Cellabs Product Profile

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 T. cruzi IgG CELISA is a solid phase enzyme immunoassay. Antibody is bound by the *T. cruzi* antigen coated on the inner surface of the test strip. Peroxidase-conjugated antibody to human IgG is added and reacts with bound antibody. A chromogenic substrate for peroxidase is added. If antibody to *T. cruzi* is present there is a reaction which results in the development of a blue colour, which is in proportion to the serum level of the antibody.

CONTENTS OF THE KIT

TCMW	Celisa Plate – 1 x 96 wells - (single use only)	2 plates
TCPC	Positive Control	0.2mL
TCNC	Negative Control	0.2mL
TCPO	Enzyme Conjugate (200x)	0.12mL
TCPT	PBS/Tween (20x)	110mL
TCSC	Substrate Chromogen (TMB) (20x)	1.2mL
TCSB	Substrate Buffer	24mL
TCSS	Stopping Solution	12mL

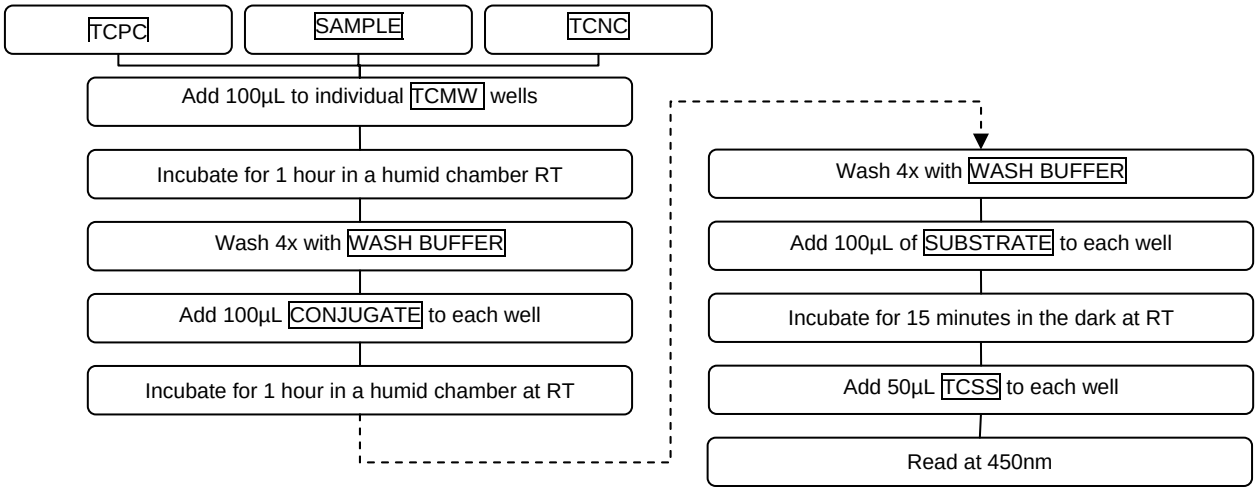
All components should be stored at 2-8^{O}C, and are supplied ready for use. Expiry dates are clearly marked on each kit component and on the box and do not change once opened.

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 Cellabs 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.

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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

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