



SAFETY DATA SHEET

rapindo™ Malaria Pan/Pf

Version 02
Release Date 04.06.2025
Page 1 / 4

Section 1. Information of the Product & Company

- 1.1 Product Name : RAPINDO™ Malaria Pan/Pf
Brand Name : rapindo™
- 1.2 Catalogue No. (Ref.No) : 6215060025
Pack Size : 25 test / box
Kit Components : 25 pouch device test RAPIDO™ Malaria Pan/Pf Contains : Device test & silica gel
1 bottle Sample Running Buffer
1 pcs Pack Insert RAPINDO™ Malaria Pan/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 P.falciparum specific histidine rich protein-2 (Pf. HRP-2) and Plasmodium Lactate Dehydrogenase (pLDH) antigens produced by P.falciparum, P.vivax, P.ovale and P.malariae species. It is used in the diagnosis of malaria for differentiation of P.falciparum and other malaria species. This product is intended for IN VITRO diagnostic 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/vPanB substance.

Section 3. Information on Ingredients

Ingredients of RAPINDO™ Malaria Pan/Pf for each packaging contains :

25 pouch device test RAPINDO™ Malaria Pan/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 Pan Specific pDLH antigen in Human whole blood specimens.

1 bottle clearing Buffer with 4 ml filled volume

1 pcs Packinsert of RAPINDO™ Malaria Pan/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



SAFETY DATA SHEET

rapindo™ Malaria Pan/Pf

Version 02
Release Date 04.06.2025
Page 2 / 4

Section 4. First Aid Measures

4.4 After Swallowed : medical assistance.
: 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.

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
- Personal : 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 Pan/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 Pan/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.



SAFETY DATA SHEET

rapindo™ Malaria Pan/Pf

Version 02
Release Date 04.06.2025
Page 3 / 4

Section 9. Physical & Chemical Properties

| | | 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.



SAFETY DATA SHEET

rapindo™ Malaria Pan/Pf

Version 02
Release Date 04.06.2025
Page 4 / 4

Section 12. Ecological Information

12.7 Other Adverse Effects : No Data Available.

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 contains 0.1% of Sodium Azide (NaN₃) 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.