
	MATERIAL SAFETY DATA SHEET	Rev. 01 14/12/09
	IMUNO-RÁPIDO HCV	

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.wamadiagnóstica.com.br atendimento@wamadiagnostica.com.br</p>
Product Name	<p>Trade name: IMUNO-RÁPIDO HCV Code: 621010-R - 10 determinations Code: 621020-R - 20 determinations Code: 621040-R - 40 determinations</p>
Intended use	<p><i>A rapid chromatographic immunoassay test for the qualitative detection of anti-HCV antibodies using synthetic antigens and recombinants immobilized on the membrane for the selective identification of anti-HCV in serum or whole blood specimens.</i></p>

2. PRODUCT INFORMATION	
Description	<p>Kit comprises: - Test Device – It is made of a plastic base where there is the specimen filter (fiberglass), a conjugate region (fiberglass) coated with conjugate (protein G labeled with gold colloidal), a nitrocellulose membrane presenting two bands - Test Line- (antigenic fractions of HCV) and Control Line (anti-Mouse IgG) plus an absorbent base. - Diluent Solution – PBS - It contains sodium azide 0.095% as preservative.</p>
Product Use	In Vitro Diagnostic only
Hazard Components	Diluent Solution – It contains sodium azide 0.095% as preservative

3. HAZARD IDENTIFICATION	
<p>This kit does not contain ingredients listed as dangerous substances.</p> <p>Obs.: Sodium azide 0.095% may react with lead and cooper plumbing to form highly explosive metal azides. Upon disposal of liquids, flush with large volumes of water to prevent azide buildup.</p>	

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.
Ingestion	Seek medical advice.

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12. ECOLOGICAL INFORMATION

No ecological data is available for this product.

Obs: Sodium azide may react with lead and copper plumbing to form highly explosive salts. On disposal, flush with large quantities of water.

13. DISPOSAL CONSIDERATIONS

Disposal in accordance with local regulations.
Brazil: See RDC 306 of 07/12/04 from ANVISA

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.