



### SAFETY DATA SHEET

rapindo™ Malaria Pv/Pf

Version 02  
Release Date 04.06.2025  
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#### Section 1. Information of the Product & Company

- 1.1 Product Name : RAPINDO™ Malaria Pv/Pf  
Brand Name : rapindo™
- 1.2 Catalogue No. (Ref.No) : 6215060025  
Pack Size : 25 test / box  
Kit Components : 25 pouch device test RAPINDO™ Malaria Pv/Pf Contains : Device test & silica gel  
1 bottle Sample Running Buffer  
1 pcs Pack Insert RAPINDO™ Malaria Pv/Pf
- 1.3 Group / Risk Class : In Vitro Diagnostics / B Class  
Product Category : Immunology & Microbiology Equipments  
Sub Category : Serological Reagents  
Product Type : Plasmodium species antigen detection assays
- 1.4 Company Name : PT TULIP DIAGNOSTICS INDONESIA  
Kawasan Industri Candi Blok H3,  
Purwoyoso, Ngaliyan, Semarang, Jawa Tengah - Indonesia (50184)
- 1.5 Intended Use of Product : Rapid test device, Qualitative assessment for detection of Pf. HRP-2 and Pv Specific pDLH antigen in Human whole blood for In Vitro Diagnostics use only.
- 1.6 In Emergencies : Call (024) 7627321 / (024) 7627323 (office hours only) or Call your local emergency center

#### Section 2. Hazards Identification

- 2.1 Classification of the Substance or Mixture  
Classification under CLP : This product has no classification under CLP.  
Classification according to regulation (EC) No. 1272/2008 : The product is regulated as an in vitro diagnostic medical device and is not considered hazardous in accordance with regulation (EC) No.1272/2008.
- 2.2 Label Elements  
Hazard pictogram : None  
Signal word : None  
Hazard statements : None
- 2.3 Other Label  
Ⓟ symbol (white P letter inside the black circle) : Professional use only
- 2.4 Other Hazards  
This product is not identified as a PBT/vPvB substance.

#### Section 3. Information on Ingredients

Ingredients of RAPINDO™ Malaria Pv/Pf for each packaging contains :  
 25 pouch device test RAPINDO™ Malaria Pv/Pf contains : Device test, silica gel & Sample applicator.  
 Device test in each pouch is an in-vitro Diagnostics rapid test for detection of Pf. HRP-2 and Pv Specific pDLH antigen in Human whole blood specimens.  
 1 bottle clearing Buffer with 4 ml filled volume  
 1 pcs Packinsert of RAPINDO™ Malaria Pv/Pf

#### Section 4. First Aid Measures

- 4.1 Eye Contact : Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do so. Continue rinsing. If eye irritation persists, seek medical advice/attention.
- 4.2 Skin Contact : Wash immediately with plenty of soap and water.
- 4.3 After inhalation : Irritation is unlikely to occur but in the event of discomfort, provide plenty of fresh air and if necessary seek medical assistance.
- 4.4 After Swallowed : Do not induce vomiting. Wash your mouth with water and give plenty of water or milk to drink immediately. Obtain medical attention if necessary and show a label on the container.



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### Section 4. First Aid Measures

Symptoms / routes of exposure :

- Skin contact: There may be mild irritation at the site of contact
- Eye contact: There may be irritation and redness.
- Ingestion: There may be irritation of the throat.
- Inhalation: No symptoms.

Immediate / Special treatment : Not applicable.

### Section 5. Fire Fighting Measures

- 5.1 Suitable extinguishing media : Suitable extinguishing media such as carbon dioxide, dry chemical powder or polymer foam for the surrounding fire should be used.  
Use water spray to cool containers.
- 5.2 Unsuitable extinguishing media : No data available
- 5.3 Special exposure hazards : No known specific hazards
- 5.4 Instructions : - Take account of toxic firefighting water  
- Use firefighting water moderately and contain it
- 5.5 Advice for firefighters : - Heat/fire exposure: compressed air/oxygen apparatus  
- Personnel : Do not enter fire without proper protective equipment, including respiratory protection.

### Section 6. Accidental Release Measures

- 6.1 Personal protection : a. Follow Standard Biosafety guidelines during handling of potentially infectious human specimens.  
b. Refer to section 8 of SDS for personal protection details.  
c. Turn leaking containers leak-side up to prevent the escape of liquid.
- 6.2 Environmental Precautions : Do not discharge into drains or rivers.
- 6.3 Clean-up : - For small spills, clean up with paper/cloth, or mop up, and dispose of it safely.  
- Clean area of spillage down with plenty of water.
- 6.4 Reference to other sections : Refer to section 8 of SDS.

### Section 7. Handling and Storage

- 7.1 Handling Requirements : - Refer IFU for RAPINDO™ Malaria Pv/Pf
- 7.2 Storage conditions : Store in the original container between 1°C to 40°C. Keep the buffer container tightly closed and once opened must be carefully closed back and kept in an upright position to prevent leakage.
- 7.3 Specific Purpose : Refer to IFU for RAPINDO™ Malaria Pv/Pf
- 7.4 Suitable Packaging : kept in original packaging.
- 7.5 Specific end use(s) : Refer to Section 12.

### Section 8. Exposure Control / Personal Protection

- 8.1 Control Parameters : Does not contain substances with exposure limit values.
- 8.2 Control of Exposure : - Engineering measures : Ensure all engineering measures mentioned in section 7 of SDS are in place.  
- Respiratory Protection : Insufficient ventilation: wear respiratory protection  
- Hand Protection : Protective gloves.  
- Eye Protection : No specific measures are required when using good safe practice.  
- Skin Protection : Protective clothing not required in normal use. Use proper glove removal technique to avoid skin contact.

### Section 9. Physical & Chemical Properties



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		Device	Diluent Buffer
a	State	Solid	Liquid
b	Colour	White	Colourless
c	Odour	Odourless	Odourless
d	Solubility in water	Insoluble	Not Applicable
e	Viscosity	Not Applicable	No data available
f	Boiling point/range°C	No data available	No data available
g	Flash point°C	No data available	No data available
h	Vapour pressure	No data available	No data available
i	pH	No data available	8.5
j	Melting point/range °C	No data available	No data available
k	Auto flammability °C	No data available	No data available
l	Relative density	No data available	1.0

## Section 10. Stability & Reactivity

- 10.1 Stability : The component is stable until expiry date if stored in specified conditions (see IFU)
- 10.2 Reactivity/Hazardous reaction : Stable under normal conditions. Hazardous reactions will not occur under normal transport or storage conditions.
- 10.3 Conditions/Materials to avoid : Heat and moisture and direct sunlight.
- 10.4 Hazardous decomposition products : No known hazardous decomposition products are formed in high quantities

## Section 11. Toxicological Information

- 11.1 Toxicity values : No data Available
- 11.2 Routes of exposure : Skin contact : There may be mild irritation at the site of contact.  
Eye contact : There may be irritation and redness.  
Ingestion : There may be irritation of the throat.  
Inhalation : No symptoms

## Section 12. Ecological Information

- 12.1 Ecotoxicity : No Data Available.
- 12.2 Environmental Fate : No data Available
- 12.3 Environmental Toxicity : No data Available
- 12.4 Persistence and degradability : No data available.
- 12.5 Bioaccumulative potential : No data available.
- 12.6 PBT assessment : No data available.
- 12.7 Other Adverse Effects : No Data Available.



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### Section 13. Waste Disposal Considerations

13. 1 Disposal operations : Disposal of chemical, hazardous or laboratory wastes / waste product and / or packaging must be carried out in accordance with all applicable local/regional official regulations.  
Uncleaned packaging should be disposed of in accordance. Water if necessary together with appropriate cleansing agents may be used for decontamination before disposal.
- Note : The user's attention is drawn to the possible existence of regional or national regulations regarding disposal.

### Section 14. Transport Information

- Special precautions:
1. Shipper boxes should be arranged / stacked in the direction as indicated by the shipper label / Carton.
  2. Avoid over-stacking. Do not stack more than 5 boxes.
  3. The reagent in this clearing buffer contains Sodium Azide as a preservative.  
Sodium Azide has been reported to form Lead or Copper Azide in laboratory plumbing, which may explode on percussion. Flush drains with large volumes of water thoroughly after disposing of fluids containing Sodium Azide.

### Section 15. Regulatory Information

Chemical Safety Assessment : The Clearing buffer contain 0.1% of Sodium Azide (NaN<sub>3</sub>) as preservative. CAS:No.: 26628-228  
EINECS-No.: 247-852-1

### Section 16. Other Information

This safety data sheet is prepared in accordance with Commission Regulation (EU) No 453/2010.

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. This company shall not be held liable for any damage resulting from handling or from contact with the above product.

This product is designed for use by professionals.

The information provided on this SDS is correct to the best of our knowledge, information and belief at the date of its publication.

The information given is designed only as guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification.

The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

It remains the user's own responsibility to make sure that the information is appropriate and complete for his specific use of this product. The user is also responsible for observing any laws and applicable guidelines.