

SARS-CoV-2 Ag Quality Controls Kit Safety Data Sheet

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

Identification of the substance: SARS-CoV-2 Ag Quality Control Kit

Product numbers:

LumiraDx Product Code	Product Description
L016080109002/L016080101002	LumiraDx SARS-CoV-2 Ag Liquid Quality Control Kit

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: In-vitro laboratory reagent or component, Quality Control Kit for use in conjunction with the LumiraDx SARS-CoV-2 Ag Test Strip System on the LumiraDx Instrument.

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2. HAZARDS IDENTIFICATION

Classification of the substance: This material has the potential to transmit infectious agents and should be handled according to Biosafety Level 2. This product has SARS-CoV-2 viral strains that have been chemically inactivated to render them non-infectious

Hazard Statements: The use of universal precautions is required by trained personnel. Treat all specimens (Patient and Quality Control) as potentially infectious, follow universal precautions when handling the kits and its contents and carry out the necessary risk assessments.

Precautionary Statement(s): Biohazard: handle as if capable of transmitting infectious agents.

Other Hazards: Contains chemically inactivated and lysed SARS-CoV-2 virus, exercise universal precautions.

3. INFORMATION ON INGREDIENTS

Material within the SARS-CoV-2 Ag QC Kit: Buffered and stabilized formulation containing the hazardous ingredients listed below.

Component	CAS-No.	Concentration
ProClin 950	2682-20-4	<0.1%
Sodium azide	26628-22-8	<0.1%

4. FIRST AID MEASURES

Inhalation: In case of inhalation, proceed to an area containing fresh air and keep at rest in a position comfortable for breathing.

Skin contact: In case of skin contact, immediately wash thoroughly with warm water and antibacterial soap. Flush with water and seek medical attention.

Ingestion: Do not induce vomiting. Rinse mouth with water provided the person is conscious. Never give anything by mouth to an unconscious person. Seek medical attention.

Eye contact: Rinse immediately with copious amounts of water for several minutes. Use of an eye wash station is preferable. Remove contact lenses if applicable and continue to rinse. Seek medical attention.

5. FIRE-FIGHTING

5.1. FIRE-FIGHTING MEASURES

Flash point: Not applicable.

Flammable limits (Upper/Low): Not applicable.

Suitable extinguishing media: Use extinguishing measures and methods that are appropriate to local circumstances and the surrounding environment. Use water spray to cool fire-exposed containers.

Special firefighting procedure: Not applicable.

Unusual hazards: Not applicable.

6. ACCIDENTAL RELEASE MEASURES

In case of spill or leak: In case of spill or leak, wear appropriate personal protective equipment, for example laboratory coat, gloves and safety glasses. Avoid contact with skin and eyes.

Environmental Precautions: Do not allow discharge into the environment. Prevent leakage or spillage.

Methods and Materials for Containment and Cleaning Up: Clean in accordance with applicable effective procedures and in compliance with state and federal regulations.

7. HANDLING AND STORAGE

Precautions to be taken in handling and storage: Avoid contact with skin and eyes. Wear personal protective equipment. Wash hands thoroughly after handling. Do not eat or drink while handling product.

Storage conditions: Store in accordance with labelled or recommended storage temperature (2-8°C). Keep containers properly labelled.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Respiratory Protection: In the case of insufficient ventilation wear suitable respiratory equipment.

Skin: Use of a laboratory coat and gloves is required. 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: Use of equipment for eye protection is required. Avoid exposure to liquid splashes.

Ventilation: Ensure adequate ventilation or other engineering controls to reduce airborne levels.

Control Parameters: To the best of our knowledge this product does not contain substances with occupational or national exposure limit values.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. **Appearance:** Viscous liquid, transparent.

Physical state: Liquid.

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: Viscous liquid, transparent.

Odour: None.

10. STABILITY AND REACTIVITY

Stability: Stable under recommended storage conditions.

Conditions to avoid: Storage temperatures below 2°C and above 8°C.

Materials to avoid: None.

Hazardous decomposition products: None.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity: No data available.

Skin Corrosion/Irritation: No data available.

Serious Eye Damage/Irritation: No data available.

Respiratory or Skin Sensitization: No data available.

Germ Cell Mutagenicity: No data available.

Carcinogenicity: No data available.

Reproductive Toxicity: No data available.

STOT-Single Exposure: No data available.

Aspiration Hazard: No data available.

12. ECOLOGICAL INFORMATION

Toxicity: No data available.

Persistence and Degradability: No data available.

Bioaccumulative Potential: Adverse ecological effects cannot be excluded in the event of improper handling or disposal.

Mobility in Soil: No data available.

Other Adverse Effects: No data available.

13. DISPOSAL CONSIDERATIONS

Appropriate methods of disposal: Material has undergone chemical inactivation. All human derived materials should be handled as if the material is infectious. The use of universal precautions is required by trained personnel. 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: Not applicable.

Hazard class: Non-Hazardous.

Bulk Transport:

Labels Required: Exempt Human Specimen Label, per Classification section 3.6.2.2.3.8 of IATA DGR.

IATA Packaging Requirements: Packed in accordance with Classification section 3.6.2.2.3.8 of IATA DGR.

Transport Considerations: Product can be transported within temperature range of -80°C and 30°C, for up to 14 days or between -80°C and 45°C for up to 3 days

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 LumiraDx SARS-CoV-2 Ag Quality Controls kit is subject to referenced and limitations included the product specifications.

LumiraDx UK (company number: 09206123)

END OF SAFETY DATA SHEET