

Safety Data Sheet LumiraDx INR Quality Control Kit

Product Code	Description
L003080101003	LumiraDx INR Quality Control Kit

Component Code	Description
HB-4865-SA	LumiraDx INR Quality Control Level 1
HB-4866-SA	LumiraDx INR Quality Control Level 2
HB-4922-SA	LumiraDx INR Quality Control, Reconstitution Solution

Safety Data Sheet

According to EC Directive 1907/2006/EC

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

1.1. Identification of the substance or preparation

Product Name : LumiraDx INR Quality Controls Level 1 and 2

Product Number : QC Level 1- HB-4865-SA
QC Level 2- HB-4866-SA

Reach No : A registration number is not available for this substance as the substance or its uses are exempted from registration, the annual tonnage does not require a registration.

1.2. Use of the substance/preparation

Identified Uses : In-vitro laboratory reagent or component, liquid quality control testing performed on the LumiraDx Instrument when used with the LumiraDx INR Test Strip

1.3. Company/undertaking identification

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

Telephone Number : 00800 58647239
Email : customerservices@lumiradx.com
Website : www.lumiradx.com

1.4. Emergency telephone

Emergency Phone # : 00800 58647239, open 09:00 -17:00

2. HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.2. Label elements

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008. The product does not need to be labelled 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.

2.3. Other hazards



The plasma control contains human source material that was tested and found nonreactive for HIV antibody, Hepatitis B Surface Antigen and Anti-HCV at the donor stage. This product, as with all human based specimens, should be treated as potentially infectious and handled with proper laboratory safety procedures to minimize the risk of transmission of infectious disease.

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Chemical characterisation: Mixtures

Mixture of the substances listed below with non-hazardous addition

Synonym : Citrated human plasma

: Heparin lithium salt, CAS-No: 9045-22-1

Each bottle contains lyophilised solid from 1mL of liquid mixture.

Additional information:

Contains human sourced potentially infectious components

No components need to be disclosed according to the applicable regulations.

4. FIRST AID MEASURES

4.1. Description of first-aid measures.

General Information: No special measures required

After inhalation: Supply fresh air, consult doctor in case of complaints

After skin contact: Immediately wash with water and soap and rinse thoroughly.

After eye contact: Rinse opened eye for several minutes under running water. Then consult a doctor.

After swallowing: Rinse mouth with water. Seek medical attention and appropriate follow-up.

4.2. Most important symptoms and effects, both and acute and delayed:

No further relevant information available.

4.3. Indication of any immediate medical attention and special treatment needed:

Call an internal person trained in First Aid if available, or contact a physician.

5. FIRE-FIGHTING MEASURES

5.1. Suitable extinguishing agents

CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

5.2. Special hazards arising from the substance or mixture

No further relevant information available.

5.3. Advice for firefighters

Protective equipment: Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes if necessary.

6. ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Ensure suitable personal protection during removal of spillages. Avoid dust formation and ensure adequate ventilation. For personal protection see section 8.

Handle as potentially infectious.

6.2. Environmental precautions:

Keep contaminated washing water and dispose of appropriately.
Do not allow to enter sewers/ surface or ground water.

6.3. Methods and material for containment and cleaning up:

Before reconstitution:

Sweep up and shovel, ensuring to avoid dust formation
Clean the affected area carefully; disinfectant is a suitable cleaning agent.
Discard as Biohazard waste according to local guidelines.

After reconstitution:

Absorb liquid components with liquid-binding material.
Pick up mechanically.
Clean the affected area carefully; disinfectant is a suitable cleaning agent.
Discard as Biohazard waste according to local guidelines.

6.4. Reference to other sections

See Section 13 for disposal information.

7. HANDLING AND STORAGE

7.1. Handling

Wear personal protective equipment (see section 8) and avoid contact with eyes, skin and clothing. Wash and dry hands thoroughly after handling. Provide appropriate exhaust ventilation at places where dust is formed.

Information about protection against explosions and fires: No special measures required.

7.2. Storage

Keep container tightly closed.
Recommended storage temperature 2 - 8°C.

7.3. Specific use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Exposure limit values

Components with limit values that require monitoring at the workplace: The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

8.2. Exposure controls

Appropriate engineering controls:

Ensure adequate ventilation.

General protective and hygienic measures:

Follow usual biosafety practices for handling potentially infectious materials.
The usual precautionary measures should be adhered to when handling chemicals.

Personal protective equipment:

Eye/face protection:

Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection:

Handle with gloves. 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.

The selected protective gloves should satisfy the specifications of relevant standards for handling this material.

Penetration time of glove material

The exact break through time of the protective gloves determined by the manufacturer should be observed.

Body Protection

Protective work clothing.

Respiratory protection

Respiratory protection is not required.

Environmental exposure controls:

Do not let product enter the drains

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. General information

Appearance

Form	: Solid
Colour	: Light yellow
Odour	: Light

9.2. Important health, safety and environmental information

pH	: No data available
Melting point/freezing point	: No data available
Boiling point/boiling range	: No data available
Flash point	: No data available
Flammability (solid, gas)	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Vapour pressure	: No data available
Relative density	: No data available
Solubility	: Soluble in water
Water solubility	: Soluble
Partition coefficient: n-octanol/water	: No data available
Viscosity	: No data available
Vapour density	: No data available
Evaporation rate	: No data available

9.3. Other safety information

No further relevant information available.

10. STABILITY AND REACTIVITY

10.1. Reactivity

No data available

10.2. Chemical stability

Stable under recommended storage conditions

10.3. Possibility of hazardous reactions

No dangerous reactions known

10.4. Conditions to avoid

No further relevant information available.

10.5. Materials to avoid

No further relevant information available.

10.6. Hazardous decomposition products

No dangerous decomposition products known

11. TOXICOLOGICAL INFORMATION

Description of the various toxicological (health) effects, which can arise if the user comes into contact with the substance or preparation.

This may include the following:

11.1. Information on toxicological effects

Acute toxicity : No data available

Skin corrosion/irritation : No data available

Serious eye damage/eye irritation : No data available

Respiratory or skin sensitisation : No data available

Germ cell mutagenicity : No data available

Carcinogenicity:

Based on the available data, the classification criteria are not met

Reproductive toxicity : No data available

Specific target organ toxicity – single exposure : No data available

Specific target organ toxicity – repeated exposure : No data available

Aspiration hazard : No data available

Additional Information : RTECS: Not available

11.2. Additional toxicological information

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

11.3. Other adverse effects

Heparin and its salts act as anticoagulants subcutaneously or intravenously. To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

12. Ecological information

12.1. Toxicity

No data available

12.2. Persistence and Degradability

No data available

12.3. Bioaccumulative Potential

No data available

12.4. Mobility in Soil

No data available

12.5. Results of PBT and vPvB Assessment

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6. Other Adverse Effects

No data available

13. DISPOSAL CONSIDERATIONS

Waste treatment methods:

Recommendation: Dispose of waste in accordance to applicable national, regional, or local regulations.

Uncleaned packaging:

Recommendation: Disposal must be made according to official regulations.

Recommended cleansing agent: Water, if necessary with cleansing agents.

14. TRANSPORT INFORMATION

14.1. UN number

ADR, ADN, IMDG, IATA: Void

14.2. UN proper shipping name

ADR/RID: Not dangerous goods

IMDG: Not dangerous goods

IATA: Not dangerous goods

14.3. Transport hazard class(es)

ADR/RID: Void

IMDG: Void

IATA: Void

14.4. Packaging group

ADR/RID: Void

IMDG: Void

IATA: Void

14.5. Environmental hazards

ADR/RID: no **IMDG Marine pollutant:** no **IATA:** no— class,

14.6. Special precautions for user

Not applicable.

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code:

Not applicable

15. REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture


This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

International Chemical Weapons Convention (CWC) : Neither banned nor restricted Schedules of Toxic Chemicals and Precursors

Restrictions on the marketing and use of certain dangerous substances and preparations : Neither banned nor restricted

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Neither banned nor restricted

Candidate List of Substances of Very High Concern for Authorisation : Neither banned nor restricted

European labelling in accordance with EC Directives Hazard Symbols: The INR Quality Controls pack insert contains the following symbol  which indicates that potential biological risks are associated with the Quality Control material.

Risk Phrases: The pack insert contains the following risk phrases:

- The plasma control contains human source material that was tested and found nonreactive for HIV antibody, Hepatitis B Surface Antigen and Anti-HCV at the donor stage. This product, as with all human based specimens, should be treated as potentially infectious and handled with proper laboratory safety procedures to minimize the risk of transmission of infectious disease.
- All components of this kit can be discarded as Biohazard waste according to the local guidelines.

Additional information: Consult country codes for specific requirements.

15.2. Chemical Safety Assessment

For this product a chemical safety assessment was not carried out.

16. OTHER INFORMATION

Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route
(European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

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 Quality Controls is subject to referenced and limitations included in the product specifications.

LumiraDx UK (company number: 09206123)

Safety Data Sheet

According to EC Directive 1907/2006/EC

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

1.1. Identification of the substance or preparation

Product Name : LumiraDx INR Quality Control, Reconstitution Solution
Product Number : HB-4922-SA
Reach No : A registration number is not available for this substance as the substance or its uses are exempted from registration, the annual tonnage does not require a registration.

1.2. Use of the substance/preparation

Identified Uses : In-vitro laboratory reagent or component, liquid quality control testing performed on the LumiraDx Instrument when used with the LumiraDx INR Test Strip

1.3. Company/undertaking identification

Company Address : LumiraDx UK Ltd,
Dumyat Business Park,
Alloa
FK10 2PB
United Kingdom
Telephone Number : 00800 58647239
Email : customerservices@lumiradx.com
Website : www.lumiradx.com

1.4. Emergency telephone

Emergency Phone # : 00800 58647239, open 09:00 -17:00

2. HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008

2.2. Label elements

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008. The product does not need to be labelled 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.

2.3. Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

This solution contains sodium azide (<0.1%). Avoid ingestion or contact with skin or mucous membranes. Sodium azide reacts with lead or copper plumbing to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Chemical characterisation: Mixtures

Mixture of the substances listed below

Synonym : Sodium Azide, Formula: NaN_3 , CAS-No: 26628-22-8
: Calcium Chloride, Formula: CaCl_2 , CAS-No: 10043-52-4

Component	Classification	Concentration
Sodium Azide CAS-No. 26628-22-8 EC-No 247-852-1 Index-No 011-004-00-7 Registration number 01-2119457019-37-XXXXX	Acute Tox. 2; Acute Tox. 1; STOT RE 2; Aquatic Acute 1; Aquatic Chronic 1; H300, H310, H373, H400, H410 M-Factor - Aquatic Acute: 1	0.095%
Calcium Chloride CAS-No. 10043-52-4 EC-No 233-140-8 Index-No 017-013-00-2 Registration number 01-2119494219-28-XXXXX	Eye Irrit. 2; H319	0.139%

For the full text of the H-Statements mentioned in this Section, see Section 16.

Each bottle contains 1mL of aqueous mixture.

4. FIRST AID MEASURES

4.1. Description of first-aid measures.

General Information: No special measures required

After inhalation: Supply fresh air, consult doctor in case of complaints

After skin contact: Immediately wash with water and soap and rinse thoroughly

After eye contact: Rinse opened eye for several minutes under running water. Then consult a doctor.

After swallowing: Rinse mouth with water. Seek medical attention and appropriate follow-up.

4.2. Most important symptoms and effects, both and acute and delayed:

May cause irritation to skin eyes, may be irritating to the mucous membranes and upper respiratory tract. Avoid contact with skin, inhalation and ingestion.

4.3. Indication of any immediate medical attention and special treatment needed:

Call an internal person trained in First Aid if available, or contact a physician.

5. FIRE-FIGHTING MEASURES

5.1. Suitable extinguishing agents

CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

5.2. Special hazards arising from the substance or mixture

No further relevant information available.

5.3. Advice for firefighters

Protective equipment: Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes if necessary.

6. ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Ensure suitable personal protection during removal of spillages. Ensure adequate ventilation. For personal protection see section 8.

6.2. Environmental precautions:

Keep contaminated washing water and dispose of appropriately.

Do not allow to enter sewers/ surface or ground water.

6.3. Methods and material for containment and cleaning up:

Absorb liquid components with liquid-binding material.

Pick up mechanically.

Clean the affected area carefully; neutral detergent is a suitable cleaner.

Discard according to local guidelines.

6.4. Reference to other sections

See Section 13 for disposal information.

7. HANDLING AND STORAGE

7.1. Handling

Wear personal protective equipment (see section 8) and avoid contact with eyes, skin and clothing. Wash and dry hands thoroughly after handling.

Information about protection against explosions and fires: No special measures required.

7.2. Storage

Keep container tightly closed.
Recommended storage temperature 2 - 8°C.

7.3. Specific use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Exposure limit values

Components with limit values that require monitoring at the workplace: The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

8.2. Exposure controls

Appropriate engineering controls:

Ensure adequate ventilation.

General protective and hygienic measures:

The usual precautionary measures should be adhered to when handling chemicals.

Personal protective equipment:

Eye/face protection:

Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection:

Handle with gloves. 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.

The selected protective gloves should satisfy the specifications of relevant standards for handling this material.

Penetration time of glove material

The exact break through time of the protective gloves determined by the manufacturer should be observed.

Body Protection

Protective work clothing.

Respiratory protection

Respiratory protection is not required.

Environmental exposure controls:

Do not let product enter the drains

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. General information

Appearance

Form : Liquid
Colour : Colourless
Odour : None

9.2. Important health, safety and environmental information

pH : No data available
Melting point/freezing point : No data available
Boiling point/boiling range : No data available
Flash point : No data available
Flammability (solid, gas) : No data available
Explosive properties : No data available
Oxidising properties : No data available
Vapour pressure : No data available
Relative density : No data available
Solubility : N/A
Water solubility : N/A
Partition coefficient: n-octanol/water : No data available
Viscosity : No data available
Vapour density : No data available
Evaporation rate : No data available

9.3. Other safety information

No further relevant information available.

10. STABILITY AND REACTIVITY

10.1. Reactivity

No data available

10.2. Chemical stability

Stable under recommended storage conditions

10.3. Possibility of hazardous reactions

No dangerous reactions known

10.4. Conditions to avoid

No further relevant information available.

10.5. Materials to avoid

Strong oxidising agents and acids.

10.6. Hazardous decomposition products

No dangerous decomposition products known

11. TOXICOLOGICAL INFORMATION

Description of the various toxicological (health) effects, which can arise if the user comes into contact with the substance or preparation.

This may include the following:

11.1. Information on toxicological effects

Acute toxicity : No data available

Skin corrosion/irritation : No data available

Serious eye damage/eye irritation : No data available

Respiratory or skin sensitisation : No data available

Germ cell mutagenicity : No data available

Carcinogenicity:

Based on the available data, the classification criteria are not met

Reproductive toxicity : No data available

Specific target organ toxicity – single exposure : No data available

Specific target organ toxicity – repeated exposure : No data available

Aspiration hazard : No data available

Additional Information : RTECS: Not available

11.2. Additional toxicological information

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

11.3. Other adverse effects

No data available

12. Ecological information

12.1. Toxicity

No data available

12.2. Persistence and Degradability

No data available

12.3. Bioaccumulative Potential

No data available

12.4. Mobility in Soil

No data available

12.5. Results of PBT and vPvB Assessment

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6. Other Adverse Effects

No data available

13. DISPOSAL CONSIDERATIONS

Waste treatment methods:

Recommendation: Dispose of waste in accordance to applicable national, regional, or local regulations.

Uncleaned packaging:

Recommendation: Disposal must be made according to official regulations.

Recommended cleansing agent: Water, if necessary with cleansing agents.

14. TRANSPORT INFORMATION

14.1. UN number

ADR, ADN, IMDG, IATA: Void

14.2. UN proper shipping name

ADR/RID: Not dangerous goods

IMDG: Not dangerous goods

IATA: Not dangerous goods

14.3. Transport hazard class(es)

ADR/RID: Void

IMDG: Void

IATA: Void

14.4. Packaging group

ADR/RID: Void

IMDG: Void

IATA: Void

14.5. Environmental hazards

ADR/RID: no **IMDG Marine pollutant:** no **IATA:** no— class,

14.6. Special precautions for user

Not applicable.

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code:

Not applicable

15. REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture


This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

International Chemical Weapons Convention (CWC) : Neither banned nor restricted Schedules of Toxic Chemicals and Precursors

Restrictions on the marketing and use of certain dangerous substances and preparations : Neither banned nor restricted

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Neither banned nor restricted

Candidate List of Substances of Very High Concern for Authorisation : Neither banned nor restricted

European labelling in accordance with EC Directives Hazard Symbols: The INR Quality Controls pack insert contains the following symbol  which indicates that potential biological risks are associated with the Quality Control material.

Risk Phrases: The pack insert contains the following risk phrases:

- The plasma control contains human source material that was tested and found nonreactive for HIV antibody, Hepatitis B Surface Antigen and Anti-HCV at the donor stage. This product, as with all human based specimens, should be treated as potentially infectious and handled with proper laboratory safety procedures to minimize the risk of transmission of infectious disease.
- All components of this kit can be discarded as Biohazard waste according to the local guidelines.

Additional information: Consult country codes for specific requirements.

15.2. Chemical Safety Assessment

For this product a chemical safety assessment was not carried out

16. OTHER INFORMATION

Full text of H-Statements referred to under section 3.

EUH032 – Contact with acids liberates very toxic gas.

H319 Causes serious eye irritation

H300 Fatal if swallowed.

H310 Fatal in contact with skin.

H373 May cause damage to organs through prolonged or repeated exposure if swallowed.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route
(European Agreement concerning the International Carriage of
Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

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 Quality Controls is subject to referenced and limitations included in the product specifications.

LumiraDx UK (company number: 09206123)

END OF SAFETY DATA SHEET