

T. CRUZI IgG CELISA

INTENDED USE AND PRINCIPLE OF THE TEST

The T. cruzi IgG CELISA is designed to detect and measure antibodies produced during *Trypanosoma cruzi* infection. The indirect ELISA principle is employed by using microwells coated with *T. cruzi* antigen. The test sample is added and incubated to allow the binding of the antibody, washed to remove any unbound then followed by adding a conjugate of enzyme labelled anti-human monoclonal antibody. The addition of a substrate solution allows the development of a blue colour complex proportional to the amount of antibody present in the sample.

CONTENTS OF THE KIT

TCMW	Celisa Plate – 1 x 96 wells - (single use only)	1 plate
CONTROL +	Positive Control	0.1mL
CONTROL -	Negative Control	0.1mL
TCPO	Enzyme Conjugate (200x)	0.07mL
TCPT	PBS/Tween (20x)	60mL
TCSC	Substrate Chromogen (TMB) (20x)	0.7mL
TCSE	Substrate Buffer	12mL
TCSS	Stopping Solution	6mL

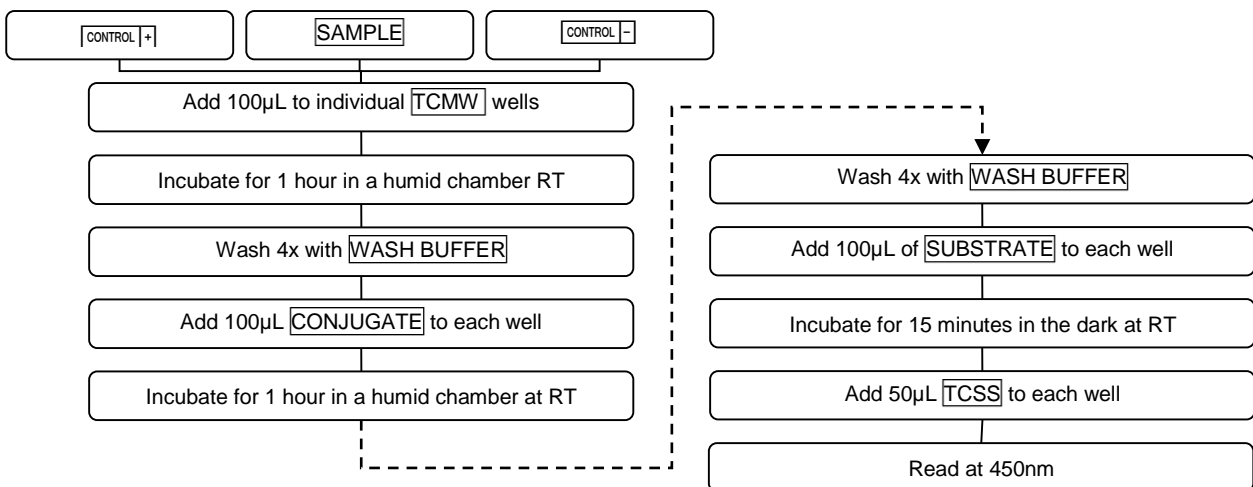
All components should be stored at 2-8°C, and are supplied ready for use. Expiry dates are clearly marked on each kit component and on the box and do not change once opened.

MATERIALS REQUIRED BUT NOT PROVIDED

- Micropipettes and tips
- Clean glassware or plastic containers for solutions
- Humid chamber
- ELISA washer
- Spectrophotometer to read absorbances at a single wavelength of 450nm

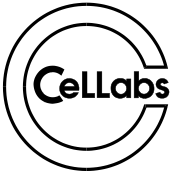
DIAGRAM FOR USE

Use Celllabs Instructions for Use Insert contained in kit when performing test, and refer to Material Safety Data Sheet (MSDS) for further information.



READING AND INTERPRETATION OF RESULTS AND DIAGNOSIS

Samples may be read visually or photometrically. Visually, samples giving the same or less colour than the negative control are considered negative. Samples giving colour greater than the negative control, similar to the positive control, are considered positive. Using a spectrophotometer, negative samples should give an optical density below a certain level and positive samples should give an optical density above a certain level. Please refer to the kit insert for detailed information.



Cellabs Product Profile

PERFORMANCE DATA FOR T. CRUZI IgG CELISA

Sensitivity/Specificity

A	n = 123 plasma samples. T. cruzi IgG CELISA versus IFA.	Sensitivity: 98.5% Specificity: 98.3%
---	---	--

Repeatability

4 Positive samples and a Negative sample were tested in replicates of 8, by two different operators. The coefficient of variation for repeatability ranged between 1.79% and 7.84%, with an average of 4.02% for Positive samples. The average coefficient of variation for repeatability for the Negative sample was 12.52%.

Reproducibility

4 Positive samples were tested in replicates of 8, by two different operators. The coefficient of variation for reproducibility ranged between 2.57% and 10.78%, with an average of 5.63% for Positive samples.

Cross reactivity

The T. cruzi IgG CELISA may give positive results for samples taken from patients infected with *Trypanosoma rangeli* or *Leishmania sp.*

For Ordering Assistance:

See Your Local Distributor:

OR

Cellabs Pty Ltd
Unit 7, 27 Dale Street (PO Box 421)
Brookvale, NSW 2100 Australia
Tel: +61 2 9905 0133 Fax: +61 2 9905 6426
Web: <http://www.cellabs.com.au>
Email: sales@cellabs.com.au



Authorised Representative in the European Community:

WMDE
Bergerweg 18
6085 AT Horn
The Netherlands