	MATERIAL SAFETY DATA SHEET	Rev. 02 08/10/08
	IMUNO-RÁPIDO HCG	


1. COMPANY AND PRODUCT IDENTIFICATION	
Company	<p>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</p>
Product Name	<p>Trade name: IMUNO-RÁPIDO HCG Code: 620001T-R – 01 determination (self-test) Code: 620020T-R – 20 determinations Code: 620040T-R – 40 determinations Code: 620080T-R – 80 determinations Code: 620001-R – 01 determination (self-test) Code: 620010-R – 10 determinations Code: 620020-R – 20 determinations Code: 620040-R – 40 determinations</p>
Intended Use	<p><i>A rapid chromatographic immunoassay kit for the qualitative detection of hCG in serum and urine to aid in the early detection of pregnancy.</i></p>

2. PRODUCT INFORMATION	
Description	<p>Kit comprises: <i>It is made of a plastic base where there is the specimen filter (fiberglass), a conjugate region (fiberglass) coated with conjugate (IgG anti-fraction β hCG labeled with gold colloidal), a nitrocellulose membrane presenting two bands - Test Line- (Mouse IgG anti-fraction α) - Control Line- (anti-Mouse IgG) plus an absorbent base</i></p>
Product Use	In Vitro Diagnostic only
Hazard Components	Test device is composed of plastic and test strip coated,

3. HAZARD IDENTIFICATION	
This kit does not contain ingredients listed as dangerous substances.	

4. FIRST AID MEASURES	
Contact with eyes	N/A
Contact with skin	N/A
Inhalation	N/A
Ingestion	N/A

5. FIRE FIGHTING MEASURES	
Non-inflamable	

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6. MEASURES OF CONTROL – LEAKING/SPILLAGE	
N/A	

7. HANDLING AND STORAGE	
Handling	Wash hands after handling.
Storage	Keep at 15 to 30°C

8. EXPOSURE CONTROL AND PERSONAL PROTECTION	
Preventive Measure	Protection for hands: wear gloves; wash hands after handling.


9. PHYSICAL AND CHEMICAL PROPERTIES	
<i>Appearance</i>	<i>Test device: Plastic Device- solid</i> <i>Strip Test: solid</i>
<i>Color:</i>	<i>Cassette – White</i> <i>Strip: White and blue</i>
<i>Odor:</i>	<i>None</i>
<i>pH:</i>	<i>No applicable</i>
<i>Solubility:</i>	<i>Test Device: Insoluble</i>
<i>Explosive properties:</i>	<i>No applicable</i>
Others	None relevant data for safety

10. STABILITY AND REACTIVITY	
Stability	The product is stable when used appropriately.
Avoid	Exposure to heat can damage the product. Do not freeze.

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	

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14. TRANSPORT INFORMATION

This product is not hazardous when transported by sea, land or air.

15. REGULATORY INFORMATION

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 13485:200) and labelling and symbols information in accordance with Ordinance 206 of 17/11/06, NBR ISO 15223:2004, EN 980:2008.

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.