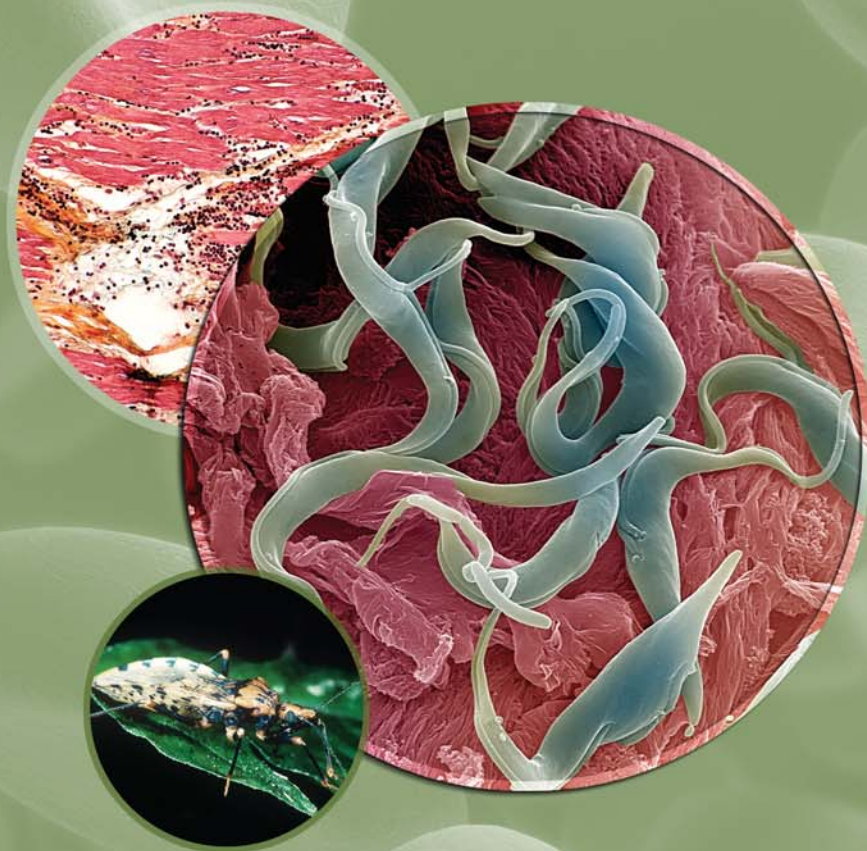


ORTHO<sup>®</sup> *T. cruzi* ELISA Test System

**BLOOD SAFETY IS EVERYTHING**



The New Industry Benchmark for Specificity

# ORTHO® *T. cruzi* ELISA Test System

## MAJOR BLOOD SAFETY ISSUE IN NORTH AMERICA

- Chagas Disease is untreatable in late chronic phase
- Endemic in Latin America
- Documented transmission by transfusion and transplantation in USA, Canada and Mexico<sup>1,2,3,4</sup>
- National Sero-prevalence in USA estimated at 1/25,000 – 1/40,000<sup>1</sup>

The ORTHO® *T. cruzi* ELISA Test System is an enzyme-linked immunosorbant assay for the qualitative detection of antibodies to *Trypanosoma cruzi* (*T. cruzi*) in human serum and plasma specimens.

## ORTHO® *T. cruzi* ELISA Test System Enhances Safety of the Blood Supply

Excellent detection of all geographic strains tested using full lysate antigen set.

Observed Sensitivity*	
Parasite Positive Population Bolivia, Chile, Colombia, and Nicaragua	100% [106/106 Reactive (95% CI: 96.6 – 100.0%)]
Serological Positive Population Bolivia, Brazil, Chile, Guatemala, Mexico, and Nicaragua	100% [662/662 Reactive]
High Risk Populations** Bolivia, Columbia, Guatemala, Mexico, and Nicaragua	98.9% [92/93 Reactive (95% CI: 94.2 – 100.0%)]

\* Source: Performance study data, see Package Insert for details

\*\* The observed specificity of the ORTHO *T. cruzi* ELISA Test System in the High Risk population in this study was 99.4% (478/481) with a 95% confidence interval of 98.2% to 99.9%

## The New Industry Benchmark for Specificity<sup>^</sup>

Two performance studies were conducted on a total of 70,760\* serum and plasma donations using the Ortho Summit™ System.\*\*\*

Observed seroprevalence of 1 in 3010 in volunteer US blood donors tested from high risk areas (n = 30095).

Observed Specificity 99.997% (95% CI: 99.982 - 100.000%)***				
Observed ELISA Results	Positive**	Negative**	Indeterminate**	Total
Reactive	9	2	0	11
Nonreactive	1 <sup>#</sup>	70748	0	70749
Total	10	70750	0	70760

<sup>^</sup> Compared to all currently licensed serology Donor Screening assays in North America - data on file

\* Performance study data (n = 40,665) Prevalence Study (n=30095), see Package Insert

\*\* Based on RIPA Supplemental Test

\*\*\* See Package Insert for Serum and Plasma claims and details

<sup>#</sup> Sample initially non-reactive, S/Co 0.964. Both repeats tests were reactive, S/Co 1.204 and 1.084)

In a performance study, 616 potentially cross reacting samples were tested. In the 516 non-Leishmania samples, specificity was 99%. 74 of the 100 Leishmania samples were reactive. The test may yield falsely reactive results with old world Leishmania samples.

### Performance by Design

- Six Sigma assay design and manufacturing process
- Fully automated on the Ortho Summit™ System
- Full lysate antigen set – Excellent sensitivity to geographic strains
- Low concentration of enzyme conjugate – Lower cross reactivity
- Ultra low signal with negative donations – Excellent specificity

## Description

## Product Code

ORTHO® <i>T. cruzi</i> ELISA Test System 480T	6901968
ORTHO® <i>T. cruzi</i> ELISA Test System 2400T	6901969

### Intended use

This product is intended for use as a donor screening test to detect antibodies to *T. cruzi* in plasma and serum samples for individual human donors, including donors of whole blood, blood components or source plasma, and other living donors. It is also intended for use to screen organ and tissue donors when specimens are obtained while the donor's heart is still beating. This test is not intended for use on specimens from cadaveric (non-heart-beating) donors. This test is not intended for use on samples of cord blood. This assay is not intended for use as an aid in diagnosis.

### Precautions

**CAUTION:** Some components of this kit contain human blood derivatives. No known test method can offer complete assurance that products derived from human blood will not transmit infectious agents. Therefore, all blood derivatives should be considered potentially infectious. It is recommended that these reagents and human specimens be handled using established good laboratory working practices.

### Limitations:

Because the ORTHO® *T. cruzi* ELISA Test System was designed to screen individual units of blood or plasma, most data regarding its interpretation were derived from testing individual specimens. Insufficient data are available to interpret tests performed on other body fluids including cadaveric fluids, pooled blood, or processed plasma and products made from such pools; testing of these specimens is not recommended.

A nonreactive test result does not exclude the possibility of exposure to *T. cruzi*. Levels of antibodies to *T. cruzi* may be below the detectable limit of the assay or undetectable during an early stage following exposure to *T. cruzi*.

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### References:

1. Leiby et al. Trypanosoma cruzi in Los Angeles and Miami blood donors: impact of evolving donor demographics on seroprevalence and implications for transfusion transmission. *Transfusion*. 2002 May; 42(5):549-55
2. Chagas Disease After Organ Transplantation – Los Angeles, California, 2006  
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<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5110a3.htm>
4. Kirchhoff et al. Transfusion-associated Chagas disease (American trypanosomiasis) in Mexico: implications for transfusion medicine in the United States, *Transfusion*, 2006 February; 46: 298-304

To place an order, please contact Customer Service at 1-800-828-6316 or order online at [www.orthoclinical.com](http://www.orthoclinical.com)