

**SAFETY DATA SHEET**

rapindo™ HBsAg

Version 02

Release Date 04.06.2025

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Section 1. Information of the Product & Company

- 1.1 Product Name : RAPINDO™ HBsAg
Brand Name : rapindo™
- 1.2 Catalogue No. (Ref.No) : 6215040025
Pack Size : 25 test / box
Kit Components : 25 pouch device test RAPINDO™ HBsAg contains : Device test & silica gel
1 pcs Packinsert RAPINDO™ HBsAg
- 1.3 Group / Risk Class : In Vitro Diagnostics / D Class
Product Category : Immunology & Microbiology Equipments
Sub Category : Immunological Test System
Product Type : Antimitochondrial antibody immunological test system
- 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, Two-site sandwich immunoassay for detection of Hepatitis B surface antigen (a marker of Hepatitis B infections in serum / plasma specimen) for In Vitro Diagnostics use only.
- 1.6 In Emergencies : Call (024) 7627321 / (024) 7627323 or Call your local emergency center

Section 2. Hazards Identification

- 2.1 Classification of the Substance or Mixture
Hazard Classification system : 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
PBT : This product is not identified as a PBT/vPvB substance.

Section 3. Information on Ingredients

Ingredients of RAPINDO™ HBsAg for each packaging contains :

25 pouch device test RAPINDO™ HBsAg contains : Device test, silica gel & Sample applicator.

Device test in each pouch is an in-vitro Diagnostics rapid test for detection of Hepatitis B surface antigen, a marker of Hepatitis B infections in serum / plasma specimens.

1 pcs Packinsert of RAPINDO™ HBsAg

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 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 : - All non combustible extinguishing media allowed
- For surrounding fires: all extinguishing media allowed
- 5.2 Unsuitable extinguishing media : No data available
- 5.3 Special exposure hazards : On heating/burning: formation of small quantities of nitrous vapors, carbon monoxide, carbon dioxide
- 5.4 Instructions : - Take account of toxic firefighting water
- Use firefighting water moderately and contain it
- 5.5 Special protective equipment for firefighters : - Heat/fire exposure: compressed air/oxygen apparatus
- Heat/fire exposure: gas-tight suit

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™ HBsAg
- 7.2 Storage : - Store in the original container between 4°C to 30°C.
- Provide for a tub to collect spills
- Meet the legal requirements
- Keep away from: heat sources, acids
- Storage temperature: see component label
- 7.3 Specific Purpose : Refer to IFU for RAPINDO™ HBsAg
- 7.4 Suitable Packaging : kept in original packaging.

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.

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

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 Persistence and degradability : No data available.
- 12.3 Bioaccumulative potential : No data available.

Section 13. Waste Disposal Considerations

- 13.1 Disposal operations : Dispose off in accordance with current legislation and local authority regulations as per established safety procedures.
- Note : The user's attention is drawn to the possible existence of regional or national regulations regarding disposal.



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Section 14. Transport Information

No restrictions.

Section 15. Regulatory Information

No specific regulations

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.