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J M Warnecke

EUROIMMUN AG, Germany

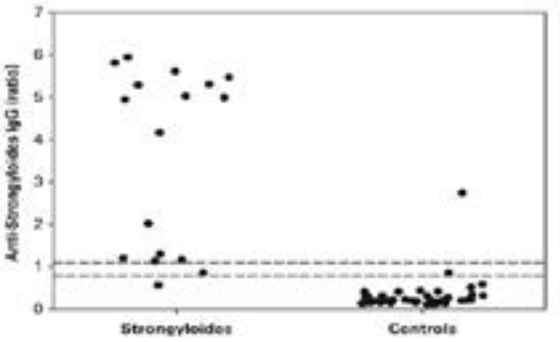
Sensitive and specific ELISA for the serological diagnosis of Strongyloides infections

Introduction: The nematode *Strongyloides stercoralis* is the causative agent of strongyloidiasis, which can manifest in humans with dermatological, pulmonal and intestinal symptoms frequently passing into a chronic disease. As stool-based microscopy and culture techniques lack sensitivity, the detection of serum antibodies is regarded as a surrogate for diagnosing Strongyloides infections. Here, we evaluated the analytical performance of a novel anti-Strongyloides IgG ELISA.

Methods: The Anti-Strongyloides ELISA IgG (Euroimmun AG, Lübeck, Germany) is based on antigen prepared from S. papillosus. ELISA sensitivity and specificity were evaluated in comparison to the serological reference standard applied at the Institute for Parasitology, University of Bern, Switzerland. The sensitivity panel comprised 17 anti-Strongyloides antibody positive sera according to the reference in-house ELISA. The specificity/cross-reactivity panel included 39 control sera classified as negative for anti-Strongyloides antibodies or positive for antibodies against other parasites, including samples from patients with other parasitic infections (Echinococcus, Filaria, Ascaris, Toxocara, Trichinella, Fasciola, Schistosoma, Trichuris, Amoeba, Leishmania, Plasmodium, multi-infection; n=25), cancer patients (n=5) and healthy blood donors (n=9). Borderline results were considered as positive.

Results: The results obtained using the Anti-Strongyloides ELISA were in agreement with reference testing in 94.6% (53/56) of all samples. In the sensitivity panel, the Anti-Strongyloides ELISA was positive in 16/17 sera, corresponding to a sensitivity of 94.1%. The serum yielding discrepant results was collected from a patient with multiple infections. Among the control samples, positivity was found in 2/39 cases (one cancer patient and one blood donor), resulting in a specificity of 94.9%.

n=56		Reference testing*	
		Strongyloides (n=17)	Controls (n=39)
Euroimmun Anti-Strongyloides ELISA (IgG)*	positive	16	2
	negative	1	37
Agreement		94.6% (53/56)	
Sensitivity		94.1% (16/17)	
Specificity		94.9% (37/39)	



Biography

Dr Jens M Warnecke is a Senior scientist at EUROIMMUN AG, an international provider of medical laboratory products for the diagnosis of autoimmune diseases, infections and allergies, and for molecular analyses. He is responsible for planning, set-up and conduct of validation studies for newly developed products in the field of infectious diseases. He received his degree in Biochemistry from the Free University of Berlin in 1993 with a Diploma thesis in experimental oncology. He did his PhD on investigation of the enzymatic mechanisms of catalytic RNA molecules in Berlin followed by a postdoc at the private University Witten/Herdecke, investigating RNA-Protein interactions. He was appointed as lecturer for molecular tumour biology in the Master degree course Molecular Life Sciences at the Medical University of Lübeck. With his research group he entered the field of tumour diagnostics, exploring the possibilities and functions of extracellular nucleic acids in body fluids.In 2008 he left academia to work as responsible Project Manager in phase II clinical trials in the field of oncology until end of 2013 before joining EUROIMMUN AG.

j.warnecke@euroimmun.de