01-23).
2. WHO: **Clinical management of severe acute respiratory infection when novel coronavirus (2019-nCoV) infection is suspected.** Interim guidance.
3. WHO: **Laboratory testing for 2019 novel coronavirus (2019-nCoV) in suspected human cases.** Interim guidance.

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