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1. COMPANY AND PRODUCT IDENTIFICATION	
Company	WAMA PRODUTOS PARA LABORATÓRIO LTDA Rua Aldo Germano Klein, 100 – CEAT – São Carlos CEP: 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-RÁPIDO PSA Code : 630010-R - 10 determinations 630020-R - 20 determinations 630040-R - 40 determinations
<i>Intended use</i>	<i>A rapid chromatographic immunoassay kit for the semi-quantitative detection of Prostate Specific Antigen (PSA) in serum.</i>


2. PRODUCT INFORMATION	
Description	Kit comprises: - Test Device – plastic cassette and test strip coated with PSA antibodies - Diluent Solution – PBS - It contains sodium azide 0.095% as preservative.
Product Use	In Vitro Diagnostic only
Hazard Components	Diluent Solution – It contains sodium azide 0.095% as preservative

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

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.

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.	

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7. HANDLING AND STORAGE	
Handling	Avoid contact with eyes, skin and mouth. Wash hands after handling.
Storage	Keep at 2 to 30°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	
Appearance	Diluent Solution: liquid in vials Test device: Plastic Cassette
Color:	Vial and Cassette – White Diluent - colorless
Odor:	None
pH:	Not relevant
Solubility:	Test device: Insoluble Diluent: Soluble in water
Explosive properties:	Not relevant
Others	None relevant data for safety


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

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.	

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

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15. REGULATORY INFORMATION

The product is manufactured in accordance with Good Manufacturing Practice (GMP) for IVD – Ordinance nº 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.