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

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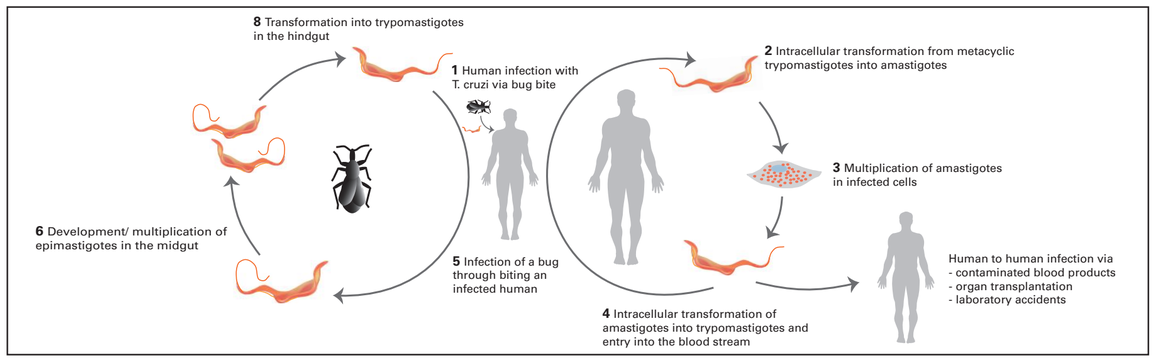


Trypanosoma cruzi life cycle and transmission to humans

| Peptide | Repetitive unit | Original context | Reference |
|---|---|---|---|
| PEP-2 | $(PFGQAAAGDKPS)_n$ | Tandem repeat antigen identified by cDNA cloning | Vergana et al., 1992 |
| TcD | $(PKPAE)_n$ | 260 kDa trypomastygote antigen | Burns et al., 1992 |
| TcE | $(PPAKAAA)_n$ | 35 kDa ribosomal protein from T. cruzi | Houghton et al., 1999 |
| SAPA | $(PVDSSAHGTPST)_n$ | Shed acute phase antigen | Affranchino et al., 1989 |

Repetetive units of the recombinant chimeric polypeptide antigen

## Introduction

*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 *Trypanosoma cruzi* is the diagnostic cornerstone. Chagas disease has an endemic focus in America, overlapping with endemic areas of Leishmaniasis.

WHO comparative evaluation data indicate a cross reactivity of assays based on *Trypanosoma cruzi* antigen extracts with anti-Leishmania antibody positive samples of up to 93%.

Here, we determined the sensitivity and specificity of a novel, fully automatable Anti-Trypanosoma cruzi screening ELISA based on a recombinant chimeric polypeptide antigen.

## Methods

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

## Results

With respect to the Chagatest ELISA, the Anti-Trypanosoma cruzi ELISA (IgG) revealed a sensitivity of 99% and a specificity of 100% excluding borderline results.

Positive serological reactivity was observed in 3 out of 50 samples (6%) from visceral leishmaniasis patients.

## Conclusion

The Euroimmun Anti-Trypanosoma cruzi ELISA (IgG) has a high sensitivity and specificity and is therefore ideally suited for Chagas disease screening.

The low number of anti-Leishmania positive sera reacting with the anti- Trypanosoma cruzi ELISA (IgG) indicates the ability of the test to discriminate between leishmaniasis and Chagas disease in areas co-endemic for both parasitic infections.

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

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