



MATERIAL SAFETY DATA SHEET

Rev. 02
31/10/08

IMUNO-LÁTEX PCR

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-LATEX PCR Code: 2960-L - 60 determinations Code: 29100-L - 100 determinations Code: 2900-L - 2.5 ml
Intended Use	<i>An indirect agglutination kit for the detection of CRP in human serum using latex particles coated with monoclonal anti-CRP antibody.</i>

2. PRODUCT INFORMATION

Description	Kit comprises: <ul style="list-style-type: none">- suspension of látex: suspension of látex coated with monoclonal anti-CRP antibody, in glycin buffer ph 8,2.- positive serum control: Human serum diluted in PBS, liquid, ready for use, it contains sodium azide 0.1% as preservative.*- negative serum control: Human serum diluted in PBS, liquid, ready for use, it contains sodium azide 0.1% as preservative.*- stirrers*- test card* <p><i>* only for 60 and 100 determinations</i></p>
Product Use	In Vitro Diagnostic only.
Hazard Components	Suspension of latex, positive serum control, negative serum control. It contains Sodium azide (0.1%) as preservative.

3. HAZARD IDENTIFICATION

Sodium azide 0.1% 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.

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.
Ingestion	Seek medical advice.

	MATERIAL SAFETY DATA SHEET	Rev. 02 31/10/08
	IMUNO-LÁTEX PCR	

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>Stirrers and cards: solid state</i>
<i>Color:</i>	<i>Stirrers - white</i> <i>Cards – White with black circles as test region</i> <i>Positive control serum: Light yellow</i> <i>Negative serum control: colorless</i> <i>Latex: Beige</i>
<i>Odor:</i>	<i>None</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 relevant</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>	

	MATERIAL SAFETY DATA SHEET	Rev. 02 31/10/08
	IMUNO-LÁTEX PCR	

12. ECOLOGICAL INFORMATION

No ecological data is available for this product.

Sodium azide 0.1% may react with lead and copper plumbing to form highly explosive metal azides.
Upon disposal of liquids, flush with large volumes of water to prevent azide buildup.

13. DISPOSAL CONSIDERATIONS

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