

INTERPRETATION INFORMATION SHEET

Trypanosoma cruzi (T. cruzi) Serology

Anti-*T. cruzi* ChLIA: This chemiluminescent assay (ChLIA) detects antibodies to *Trypanosoma cruzi*. *T. cruzi* is a parasitic infection endemic to regions in Latin America resulting in Chagas disease. It is recommended that repeatedly reactive samples be investigated by additional tests for antibody to *T. cruzi* before a specimen is considered positive, indicating *T. cruzi* infection.

Anti-*T. cruzi* EIA: This enzyme-linked immunoassay (EIA) allows detection of antibody to *Trypanosoma cruzi*. *T. cruzi* is a parasitic infection endemic to regions in Latin America resulting in Chagas disease. It is recommended that repeatedly reactive samples be investigated by additional tests for antibody to *T. cruzi* before a specimen is considered positive, indicating *T. cruzi* infection. **Due to the similarity in the recombinant proteins used for both ChLIA and ESA Chagas, the use of an alternate manufacturer's antibody assay may be helpful for counseling of ESA Chagas positive donors with no evidence of exposure.**

Abbott ESA Chagas: This enzyme strip assay is intended for the qualitative detection of antibodies to *Trypanosoma cruzi* (*T. cruzi*) in human serum and plasma specimens. The assay is intended for use as an additional, more specific test on human serum or plasma specimens found to be repeatedly reactive using a licensed screening test for antibodies to *T. cruzi*.

A negative, indeterminate, or positive interpretation for a specimen is based on the reaction pattern of the four recombinant Ag bands present on the strip (FP10, FP6, FP3, and TcF). The following criteria are used to interpret the result.

Antigen Band Pattern	Interpretation
No antigen bands visible or A SINGLE antigen band, having a +/- intensity	Negative
A SINGLE antigen band, having an intensity of 1+ or greater or Two or more bands, all having a +/- intensity	Indeterminate
Two or more bands, with at least 1 band having an intensity of 1+ or greater	Positive

- A positive ESA Chagas test result is indicative of a *T. cruzi* infection.
- A negative ESA Chagas test indicates that antibodies to *T. cruzi* are not detectable.
- An indeterminate ESA Chagas test indicates that *T. cruzi* may or may not be present. Due to potential cross-reactivity with other similar parasitic infections, retesting after six months is recommended, particularly for individuals with risk factors for infection. If the individual has risk factors for possible past exposure to *Leishmania* (e.g. travel or residence in endemic areas) testing for antibodies to *Leishmania spp.* is recommended.

Final interpretations of any serology assay must consider additional medical history. A negative serology test does not exclude the possibility of infection with *T. cruzi*.

Interpretation Table

<i>T. cruzi</i> EIA or ChLIA	ESA Chagas	Most likely interpretation
Reactive	Positive	<ul style="list-style-type: none"> ▪ <i>T. cruzi</i> antibody present, indicative of acute or chronic infection ▪ Recommend referral to physician ▪ If EIA and ChLIA results are discordant, <i>T. cruzi</i> infection is possible but, in the absence of risk factors, physician referral and follow-up are recommended due to inconsistent results
Reactive	Indeterminate	<ul style="list-style-type: none"> ▪ Possible <i>T. cruzi</i> infection ▪ In absence of risk factors, may be false positive ▪ Recommend referral to physician and follow-up due to inconclusive results ▪ Additional testing for <i>Leishmania</i> recommended for individuals with identifiable risk factors for Leishmaniasis
Reactive	Negative	<ul style="list-style-type: none"> ▪ Possible nonspecific serologic reactivity ▪ Recommend referral to physician

NOTE: Specimens stored at -20C or colder for greater than 2 months may be used for informational purposes (eg. lookback testing, discordant sample testing, clinical and validation testing.)

REFERENCES:

- Abbott ESA Chagas, Instructions for use
- Abbott Prism Chagas, Instructions for use
- Ortho *T. cruzi* ELISA, Instructions for use

Revision History

Revision	Implemented	Reason
Rev 3	12/17/2018	CTS Algorithm Modification
Rev 2	05/17/2016	Implementation of Abbott ESA Chagas
Initial Release	05/01/2013	Revision History added