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Diagnostic parasitology

Evaluation of a newly developed anti-Trypanosoma cruzi ELISA (IgG) as a screening assay for Chagas disease

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Background: The protozoan *Trypanosoma cruzi* is the pathogenic agent of Chagas disease. In the latent and particularly in the chronic phase of Chagas disease, the detection of antibodies against *T. cruzi* is the diagnostic cornerstone. Chagas disease infections have an endemic focus in the Americas overlapping with areas that are also endemic for protozoan parasites of the genus *Leishmania*. WHO comparative evaluation data indicate a cross reactivity of assays based on T. cruzi antigen extracts with anti-Leishmania antibody positive samples of up to 93%.
We have evaluated the diagnostic performance of a novel fully automatable Anti-Trypanosoma cruzi ELISA screening assay with special emphasis on anti-Leishmania cross reactivity.

Material/methods: 202 routine serum samples from Argentinean patients with suspected *T. cruzi* infection were tested using the Anti-Trypanosoma cruzi ELISA (IgG) (Euroimmun AG, Lübeck, Germany). Results were compared with the Chagatest ELISA recombinante v.4.0 (Wiener lab, Rosario, Argentina). Serological cross reactivity was determined using sera from 50 cases of microscopically confirmed visceral leishmaniasis, positive for anti-Leishmania antibodies.
Results:

n = 202		Chagatest ELISA positive	borderline	negative
EUROIMMUN	positive	100	0	0
Anti-Trypanosoma cruzi	borderline	2	0	1
ELISA (IgG)	negative	1	0	98

With respect to the Chagatest ELISA, the Anti-Trypanosoma cruzi ELISA (IgG) revealed a sensitivity of 99% and a specificity of 100% without borderline results. A positive serological reactivity with samples of visceral leishmaniasis patients was obtained in 6% (n=3).

Conclusions: The EUROIMMUN Anti-Trypanosoma cruzi ELISA (IgG) has a high specificity and sensitivity, and thus, is ideally suited for Chagas disease screening. The low amount anti-Leishmania positive sera reacting with the anti- Trypanosoma cruzi ELISA (IgG) indicate the ability to discriminate between leishmaniasis and Chagas disease also in areas co-endemic for both parasitic infections.