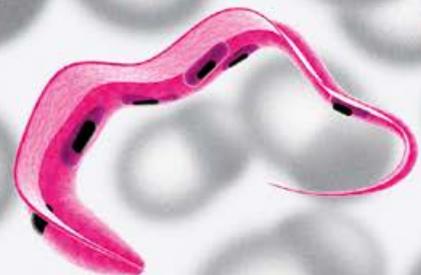


LIAISON[®] XL **murex** Chagas

Total automation for *Trypanosoma cruzi*
screening and diagnosis



Infectious Disease

A recombinant antigen based assay for an improved detection of Chagas infections

Clinical background

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. Current estimates report around 18 million people worldwide affected by this chronic, systemic, parasitic infection, of which about 8 million people are resident in Latin America. 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.

Chagas screening and diagnosis

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 triatomine bug, is instead the most common transmission route in endemic countries.

It is therefore critical that those affected by Chagas disease are diagnosed and treated accordingly.

The LIAISON® XL murex Chagas is a chemiluminescence immunoassay employing a recombinant multi-antigen protein (including TcF and SAPA) representing 9 distinct antigenic regions, designed to express different *T. cruzi* epitopes involved in the immune response. 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.

LIAISON® XL murex Chagas Specificity

| Population | N. of cases | N. IR* | N. RR* | Diagnostic specificity, % | 95% CI* % |
|-----------------------------------|-------------|--------|--------|---------------------------|-------------|
| Blood donors (Europe) | 2,301 | 10 | 8 | 99.7 (2,293/2,301) | 99.3 – 99.9 |
| Blood donors (Latin America) | 599 | 3 | 3 | 99.5 (596/599) | 98.5 – 99.9 |
| Hospitalized /diagnostic patients | 400 | 2 | 2 | 99.5 (398/400) | 98.2 – 99.9 |
| Pregnant women | 200 | 0 | 0 | 100 (200/200) | 98.2 – 100 |

*IR = Initially Reactive, RR = Repeatedly Reactive, CI = Confidence Interval

Cross-reactivity

The LIAISON® XL murex Chagas exhibited an excellent specificity on potential interference from antibodies to other organisms that may cause infectious diseases as well as from other conditions that may result from atypical immune system activity.

The presence of potential cross-reactants in individuals infected with related protozoan / other parasitic diseases (like Malaria, Visceral Leishmaniasis, Leishmaniasis) was investigated and LIAISON® XL murex Chagas specificity proved to be better than two lysate Chagas kits.

LIAISON® XL murex Chagas 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% (697/703), 95% confidence interval: 98.2-99.7%.

Main Features

- Number of tests: 100
- Solid phase: recombinant multi-antigen protein
- Conjugate: MoAb to human IgG
- Label: Isoluminol derivative
- Method: CLIA
- Assay format: Indirect

Quick and reliable results made possible by flexibility

- All reagents ready to use
- Minimum sample volume: 10 µL (plus 150 µL dead volume)
- Sample type: Serum or plasma (sodium citrate, EDTA, lithium and sodium heparin, potassium oxalate, ACD, CPD, CPDA)
- One-point calibration, stable for 4 weeks
- Calibrator included in the reagent cartridge
- Reagent stability on board: 12 weeks

Ordering information

LIAISON® XL murex Chagas (code 310280)

LIAISON® XL murex Control Chagas (code 310281)

Product availability subject to required regulatory approvals