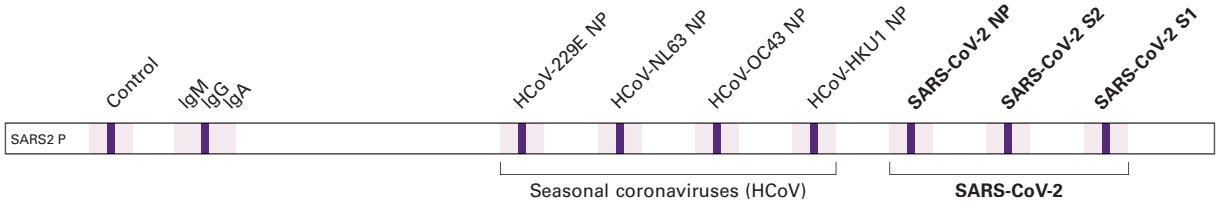
EUROLINE Anti-SARS-CoV-2 Profile (IgG)



- **Line blot for the determination of IgG antibodies against SARS-CoV-2 and seasonal coronaviruses (HCoV)***
- **Enables differentiated anti-SARS-CoV-2 IgG detection due to separate antigen bands for the S1 domain (incl. RBD) and S2 domain of the spike protein as well as for the nucleocapsid protein (NP)**
- **Fully automated incubation and evaluation using EUROBlotOne / EUROLineScan**

Technical data

Antigen	Recombinant SARS-CoV-2 antigens (S1 and S2 domains of the spike protein and modified nucleocapsid protein), recombinant nucleocapsid proteins of other human coronaviruses (HCoV)*
Sample dilution	Serum or plasma, 1 : 51 in sample buffer
Test procedure	30 min / 30 min / 10 min (sample / conjugate / substrate incubation), room temperature, fully automatable
Test kit format	16, 50 or 64 membrane strips; kit includes all necessary reagents
Automation	Compatible with all commercial blot processing systems, e.g. EUROBlotOne or EUROBlotMaster from EUROIMMUN. The evaluation is performed using EUROLineScan.
Order information	This product is not available in Canada and the USA. **DN 2606-1601-1 G (16 strips)** **DN 2606-6401-1 G (64 strips)** **DN 2606-0510-1 G Immunoblot-PreQ (pre-equipped single channels, 50 strips)**

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*. At the end of 2019, SARS-CoV-2 was identified as the causative pathogen of clustered cases of pneumonia of unclear origin. The virus caused an infection wave that has spread rapidly worldwide and was declared a pandemic by the WHO at the beginning of 2020. The disease caused by SARS-CoV-2 is called COVID-19.

SARS-CoV-2 is mainly transmitted by the respiratory uptake of virus-containing droplets and aerosols produced during speaking, breathing, coughing and sneezing. The incubation time of SARS-CoV-2 is three to seven, maximally 14 days. The infection can proceed asymptomatically or cause symptoms of a febrile diseases with irregular lung infiltrates. Some patients, especially elderly or chronically ill patients, develop acute respiratory distress syndrome (ARDS).

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). The spike and nucleocapsid proteins of SARS-CoV-2 are highly immunogenic and antibodies against the receptor binding domain (RBD) of the spike protein have a virus-neutralising effect. Cross reactions with antibodies within the genus *Betacoronavirus* have been described.

* The determination of antibodies against additional HCoV antigens is only for information purposes. A possible reactivity of the respective antigen bands has no influence on the test result.

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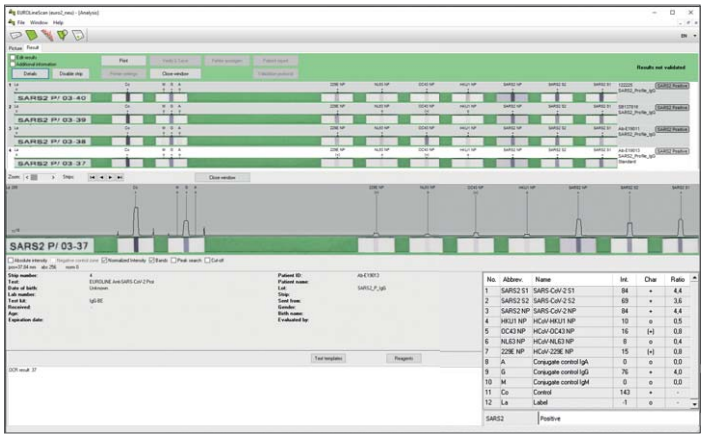
Automated processing

EUROBlotOne is a compact, fully automatic device for the standardised processing of EUROIMMUN line assays (EUROLINE, EUROLINE-WB, Westernblot) – from the sample identification to the final test result. Samples are pipetted by the device and all incubation and washing steps are carried out automatically. Finally the data of the pictures taken by the integrated camera are automatically evaluated and digitally archived by the EUROLineScan software. Alternatively, the immunoblot strips can be incubated by the EUROBlotMaster and scanned using the EUROBlotScanner. Also in this case, the automatic evaluation is carried out by EUROLineScan. The bidirectional communication with a laboratory information system for import of work lists and export of results is enabled by EUROLineScan or, optionally, the laboratory management software EUROLabOffice.



Prevalence

The prevalence of IgG antibodies against SARS-CoV-2 and further human coronaviruses (HCoV) was determined by investigating 369 samples from blood donors, children and persons aged 70 to 91 years taken before the occurrence of SARS-CoV-2 (sample collection before 2020) using the EUROLINE Anti-SARS-CoV-2 Profile (IgG). The prevalence was 0.3 % for anti-SARS-CoV-2 IgG and 74.8 % for IgG antibodies against the additional HCoV antigens.

Panel	n	EUROLINE Anti-SARS-CoV-2 Profile (IgG)	
		Anti-SARS-CoV-2 IgG	Anti-HCoV IgG*
		Prevalence	Prevalence
Blood donors	220	0.0 %	84.1 %
Children aged 0 to 10 years	100	0.0 %	56.0 %
Persons aged 70 to 91 years	49	2.0 %	71.4 %
Total	369	**0.3 %**	**74.8 %**

* Antibodies against at least one of the four other coronaviruses (HCoV)

Method comparison

By investigating 103 patient samples, the results from the EUROLINE Anti-SARS-CoV-2 Profile (IgG) (anti-SARS-CoV-2 IgG results) were compared with those obtained with two CE-marked reference tests based on the nucleocapsid protein (NP) or the S1 domain of SARS-CoV-2 spike protein. The agreement of the test results was 100 %. Borderline results were excluded from the calculation.

n = 103		CE-marked reference tests: Anti-SARS-CoV-2 NP IgG and Anti-SARS-CoV-2 S1 IgG		
		positive	borderline	negative
EUROLINE Anti-SARS-CoV-2 Profile (IgG): Anti-SARS-CoV-2 IgG	positive	85	2	0
	borderline	2	0	0
	negative	0	1	13

Diagnostic sensitivity and specificity

The sensitivity** (prevalence) was determined by investigating 78 samples from 24 European patients using the EUROLINE Anti-SARS-CoV-2 Profile (IgG). These patients had been confirmed to be infected with SARS-CoV-2 by RT-PCR based on one sample taken at the early phase of infection. The serological analysis was performed with samples taken during the further course of the infection. In samples collected after day 14 (time point after the onset of symptoms or positive direct detection of the pathogen), the EUROLINE Anti-SARS-CoV-2 Profile (IgG) showed a sensitivity of 96.0 %.

The diagnostic sensitivity and specificity of the EUROLINE Anti-SARS-CoV-2 Profile (IgG) was determined based on 25 samples from American patients precharacterised by means of SARS-CoV-2 RT-PCR (COVID-19 Validation Panel with 15 positive and 10 negative samples) and amounted to 100 % each.

n = 78		Days after symptom onset or PCR test	
		(Early) 0-14 days	(Late) >14 days
EUROLINE Anti-SARS-CoV-2 Profile (IgG): Anti-SARS-CoV-2 IgG	positive	0	72
	borderline	0	1
	negative	2	3
	Prevalence	**0.0 %**	**96.0 %**

Origin of samples: WHO Collaborating Centre for Arbovirus and Haemorrhagic Fever Reference and Research (WHOCC, Germany).

** The sensitivity depends on the prevalence of specific IgG antibodies in persons infected with SARS-CoV-2.

n = 25		COVID-19 Validation Panel	
		Positive PCR	Negative PCR
EUROLINE Anti-SARS-CoV-2 Profile (IgG): Anti-SARS-CoV-2 IgG	positive	15	0
	borderline	0	0
	negative	0	10

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