SAFETY DATA SHEET

Direct Monoclonal Pregnancy Latex Test Kit

1.PRODUCT AND COMPANY INFORMATION

Company name: **Lab21 Healthcare Ltd,**
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DT6 5BU
Tel: +44 (0) 1308 421829
Fax:+44 (0) 1308 421846 Web site: www.Lab21.com
Emergency contact: As above, during office hours.

Product name: **Direct Monoclonal Pregnancy Latex Test Kit (hCG Slide agglutination)**

Product code: **Test Kit:** DPT/010, DPT/012, 2/522, 2/524
Bulk Reagents: DPT/100 Test Latex Reagent (hCG 200iu/litre sensitivity)
DPT/101 Positive Control
DPT/102 Negative Control
and versions thereof.

2. HAZARD IDENTIFICATION

Main hazards: These products are for in vitro diagnostic use only.
Positive Control: Contains hCG 1000 mIU/L – Possible Biohazard
Specimen material may contain pathogenic organisms. Handle with the appropriate precautions, according to good laboratory practices.
Product contains 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% w/w sodium azide (NaN_3) as preservative.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Composition: Pregnancy Test Latex: Contains <0.1%Sodium Azide
Positive Control: Contains hCG 1000 mIU/L – Possible Biohazard
Negative Control: Contains <0.1%Sodium Azide

Hazardous Components: **SODIUM AZIDE**: <1% w/w EINECS: 247-852-1 CAS: 26628-22-8
[T+] R28; [-] R32; [N] R50/53
CHORIONIC GONADOTROPIN: CAS 9002-61-3

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.

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. Refer to section 8 of MSDS for personal protection details.
Environmental precautions: Properly disinfect any spills. Do not discharge into drains or rivers. Contain large spillages using bunding.

Clean-up procedures: Absorb into dry earth or sand. 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 (2º to 8ºC), well-ventilated area. Keep container tightly closed.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Hazardous ingredients:
SODIUM AZIDE: WEL (8 hr TWA): 0.1 mg/m^3 WEL (15 min STEL): 0.3 mg/m^3

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: Latex: White/Off white
Positive and Negative Controls: colourless/ straw coloured
Odour: Odourless
pH: pH6.8 – pH 8.4
Solubility: Soluble
Flammability: Not combustable

10. STABILITY AND REACTIVITY

Stability: Stable under normal storage and handling conditions. Do not use after expiry date.
Materials to avoid: Avoid contact of the products with lead and copper (plumbing metals), mercury, acids, and oxidising agents.

Hazardous decomposition products: In combustion emits toxic fumes.

11. TOXICOLOGICAL INFORMATION

Hazardous ingredients: **SODIUM AZIDE:**
ORL MUS LD50 27 mg/kg
ORL RAT LD50 27 mg/kg
SKN RAT LD50 50 mg/kg

Routes of exposure: Refer to section 4 of SDS for routes of exposure and corresponding symptoms.

12. ECOLOGICAL INFORMATION

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

Waste code number: 18 01 07 Hazardous waste.
NB: The user's attention is drawn to the possible existence of regional or national regulations regarding disposal.

14. TRANSPORT INFORMATION

SODIUM AZIDE:
ADR / RID
UN no: - Not applicable.
Shipping name: Not classified as dangerous in the meaning of transport regulations.
IMDG / IMO
UN no: - **Marine pollutant:** NO
IATA / ICAO
UN no: - Not applicable.

15. REGULATORY INFORMATION

SODIUM AZIDE:
Hazard symbols: Harmful.
Risk phrases: R22: Harmful if swallowed.
R32: Contact with acids liberates very toxic gas.
EC classification: Xn- Harmful
Safety phrases: S29/35: Do not empty into drains; dispose of this material and its container in a safe way.
S36/37/39: Wear suitable protective clothing, gloves and eye / face protection.
S46: If swallowed, seek medical advice immediately and show this container or label.

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.

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.

Sources of information used in this data sheet:
Regulation (EC) No. 1907/2006 of the European Parliament and of the Council concerning the registration, evaluation, authorisation and restriction of chemicals (REACH): Article 31:- Requirements for safety data sheets, and Annex II:- Guide to the Compilation of Safety Data Sheets, OJ L 136/35 – L 136/36 and L 136/84 – L 136/92, 29.5.2007.

The Chemicals (Hazard Information & Packaging for Supply) Regulations [CHIP], United Kingdom Statutory Instrument 2002 No. 1689, based on the European Directives on Dangerous Substances (67/548/EEC) and Dangerous Preparations (1999/45/EC).

Approved Supply List (8th edition), information approved for the classification and labelling of substances and preparations dangerous for supply, United Kingdom Health & Safety Commission, 2005, based on Annex I to 67/548/EEC.

Commission Decision 2000/532/EC establishing a list of wastes pursuant to Article 1(a) of Directive 75/442/EEC on waste and Article 1(4) of Directive 91/689/EEC on hazardous waste.
CONSLEG: 2000D0532 – 01/01/2002, Office for Official Publications of the European Communities.
Directive 98/79/EC of the European Parliament and of the Council on *in vitro* diagnostic medical devices, Annex I, Essential Requirements, OJ L 331/20, 7.12.98.

List of approved workplace exposure limits, Table 1 of EH40/2005, United Kingdom Health & Safety Commission.