

	MATERIAL SAFETY DATA SHEET	Rev. 02 10/08/09
	IMUNO-RÁPIDO SANGUE OCULTO	

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.wamadiagnostica.com.br  <a href="mailto:atendimento@wamadiagnostica.com.br">atendimento@wamadiagnostica.com.br</a></p>
Product Name	<p>Trade name: IMUNO-RÁPIDO SANGUE OCULTO FECAL  Code: 623010-R - 10 determinations  Code: 623020-R - 20 determinations  Code: 623040-R - 40 determinations</p>
Intended Use	<p><i>A rapid chromatographic immunoassay kit for the qualitative detection of occult blood in feces using a marked monoclonal antibody and polyclonal antibody anti-hemoglobin human in solid phase to selectively identify hemoglobin in feces.</i></p>

2. PRODUCT INFORMATION	
Description	<p><b>Kit contains:</b>  <b>TEST DEVICE:</b> <i>It is made of a plastic base where there is the specimen filter (fiberglass), the conjugate base (fiberglass) coated with conjugate (Mouse IgG anti-hemoglobin A-fraction <math>\beta</math>- labeled with gold colloidal), a nitrocellulose membrane presenting two bands - Test Line- (Mouse IgG anti-hemoglobin A- fraction <math>\alpha</math>) - Control Line- (anti-Mouse IgG) plus an absorbent base. All material is mounted on this plastic base and fitted inside a plastic device. The test is individually packed in an aluminium sealed poche with silica.</i></p> <p><b>SPECIMEN COLLECTION TUBE:</b> <i>Plastic tube for specimen collection. It contains sodium phosphate solution 0.001M (PBS) with detergent Triton 100X, BSA and sodium azide 0.01% as preservative.</i></p>
Product Use	In Vitro Diagnostic only
Hazard Components	Test device is composed of plastic and test strip coated, Specimen collection tube with liquid of extraction.

3. HAZARD IDENTIFICATION	
<p>The liquid of extraction can cause irritation in the skin, eyes and mucous.  Do not open the test device.</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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#### 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 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

<b>Appearance</b>	<i>Specimen Collect Tube: liquid Test-device: Plastic cassette</i>
<b>Color:</b>	<i>Cassette – White Specimen Collect Tube: Colorless</i>
<b>Odor:</b>	<i>None</i>
<b>pH:</b>	<i>Not relevant</i>
<b>Solubility:</b>	<i>Test-device: Insoluble Specimen Collect Tube: Soluble in water</i>
<b>Explosive properties::</b>	<i>Not relevant</i>
Appearance	Reagents in liquid Plastic device and tube
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

*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 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.