

SAFETY DATA SHEET

RPR Test Kit and reagents

1. PRODUCT AND COMPANY INFORMATION

Company name: **Lab21 Healthcare Ltd,**
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Emergency contact: As above, during office hours.

Product name: **RPR Test Kit (Non Treponemal - Rapid Plasma Reagin Slide Test) and Reagents**

Product code: **Test Kit:** RPR/010, RPR/012, 2/814, 2/815, 2/818 and versions thereof;
RPR/100,
RPR/101, 2/824 Positive Syphilitic Control
RPR/102, 2/826 Negative Syphilitic Control

2. HAZARD IDENTIFICATION

Main hazards: These products are for in vitro diagnostic use only.
Products contain no hazardous constituents or the concentrations of all chemical constituents are below the regulatory threshold described in Article 31 Requirements for Safety Data Sheets.

All reagents contain less than 0.1% sodium azide as preservative.

The control materials are derived from human serum. They have been tested at donor level and found negative for Hepatitis B and C and for HIV 1 and 2. They should however, be treated as if capable of transmitting disease. Specimen material may contain pathogenic organisms. Handle with the appropriate precautions, according to good laboratory practices and applicable regulations.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Composition/ information on components:

SODIUM AZIDE: <0.1% w/w EINECS: 247-852-1 CAS: 26628-22-8
[T+] R28; [-] R32; [N] R50/53
CHOLINE CHLORIDE: 10% CAS No. 67-48-1

4. FIRST AID MEASURES

Skin contact: May cause mild irritation at the site of contact. Wash skin with soap and water.
Eye contact: May cause irritation and redness. Flush with water.
Ingestion: Avoid hand to mouth contact. Obtain medical attention

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5. FIRE-FIGHTING MEASURES

Extinguishing media: Not combustible. Suitable extinguishing media for the surrounding fire should be used.
Exposure hazards: None in small quantities

6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Wear appropriate protective clothing. Handle as potentially infectious.
Environmental precautions: Properly disinfect any spills. Do not discharge into drains or rivers.
Clean-up procedures: Absorb with liquid absorbing material. Transfer to a closable, labelled salvage container for disposal by an appropriate method.

7. HANDLING AND STORAGE

Handling requirements: For in vitro diagnostic use only. Read the instructions for use. Avoid the formation of aerosols. Avoid direct contact with the substance
Storage conditions: Store in cool (2°C to 8°C), well-ventilated area. Keep container tightly closed.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Hazardous ingredients:

SODIUM AZIDE: WEL (8 hr TWA): 0.1 mg/m³ WEL (15 min STEL): 0.3 mg/m³

Respiratory protection: Respiratory protection not required.
Hand protection: Protective disposable gloves.
Eye protection: Safety glasses. Ensure eye bath is to hand.
Skin protection: Protective clothing.

9. PHYSICAL AND CHEMICAL PROPERTIES

State: Liquid
Colour: Carbon: Black suspension
Positive Control: Brown/ straw coloured solution
Negative Control: colourless/yellow
Odour: Odourless
pH: Carbon- pH 6.9 - pH 7.1
Positive and Negative Controls pH7.8 – pH 8.2
Solubility: N/A
Flammability: Not combustible

10. STABILITY AND REACTIVITY

Stability: Stable under normal storage and handling conditions. Do not use after expiry date.
Materials to avoid: Strong oxidising agents. Strong acids. This product contains sodium azide which can react with copper, brass, lead and solder to form explosive salts.
Hazardous decomposition products: None known

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11. TOXICOLOGICAL INFORMATION

Acute toxicity: N/A
Routes of exposure: Refer to section 4 of SDS for routes of exposure and corresponding symptoms.

12. ECOLOGICAL INFORMATION

General note: Generally not a hazard to water in small quantities

Mobility: Readily absorbed into soil.

Persistence and degradability: No data available.

Bio-accumulative potential: No data available.

Other adverse effects: No data available.

13. DISPOSAL CONSIDERATIONS

Use official waste disposer.

The user's attention is drawn to the possible existence of regional or national regulations regarding disposal.

14. TRANSPORT INFORMATION

Land transport ADR / RID.: Not classified as dangerous in the meaning of transport regulations.

Sea transport IMDG / IMO : Not regulated

Air transport IATA / ICAO: Not regulated.

15. REGULATORY INFORMATION

Risk phrases: Not applicable

Safety phrases: Not applicable

Note: The regulatory information given above only indicates the principal regulations specifically applicable to the product described in the safety data sheet. The user's attention is drawn to the possible existence of additional provisions that complete these regulations. Refer to all applicable national, international and local regulations or provisions.

16. OTHER INFORMATION

Warning: Because no test method can offer complete assurance that HIV, HCV, HbsAg or other infectious agents are absent, the components of this kit should be handled accordingly.

UK Legislation: Health and Safety at Work Act, 1974, and relevant statutory provisions.

SI 2002/1689: The Chemicals (Hazard Information and Packaging for Supply) Regulations 2002

SI 1988/1657 The control of Substances Hazardous to Health Regulation

Legal disclaimer: 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.