	MATERIAL SAFETY DATA SHEET	Rev. 02 04/04/08
	IMUNO-RÁPIDO CHLAMYDIA	

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.wamadiagnóstica.com.br atendimento@wamadiagnostica.com.br
Product Name	Trade name: IMUNO-RÁPIDO CHLAMYDIA Code: 618010 – 10 determinations Code: 618020 – 20 determinations Code: 618040 – 40 determinations
Intended Use	***A rapid chromatographic immunoassay kit for the qualitative detection of Chlamydia trachomatis in endocervical, urethral and male urine specimens using specific antibodies for the selective identification of Chlamydia trachomatis.***

2. PRODUCT INFORMATION	
Description	Kit contains: ***- Test Device– test strip coated with mouse IgG anti-Chlamydia trachomatis labelled with colloidal gold, two test lines (goat IgG anti-Chlamydia trachomatis) and a control line (anti-mouseIgG).*** All material is mounted and fitted inside a plastic device. The test is individually packed in an alluminiun sealed pouche with silica. ***- Reagent A - Triton 100X (1%) at 0.001M (PBS)*** ***- Reagente B - Sodium dithionate 0.01M and BSA 0.5%.*** - Specimen collection tube - Pipette and work shelf
Product Use	In Vitro Diagnostic only
Hazard Components	Reagent A and B – It contains Sodium azide (0.1%) as preservative.

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

4. FIRST AID MEASURES	
Contact with eyes	Reagent A and B: Wash with plenty of water. Seek medical advice.
Contact with skin	Reagent A and B: Wash with plenty of water.
Inhalation	Reagent A and B: Exposure to fresh air immediately. Seek medical advice.
Ingestion	Reagent A and B: 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.

7. HANDLING AND STORAGE	
Handling	Avoid contact with eyes, skin and mouth. Wash hands after handling.
Storage	Keep at 2 to 30ºC

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	***Reagent A and B: liquid –stored in vials*** ***Test-deviee: Plastic cassette***
Color:	***Vial and cassette – White*** ***Reagent A: Colorless*** ***Reagent B: Yellow***
Odor:	***None***
pH:	***Not relevant***
Solubility:	***Test-device: Insoluble*** ***Reagente A e B: Solúvel em água***
Explosive properties::	***Not relevant***
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

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
No ecological data is available for this product. 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 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.