

# SAFETY DATA SHEET

## Pregnancy (hCG) One Step Immunoassay Test Strip

### 1. PRODUCT AND COMPANY INFORMATION

**Company name:** **Lab21 Healthcare Ltd.,**  
29, Dreadnought Trading Estate  
Bridport  
Dorset  
DT6 5BU  
Tel: +44 (0) 1308 421829  
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**Product name:** **Pregnancy One Step Immunoassay Test Strip**

**Product code:** **Test Kit:** PT/025 Tube of 25 single strips  
PT/050 Carton of 50 foil wrapped strips  
PT/001 single foil wrap strip  
and versions thereof;

### 2. HAZARD IDENTIFICATION

**Main hazards:** This product is for in vitro diagnostic use only.  
Specimen material may contain pathogenic/ hazardous organisms. Handle with the appropriate precautions, according to good laboratory practices.

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

**Composition:** Immunochromatographic strip containing colloidal gold coated with anti hCG antibodies

**Hazardous Components:** None in reportable quantities

### 4. FIRST AID MEASURES

**Skin contact:** Not applicable  
**Eye contact:** Not applicable  
**Ingestion:** Avoid hand to mouth contact.

### 5. FIRE-FIGHTING MEASURES

**Extinguishing media:** 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 sample spills. Do not discharge into drains or rivers. Contain large spillages using bunding.  
**Clean-up procedures:** Not applicable

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### 7. HANDLING AND STORAGE

**Handling requirements:** For *in vitro* diagnostic use only. Read the instructions for use.  
**Storage conditions:** Store in cool, well-ventilated area. Keep container tightly closed.

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Hazardous ingredients:**

Main hazard associated with sample preparation

**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:** Paper/plastic strip

**Flammability:** Combustable

### 10. STABILITY AND REACTIVITY

**Stability:** Stable under normal storage and handling conditions. Do not use after expiry date.

**Materials to avoid:** Not known

**Hazardous decomposition products:** In combustion may emit toxic fumes.

### 11. TOXICOLOGICAL INFORMATION

**Hazardous ingredients:** Not known

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

### 12. ECOLOGICAL INFORMATION

**Mobility:** No data available  
**Persistence and degradability:** No data available.  
**Bio-accumulative potential:** No data available.  
**Other adverse effects:** No data available.

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### 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

**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

**EC classification:**

NA

**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

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

**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.

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