



MATERIAL SAFETY DATA SHEET

Rev. 01
02/07/09

IMUNO-LÁTEX β HCG

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 BETA HCG Code: 2760-L - 60 determinations Code: 27100-L - 100 determinations
Intended Use	<i>An indirect agglutination kit for the diagnosis of pregnancy in urine specimens using latex particles coated with monoclonal antibody.</i>

2. PRODUCT INFORMATION

Description	Kit comprises: - suspension of látex coated with monoclonal anti- β HCG antibody stabilized in glycin buffer ph 8,2. - positive urine control: Human urine diluted in PBS, liquid, ready for use, it contains sodium azide 0.095% as preservative. - negative urine control: Human urine diluted in PBS, liquid, ready for use, it contains sodium azide 0.095% as preservative. - stirrers - test card
Product Use	In Vitro Diagnostic only.
Hazard Components	Suspension of latex, positive urine control, negative urine control. It contains Sodium azide (0.095%) as preservative.

3. HAZARD IDENTIFICATION

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.

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.

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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.
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Storage	Keep at 2 to 8°C
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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.
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9. PHYSICAL AND CHEMICAL PROPERTIES

<i>Appearance</i>	<i>Reagents in liquid Stirrers and cards: solid state</i>
<i>Color:</i>	<i>Stirrers - white Cards – White with black circles as test region Positive control serum: Light yellow Negative serum control: colorless 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.
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Avoid	Exposure to heat can damage the product. Do not freeze.
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11. TOXICOLOGICAL INFORMATION

No toxicological data is available for this product. The product can be harmful to health if performed inappropriately. Avoid inhalation and ingestion.

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12. ECOLOGICAL INFORMATION

No ecological data is available for this product.

Sodium azide 0.095% 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.