

	MATERIAL SAFETY DATA SHEET	Rev. 01 24/08/10
	IMUNO-ELISA Chagas	

1. COMPANY AND PRODUCT IDENTIFICATION	
Company	WAMA PRODUTOS PARA LABORATÓRIO LTDA 100, Aldo Germano Klein – CEAT – São Carlos Zip Code: 13560-971 SP – Brasil Phone. 55 16 3377 9977 – Fax 55 16 3377 9970 www.wamadiagnostica.com.br atendimento@wamadiagnostica.com.br
Product Name	Trade name: IMUNO-ELISA CHAGAS Code: 44096-E - 96 determinations Code: 44192-E - 192 determinations
Intended Use	<i>An enzyme immunoassay (ELISA) kit for the qualitative and semi-quantitative detection of IgG antibodies anti-Trypanossoma cruzi in human serum using recombinant antigen.</i>

2. PRODUCT INFORMATION	
Description	Kit contains: - microplate with wells covered with recombinant antigen of <i>T.cruzi</i> - positive serum control: Positive human serum for <i>T.cruzi</i> , diluted in PBS, liquid and ready for use. It contains sodium azide 0.095% as preservative. - negative serum control Negative human serum for <i>T.cruzi</i> , diluted in PBS, liquid and ready for use. It contains sodium azide 0.095% as preservative. - diluent solution: It contains Proclin 300-0.05% as preservative. - PBS 20x concentrated - human anti-IgG conjugate marked with peroxidase - chromogen substrate: It contains *Proclin 300-0.05% as preservative. - stop solution: hydrochloric acid (Hcl) (0,2M)
Product Use	In Vitro Diagnostic only.
Hazard Components	positive serum control, negative serum control, proclim 300 (0.05%)

3. HAZARD IDENTIFICATION	
Proclim 300 (0.05%) is used as preservative. Toxic if ingested. All human derived components used have been tested for HBsAg, HIV 1 and 2, HCV and found negative. All human serum specimens and human derived products should be treated as potentially hazardous. Follow the Good Manufacturing Practices (GMP).	

4. FIRST AID MEASURES	
Contact with eyes	Wash with plenty of water. Seek medical advice.
Contact with skin	Wash with plenty of water.
Inhalation	Exposure to fresh air immediately. Seek medical advice.

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Ingestion	Seek medical advice.
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5. FIRE FIGHTING MEASURES	
Non-inflamable	

6. MEASURES OF CONTROL- LEAKING/SPILLAGE	
Isolate and ventilate the area. Remove with absorbent material. Clean up area and wash with plenty of water.	

7. HANDLING AND STORAGE	
Handling	Avoid contact with eyes, skin and mouth. Wash hands after handling.
Storage	Keep at 2 to 8°C

8. EXPOSURE CONTROL AND PERSONAL PROTECTION	
Preventive Measure	Avoid ingestion, inhalation and contact with eyes and skin. Protection for eyes: yes Protection for hands: wear gloves; wash hands after handling.

9. PHYSICAL AND CHEMICAL PROPERTIES	
<i>Appearance</i>	<i>Reagents in liquid</i> <i>Microtitration plate solid state</i>
<i>Color:</i>	<i>Microplate: Colorless</i> <i>positive serum contro lowl: Green</i> <i>positive serum contro high: Red</i> <i>negative serum control: blue</i> <i>diluent solution: Orange</i> <i>PBS 20x concentrated: colorless</i> <i>human anti-IgG conjugate: purple</i> <i>chromogen substrate: Colorless</i> <i>stop solution: colorless</i>
<i>Odor:</i>	<i>Not relevant</i>
<i>pH:</i>	<i>Not relevant</i>
<i>Solubility:</i>	<i>Reagents in liquid –soluble in water</i>
<i>Explosive properties::</i>	<i>Not available</i>
Others	None relevant data for safety.

10. STABILITY AND REACTIVITY	
Stability	The product is stable when used appropriately.

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Avoid	Exposure to heat can damage the product. Do not freeze.
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11. TOXICOLOGICAL INFORMATION
<i>No toxicological data is available for this product. The product can be harmful to health if performed inappropriately. Avoid inhalation and ingestion.</i>

12. ECOLOGICAL INFORMATION
<i>No ecological data is available for this product.</i>

13. DISPOSAL CONSIDERATIONS
Disposal in accordance with local regulations. Brazil: See RDC 306 of 07/12/04 - ANVISA

14. TRANSPORT INFORMATION
<i>This product is not hazardous when transported by sea, land or air.</i>

15. REGULATORY INFORMATION
<i>The product is manufactured in accordance with Good Manufacturing Practice (GMP) for IVD – Ordinance n° 686 of 27/08/98, Directive 98/79 – CE, Quality Management System NBR ISO 13485:2004 (EN ISO 13485:2003) and labelling and symbols information in accordance with Ordinance 206 of 17/11/06, NBR ISO 15223:2004, EN 980:2008.</i>

16. OTHER INFORMATION
All products can contain unknown risks and they should be handled with care. It is the duty of the user to comply with all local regulations.