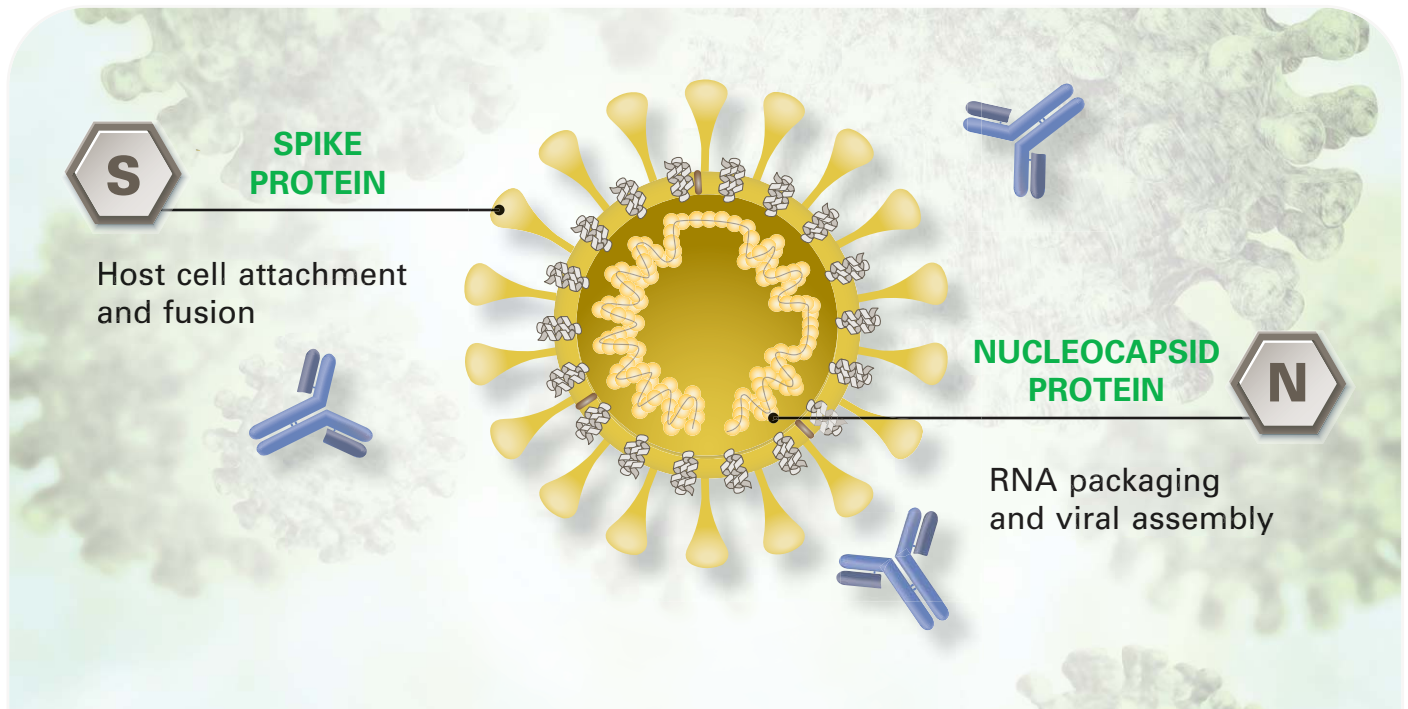




Characteristics of EUROIMMUN ELISA for COVID-19 diagnostics



Antigens

Anti-SARS-CoV-2 ELISA (IgG, IgA)

Spike protein S1 domain



- S1 contains immunologically crucial receptor binding domain (RBD)
- Key target antigen for virus neutralisation
- RBD is presented in its active state (inaccessible in full length S protein prior to cell contact)
- Evolutionary low protein homologies within the coronavirus family

Order number: EI 2606-9601 G, A
EI 2606-9620 G, A

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

Modified nucleocapsid protein



- Only diagnostically relevant epitopes are used – for optimised performance in comparison to full length N protein
- Highly specific due to removal of unspecific epitopes
- Most immunodominant antigen of the coronavirus family

Order number: EI 2606-9601-2 G, M
EI 2606-9620-2 G



Sensitivity

Days after onset of symptoms or positive direct detection	EUROIMMUN Anti-SARS-CoV-2 ELISA (IgG)			EUROIMMUN Anti-SARS-CoV-2 NCP ELISA (IgG)		
	Positive	Negative	Sensitivity (prevalence)*	Positive	Negative	Sensitivity (prevalence)*
≤ 10	38	49	43.7%**	12	3	80.0%
> 10	68	4	94.4%	53	3	94.6%

* Borderline results were not included. To determine the diagnostic sensitivity, samples from patients with confirmed SARS-CoV-2 infection were analysed. The sensitivity therefore corresponds to the prevalence of antibodies against SARS-CoV-2 in COVID-19 infected persons.

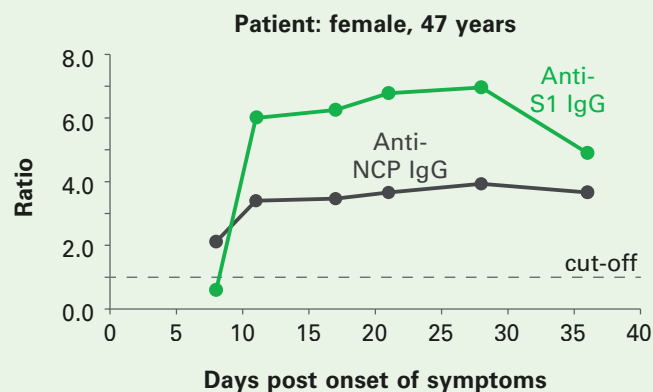
** Low sensitivity due to the limited prevalence of specific antibodies. Antibodies against the S1 domain of the spike protein of SARS-CoV-2 are produced several days after infection and can only be detected with high sensitivity from day 10 after the onset of symptoms. In some isolated cases the onset of antibody secretion was detected only after a period of >4 weeks post symptom onset.

Specificity

Panel	EUROIMMUN Anti-SARS-CoV-2 ELISA (IgG)		EUROIMMUN Anti-SARS-CoV-2 NCP ELISA (IgG)	
	n	Specificity*	n	Specificity*
Blood donors	849	99.5%	849	99.8%
Pregnant women	199	99.5%	99	100%
Children	74	100%	74	100%
Elderly patients	97	100%	97	99.0%
Infections with other human pathogenic coronaviruses	23	100%	27	100%
Antibodies against influenza (freshly vaccinated, incl. courses)	40	100%	40	100%
Acute EBV infection & heterophilic antibodies	22	100%	22	100%
Rheumatoid factors	40	100%	40	100%
Total	1,367	99.6%	1,248	99.8%

* Borderline results were not included.

Immune response in SARS-CoV-2 infections



■ Anti-NCP IgG positive from day 8 post onset, anti-S1 IgG still negative at that time point

■ Anti-S1 IgG levels positive from day 11 post onset