

INR Test Strip Safety Data Sheet

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Identification of the substance: LumiraDx INR Test Strip

Product numbers:

LumiraDx Catalogue	Product Description	Kit Size
L003000101012	LumiraDx INR Test Strips (12 Tests / EN,FR,DE,IT,NL,ES)	12
L003000102012	LumiraDx INR Test Strips (12 Tests / EN,NO,FI,DK,SE)	12
L003000103012	LumiraDx INR Test Strips (12 Tests / EN,KR,TH,CN (MA),CN (CA))	12
L003000104012	LumiraDx INR Test Strips (12 Tests / EN,ES,PT (EU),PT (BR))	12
L003000105012	LumiraDx INR Test Strips (12 Tests / EN,PL,TR,GR,RU,SA)	12
L003000106012	LumiraDx INR Test Strips (12 Tests / EN,ID,VN,BU,IL)	12
L003000101048	LumiraDx INR Test Strips (48 Tests / EN,FR,DE,IT,NL,ES)	48
L003000102048	LumiraDx INR Test Strips (48 Tests / EN,NO,FI,DK,SE)	48
L003000103048	LumiraDx INR Test Strips (48 Tests / EN,KR,TH,CN (MA), CN (CA))	48
L003000104048	LumiraDx INR Test Strips (48 Tests / EN,ES,PT (EU),PT (BR))	48
L003000105048	LumiraDx INR Test Strips (48 Tests / EN,PL,TR,GR,RU,SA)	48
L003000106048	LumiraDx INR Test Strips (48 Tests / EN,ID,VN,BU,IL)	48

Reach No: The product(s) contains substances that are exempt from registration in accordance with the Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals.

Use of the substance: Strips contain dry reagent for in vitro quantitative analysis of human capillary blood thrombin. Additionally, the strips can be used with the LumiraDx INR Quality Controls. This product is for single use.

Company identification: LumiraDx UK Ltd,
Dumyat Business Park,
Alloa
FK10 2PB
United Kingdom

Emergency telephone: 00800 58647239

Customer Services Email: customerservices@lumiradx.com

Website: www.lumiradx.com

2. HAZARDS IDENTIFICATION

Principle routes of exposure: Ingestion and/or eye contact.

Ingestion: Ingestion of strips or other solid pieces may cause choking.

Skin contact: None.

Eye contact: Contact with eyes may cause irritation.

Hazardous decomposition products: When exposed to fire, produces normal products of combustion.

Unusual fire, explosion and reactivity hazards: No special hazards known.

3. INFORMATION ON INGREDIENTS

Material within the reaction area: Test strip containing a mixture of dried substances.

Hazardous Components: None in reportable quantities.

4. FIRST AID MEASURES

Inhalation: Not applicable.

Skin contact: Not applicable.

Ingestion: If swallowed, seek medical attention.

Eye contact: In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

5. FIRE-FIGHTING

5.1. FIRE-FIGHTING MEASURES

Flash point: Not applicable.

Flammable limits (Upper/Low): Not applicable.

Suitable extinguishing media: Use dry chemical, CO₂, water spray or `alcohol` foam.

Special firefighting procedure: Not applicable.

Unusual hazards: Not applicable.

6. ACCIDENTAL RELEASE MEASURES

In case of spill or leak: There is no spill potential under normal use. If leaked reagents of reaction area happened, dispose the strip into a suitable container and wash contact area with soapy water.

7. HANDLING AND STORAGE

Safety information: Wear personal protective equipment (see section 8).

Precautions to be taken in handling and storage: Store in secure area. Keep out of reach of children.

Storage conditions: Store in a cool and dry place (5°C-32°C). Do not expose direct to light and moisture for more than 15 minutes. Must be stored in original pouch.

Handle conditions: Handle as directed in the package insert.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Respiratory Protection: None required.

Skin: Handle with gloves when performing a test. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands thoroughly.

Eye: None required.

Ventilation: Normal ventilation exposure controls.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. **Appearance:** Solid strip.

Physical state: Solid.

9.2. **Important health, safety and environmental information**

Boiling point: Not applicable.

pH: Not applicable.

Solubility in Water: Not applicable.

Vapor Pressure: Not available.

Vapor Density (air = 1): Not available.

Evaporation Rate (water = 1): Not applicable.

Appearance: Transparent plastic strip with black lines and blue sticker.

Odour: None.

10. STABILITY AND REACTIVITY

Stability: Stable when stored under proper conditions.

Conditions to avoid: Temperature below 5°C and above 32°C, light and moisture exposure longer than 15mins.

Materials to avoid: Acids, strong oxidising agents.

Hazardous decomposition products: None.

11. TOXICOLOGICAL INFORMATION

Routes of entry: Ingestion.

Health Hazards Acute: Choking if swallowed.

Chronic: None.

Carcinogenicity: No data is available on the product itself.

Medical Conditions Aggravated: No data is available on the product itself.

12. ECOLOGICAL INFORMATION

No ecological information available.

13. DISPOSAL CONSIDERATIONS

Appropriate methods of disposal: Dispose waste in accordance with Federal, State, and Local regulations.

European Community (EC) consideration: Use appropriate waste codes based on ingredients

14. TRANSPORT INFORMATION

IATA/DOT/IMDG

UN-Number: Not applicable.

Material Proper shipping name: INR Test Strips.

Hazard class: Non-Hazardous.

15. REGULATORY INFORMATION

European labelling in accordance with EC Directives Hazard Symbols: Not applicable.

Risk Phrases: None.

Additional information: Consult country codes for specific requirements.

16. OTHER INFORMATION

Additional advice: None.

Information contained herein are based on reasonable investigation and research. However, LumiraDx UK or its affiliates do not warrant the accuracy of this information. All materials may present unknown hazards and should be used with caution. This document is intended only as a guide to the appropriate precautionary handling of the materials contained in this product by a properly trained person using this product. In no case shall LumiraDx be liable for incidental or consequential damages. Use of INR Test Strips is subject to referenced and limitations included the product specifications.

LumiraDx UK (company number: 09206123)

END OF SAFETY DATA SHEET