Detection of antibodies to *Trypanosoma cruzi* (*T. cruzi*) in human serum/plasma with a new fully automated assay, LIAISON® XL MUREX Chagas

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**INTRODUCTION**

Chagas disease, or American trypanosomiasis, is a zoonosis due to the flagellated protozoan *Trypanosoma cruzi* (*T. cruzi*). Endemic in Central and Latin American countries, the disease also has growing presence in non-endemic countries through migration of people, becoming nowadays an emerging health problem. Chagas disease presents itself in two phases. The initial acute phase, with a high parasitaemia, lasts for about two months after infection. In most cases, symptoms are absent or mild. Up to 30% of patients will develop heart damage, and up to 10% will develop damage to their oesophagus, colon or autonomic nervous system, or all of these, in the late chronic phase of the disease. Patients ultimately die.

The majority of Chagas disease patients are chronic patients. These patients also could transmit the disease through blood donations, organ transplants or mother to child. Contact with infected insect, the triatomin bug, is instead the most common transmission route in endemic countries. The antibodies to *T. cruzi* appear soon after infection and rise to high levels and may persist, along with infection, for many years, although the parasite is located inside the cells of the host.

**RESULTS: Sensitivity**

LIAISON® XL MUREX Chagas - Diagnostic Sensitivity

Diagnostic sensitivity was assessed by testing a total of 703 specimens reactive for antibodies to *T. cruzi*, resulting in a sensitivity of 99.1% (987/993), 95% confidence interval: 98.2-99.7%. The specimens used in this study were obtained from several endemic countries: Argentina, Bolivia, Brazil, Colombia, Ecuador, El Salvador, Guatemala, Mexico, Nicaragua, Paraguay and Peru.

**RESULTS: Cross Reactions**

LIAISON® XL MUREX Chagas - Specificity on Cross Reactions

The LIAISON® XL MUREX Chagas exhibited an excellent specificity on potential interference from antibodies to other organisms that may cause infectious diseases (i.e. HBV, HCV, CMV, Rubella, HIV, HAV, HTLV, VZV, Toxoplasma gondii, Trypanosoma pallidum, EBV, HCV) as well as from other conditions that may result from atypical immune system activity (anti-nuclear autoantibodies, human anti-mouse antibodies, rheumatoid factor). A total of 163 samples with potential cross-reactants was tested and none of these specimens was found positive.

Moreover, the presence of potential cross-reactants in 113 individuals infected with related protozoan/other parasitic diseases (Malaria and Leishmaniasis) was also investigated. The use of the recombinant antigen allowed LIAISON® XL MUREX Chagas to obtain improved specificity in comparison to lysate Chagas kit.

**RESULTS: Specificity**

**RESULTS: Flexibility**

The LIAISON® XL MUREX Chagas is able to detect specific IgG antibodies to *T. cruzi*. With complete automation and with its excellent sensitivity and specificity performance, it is an effective test for the diagnosis of Chagas infection and also for blood donor screening.

**CONCLUSIONS**

- Main Features
  - Number of tests: 100
  - Platform: LIAISON® XL
  - Instrument: fully automated
  - Method: CLIA
  - Assay format: Indirect, qualitative
  - Solid phase: recombinant multi-antigen
  - Conjugate: Mouse anti-IgG:ABEI
  - Grayzone: No

- Quick and reliable results made possible by flexibility
  - Throughput: 171 tests/h
  - Time to 1st result: 32 minutes
  - All reagents ready to use
  - Minimum sample volume: 10 μL (plus 150 μL dead volume)
  - Matrix: serum/plasma (Na citrate, EDTA, Li and Na heparin, K oxalate, ACD, CPD, CPDA)
  - One-point calibration, stable for 4 weeks
  - Calibrator included in the reagent cartridge
  - Reagent stability on board: 12 weeks