



SAFETY DATA SHEET

rapindo™ HIV Screen

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

- 1.1 Product Name : RAPINDO™ HIV Screen
Brand Name : rapindo™
- 1.2 Catalogue No. (Ref.No) : 6215130025
Pack Size : 25 test / box
Kit Components : 25 pouch device test RAPIDO™ HIV Screen contains : Device test & silica gel
1 bottle Sample Running Buffer
1 pcs Pack Insert RAPINDO™ HIV Screen
- 1.3 Group / Risk Class : In Vitro Diagnostics / D Class
Product Category : Immunology & Microbiology Equipments
Sub Category : Immunological Test System
Product Type : Multiple autoantibodies 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 for detection of total antibodies (example : IgG, IgM, IgA,) to HIV1 & HIV2 viruses in Human serum / plasma 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
Classification under CLP : This product has no classification under CLP.
Substance containing Hazardous Ingredients : Sample Running Buffer (contains 0.1% Sodium Azide, non-flammable properties)
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
No data available.

Section 3. Information on Ingredients

Ingredients of RAPINDO™ HIV Screen for each packaging contains :

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

Device test in each pouch is an in-vitro Diagnostics rapid test for detection of total antibodies (example : IgG, IgM, IgA,) to HIV1 & HIV2 viruses in Human serum / plasma specimens.

1 bottle Sample running Buffer with 5 ml filled volume

1 pcs Packinsert of RAPINDO™ HIV Screen

Section 4. First Aid Measures

- 4.1 Health effects : Symptoms of overexposure may include headache & dizziness.
- 4.2 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.
- 4.3 Skin Contact : Wash immediately with plenty of soap and water.
- 4.4 After inhalation : Irritation is unlikely to occur but in the event of discomfort, provide plenty of fresh air and if necessary seek



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Section 4. First Aid Measures

medical assistance.

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.

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 : Treat symptomatically and supporting to eliminate overexposure.

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
- Personal : Protection suit including eye 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™ HIV Screen
- 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™ HIV Screen
- 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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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	Water soluble
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	8.0
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 : The Sample running Buffer product is not known to cause any known significant ecological damage on disposal. A Toxicity potential of the product contains Sodium azide:
 LC50 (96 h): 0.8 mg/l (SALMO GAIRDNERI/ONCORHYNCHUS MYKISS)
 LC50 (96 h): 0.7 mg/l (LEPOMIS MACROCHIRUS)
 LC50 (48 h): 9 mg/l (GAMMARUS SP)



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Section 12. Ecological Information

- 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 : The acidic component stop solution can be hazardous to potable water and aquatic organisms if disposed undiluted or without neutralization of pH. Therefore, an environmental hazard can occur only in the case of unprofessional disposal.

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

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.