Anti-Strongyloides ELISA (IgG)

- **Useful supplement to direct detection**
- **Highly specific detection of strongyloidiasis even with irregular release of parasite larvae**
- **Fully automated processing and evaluation**

Technical Data

Antigen	Highly purified antigens from Strongyloides larvae
Calibration	Semiquantitative; calculation of a ratio from the extinction of the controls or sample and the extinction of the calibrator
Resultinterpretation	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 (37 °C) / 30 min (room temperature), fully automatable
Measurement	450 nm, reference wavelength between 620 nm and 650 nm
Kit format	96 break-off wells; kit includes all necessary reagents
Order number	**EI 2290-9601 G**

Clinical significance

Strongyloides stercoralis is the most frequent pathogen of human strongyloidiasis. The parasite develops into sexually mature worms within 30 days via four consecutive larval stages without an intermediate host. In its final larval stage (filariform), which penetrates the skin, the parasite infects 30 million people worldwide annually, mainly in humid tropical and subtropical regions, but also in Europe, introduced from Central Africa.

The life cycle of the parasite proceeds in two phases (free-living and parasitic). The adult females colonise the human intestine and lay their eggs, which then hatch into larvae. The eggs and larvae are released in faeces and develop in damp soil and water into free-living infectious larvae. These enter the body via the skin (cutaneous phase) and migrate haematologically to the lungs (pulmonary phase). From there the larvae move to the throat, where they are swallowed. Finally they reach the intestinal tract (intestinal phase), where they mature into adult worms. Due to the different phases of strongyloidiasis, symptoms vary from itchy skin rash to bronchitis-like symptoms or nausea, diarrhoea and colic-type pain. Autoinfection usually leads to chronic intestinal disease, whose cause often remains unknown for decades.

Diagnostic application

The EUROIMMUN Anti-Strongyloides ELISA (IgG) provides serological detection of strongyloidiasis, a gastrointestinal disease caused by nematodes of the genus Strongyloides. Depending on the severity of the infection, the disease can also lead to pneumonal symptoms (lung inflammation, bronchitis etc.). The parasite larvae can be detected microscopically in stool and in secretions, although these direct detection methods show a low sensitivity. Antibody detection, in contrast, can secure a diagnosis even with irregular release of parasite larvae, and is a useful supplement to direct detection.

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Reference range

The levels of anti-Strongyloides antibodies (IgG) were analysed in a panel of 500 healthy blood donors (origin: Germany) using the EUROIMMUN Anti-Strongyloides ELISA (IgG). With a cut-off value of ratio 1.0, 5 % of the blood donors were anti-Strongyloides positive (IgG).

Reproducibility

The reproducibility of the test was investigated by determining the intra- and inter-assay coefficients of variation using 3 samples. The intra-assay CVs are based on 20 determinations and the inter-assays CVs on 4 determinations performed in 5 different test runs.

	Intra-assay variation, n=20		Inter-assay variation, n=4 x 5	
Sample	Mean value (ratio)	CV (%)	Mean value (ratio)	CV (%)
1	0.8	2.6	0.8	7.0
2	0.8	4.6	1.0	6.2
3	2.3	2.4	2.5	9.6

Quality assessment results

Eight clinically precharacterised patient samples from the quality assessment scheme NEQAS (UK) were investigated with the EUROIMMUN Anti-Strongyloides ELISA (IgG). The results agreed 100% with the QA target results.

n = 8		Target result of QA institute		
		positive	borderline	negative
EUROIMMUN Anti-Strongyloides ELISA (IgG)	positive	4	0	0
	borderline	0	0	0
	negative	0	0	4

Sensitivity and specificity

Study I: 83 precharacterised patient samples (origin: Europe, USA; reference method: commercially available ELISA from another manufacturer) were investigated with the EUROIMMUN Anti-Strongyloides ELISA (IgG). The sensitivity amounted to 94 % at a specificity of 96 % (borderline sera excluded).

Study II: To evaluate the specificity of the Anti-Strongyloides ELISA (IgG) a further study was performed on 91 patient samples which were seropositive for rheumatoid factors or various autoantibodies (ANA). In addition, sera from patients with acute EBV infection were also tested. In this cohort the specificity amounted to 96 %.

Study III: 173 precharacterised patient samples with high antibody titers (predominantly of class IgG) against helminth and protozoon species relevant for differential diagnostics were investigated with the EUROIMMUN Anti-Strongyloides ELISA (IgG). The specificity was 93 %.

It should be taken into account that double infections are possible, particularly in endemic regions, or an earlier infection with Strongyloides spp. may have occurred. In this case, positive results are not caused by cross-reactivity, but are due to a specific reaction of existing anti-Strongyloides antibodies.

n = 83		Other manufacturer's ELISA		
		positive	borderline	negative
EUROIMMUN Anti-Strongyloides ELISA (IgG)	positive	48	0	1
	borderline	2	0	3
	negative	3	0	26

Possible influencing factors	n	Anti-Strongyloides ELISA (IgG) positive
Rheumatoid factors	35	8.6 %
Various autoantibodies (ANA)	34	2.9 %
Acute EBV infection	22	0 %

Antibodies against	n	Anti-Strongyloides ELISA (IgG) positive
Occurence in the endemic region		
Opisthorchis viverrini	10	10.0 %
Plasmodium spp.	10	10.0 %
Schistosoma spp.	8	0 %
Toxoplasma gondii	20	0 %
Trypanosoma spp.	15	13.3 %
Similar symptoms		
Ascaris lumbricoides	10	0 %
Chlamydia pneum.	10	0 %
Echinococcus spp.	10	0 %
Legionella spp.	31	12.9 %
Leishmania spp.	9	22.2 %
Mycoplasma pneum.	10	10.0 %
Toxocara spp.	10	10.0 %
Trichinella spp.	10	0 %
Trichomona spp.	10	0 %

Literature

1. Oesterreich B*, Klemens O*, Fraune J*, Streit A, Warnecke JM*, Steinhagen K* (*EUROIMMUN AG). Novel ELISA using antigens from Strongyloides papillosus instead of S. ratti exhibit increased serological specificity. Poster presentation at the 27th ECCMID, Vienna, Austria (22-25 April 2017).
2. Ericsson CD, Steffen R, Siddiqui AA, Berk SL. Diagnosis of Strongyloides stercoralis Infection. Clinical Infectious Diseases 33 (2001) 1040-1047.

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