

# Safety Data Sheet

according to Regulation (EC) No 1907/2006

## LumiraDx SARS-COV-2 Ab (Antibody Test Strip)

Revision date: 31.07.2020

Product code:

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### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

LumiraDx SARS-COV-2 Ab (Antibody Test Strip)

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

##### Use of the substance/mixture

in vitro diagnosis.

##### Uses advised against

Any non-intended use.

#### 1.3. Details of the supplier of the safety data sheet

Company name:	LumiraDx UK Ltd	
Street:	Dumyat Business Park	
Place:	GB-FK10 2PB Alloa	
Telephone:	00800 58647239	
e-mail:	customerservices@lumiradx.com	
Responsible Department:	Dr. Gans-Eichler	e-mail: info@tge-consult.de
	Chemieberatung GmbH	Tel.: +49(0)2534 6441185
	Otto-Hahn-Str. 36	www.tge-consult.de
	D-48161 Münster	

#### 1.4. Emergency telephone number:

Poison Information Center Mainz, Germany, Tel: +49(0)6131/19240

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

##### Regulation (EC) No. 1272/2008

This mixture is not classified as hazardous in accordance with Regulation (EC) No. 1272/2008.

#### 2.2. Label elements

##### Additional advice on labelling

Labelling according to Regulation (EC) No. 1272/2008 [CLP]: none

#### 2.3. Other hazards

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

No risks worthy of mention. Please observe the information on the safety data sheet at all times.

### SECTION 3: Composition/information on ingredients

#### 3.2. Mixtures

##### Chemical characterization

The product does not contain dangerous substances according to REGULATION (EU) No. 2015/830, Annex II, Part A, 3.2.2. that must be mentioned in Chapter 3.

##### Further Information

Product does not contain listed SVHC substances &gt; 0,1 % according to Regulation (EC) No. 1907/2006 Article 59 (REACH)

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

##### General information

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

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### After inhalation

In case of accident by inhalation: remove casualty to fresh air and keep at rest. In case of respiratory tract irritation, consult a physician.

### After contact with skin

Gently wash with plenty of soap and water. In case of skin irritation, seek medical treatment.

### After contact with eyes

Rinse cautiously with water for several minutes. In case of troubles or persistent symptoms, consult an ophthalmologist.

### After ingestion

Rinse mouth thoroughly with water. Let water be drunk in little sips (dilution effect). Do NOT induce vomiting. In all cases of doubt, or when symptoms persist, seek medical advice.

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

No information available.

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

Treat symptomatically.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

#### Suitable extinguishing media

Carbon dioxide (CO<sub>2</sub>). Dry extinguishing powder. alcohol resistant foam. Atomized water.

#### Unsuitable extinguishing media

High power water jet.

### 5.2. Special hazards arising from the substance or mixture

Can be released in case of fire: Carbon monoxide. Carbon dioxide (CO<sub>2</sub>).

### 5.3. Advice for firefighters

In case of fire: Wear self-contained breathing apparatus.

### Additional information

Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

Co-ordinate fire-fighting measures to the fire surroundings.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

Safe handling: see section 7

Personal protection equipment: see section 8

### 6.2. Environmental precautions

Discharge into the environment must be avoided.

### 6.3. Methods and material for containment and cleaning up

Take up mechanically.

Treat the recovered material as prescribed in the section on waste disposal.

Clean contaminated objects and areas thoroughly observing environmental regulations.

### 6.4. Reference to other sections

Disposal: see section 13

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

#### Advice on safe handling

Wear suitable protective clothing. (See section 8.)

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### Advice on protection against fire and explosion

Usual measures for fire prevention.

### Further information on handling

General protection and hygiene measures: See section 8.

### 7.2. Conditions for safe storage, including any incompatibilities

#### Requirements for storage rooms and vessels

Keep container tightly closed in a cool, well-ventilated place.

#### Hints on joint storage

Do not store together with: Explosives. Oxidizing solids. Oxidizing liquids. Radioactive substances. Infectious substances. Food and animal feedingstuff

#### Further information on storage conditions

Keep the packing dry and well sealed to prevent contamination and absorption of humidity.

Recommended storage temperature: 20°C

Protect against: frost. UV-radiation/sunlight. heat. Humidity

### 7.3. Specific end use(s)

See section 1.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### Additional advice on limit values

To date, no national critical limit values exist.

### 8.2. Exposure controls

#### Appropriate engineering controls

No special measures are necessary.

#### Protective and hygiene measures

Always close containers tightly after the removal of product. When using do not eat, drink, smoke, sniff. Wash hands before breaks and after work.

#### Eye/face protection

No special measures are necessary.

#### Hand protection

Suitable gloves type: Single-use gloves.

The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Before using check leak tightness / impermeability. In the case of wanting to use the gloves again, clean them before taking off and air them well.

#### Skin protection

Minimum standard for preventive measures while handling with working materials are specified in the TRGS 500 (D).

#### Respiratory protection

With correct and proper use, and under normal conditions, breathing protection is not required.

#### Environmental exposure controls

No special precautionary measures are necessary.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state:	solid
Colour:	not determined

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Odour: odourless

pH-Value: not determined

#### Changes in the physical state

Melting point: not determined

Initial boiling point and boiling range: not determined

Sublimation point: not determined

Softening point: not determined

Pour point: not determined

Flash point: not determined

Sustaining combustion: Not sustaining combustion

#### Explosive properties

none

Lower explosion limits: not determined

Upper explosion limits: not determined

Ignition temperature: not determined

#### Auto-ignition temperature

Gas:

not determined

Decomposition temperature: not determined

#### Oxidizing properties

none

Vapour pressure: not determined

Density: not determined

Water solubility: not determined

#### Solubility in other solvents

not determined

Partition coefficient: not determined

Viscosity / dynamic: not determined

Viscosity / kinematic: not determined

Flow time: not determined

Vapour density: not determined

Evaporation rate: not determined

Solvent separation test: not determined

Solvent content: not determined

#### 9.2. Other information

Solid content: not determined

### SECTION 10: Stability and reactivity

#### 10.1. Reactivity

No information available.

#### 10.2. Chemical stability

The product is chemically stable under recommended conditions of storage, use and temperature.

#### 10.3. Possibility of hazardous reactions

Refer to chapter 10.5.

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#### **10.4. Conditions to avoid**

Protect against: UV-radiation/sunlight. heat.

#### **10.5. Incompatible materials**

Materials to avoid: Oxidizing agents, strong. Reducing agents, strong.

#### **10.6. Hazardous decomposition products**

Can be released in case of fire: Carbon monoxide. Carbon dioxide (CO<sub>2</sub>).

### SECTION 11: Toxicological information

#### **11.1. Information on toxicological effects**

##### **Toxicokinetics, metabolism and distribution**

No data available.

##### **Acute toxicity**

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

##### **Irritation and corrosivity**

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

##### **Sensitising effects**

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

##### **Carcinogenic/mutagenic/toxic effects for reproduction**

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

##### **STOT-single exposure**

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

##### **STOT-repeated exposure**

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

##### **Aspiration hazard**

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

##### **Specific effects in experiment on an animal**

No data available.

### SECTION 12: Ecological information

#### **12.1. Toxicity**

The product has not been tested.

#### **12.2. Persistence and degradability**

The product has not been tested.

#### **12.3. Bioaccumulative potential**

No indication of bioaccumulation potential.

#### **12.4. Mobility in soil**

No data available.

#### **12.5. Results of PBT and vPvB assessment**

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

#### **12.6. Other adverse effects**

No data available.

#### **Further information**

Do not allow to enter into surface water or drains.

### SECTION 13: Disposal considerations

#### **13.1. Waste treatment methods**

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#### Disposal recommendations

Observe in addition any national regulations! Consult the local waste disposal expert about waste disposal.  
 Non-contaminated packages may be recycled.  
 According to (EWC) European Waste Catalogue, allocation of waste identity numbers/waste descriptions must be carried out in a specific way for every industry and process.  
 Control report for waste code/ waste marking according to (EWC) European Waste Catalogue:

#### List of Wastes Code - residues/unused products

200132 MUNICIPAL WASTES (HOUSEHOLD WASTE AND SIMILAR COMMERCIAL, INDUSTRIAL AND INSTITUTIONAL WASTES) INCLUDING SEPARATELY COLLECTED FRACTIONS; separately collected fractions (except 15 01); medicines other than those mentioned in 20 01 31

#### List of Wastes Code - used product

200132 MUNICIPAL WASTES (HOUSEHOLD WASTE AND SIMILAR COMMERCIAL, INDUSTRIAL AND INSTITUTIONAL WASTES) INCLUDING SEPARATELY COLLECTED FRACTIONS; separately collected fractions (except 15 01); medicines other than those mentioned in 20 01 31

#### List of Wastes Code - contaminated packaging

150106 WASTE PACKAGING; ABSORBENTS, WIPING CLOTHS, FILTER MATERIALS AND PROTECTIVE CLOTHING NOT OTHERWISE SPECIFIED; packaging (including separately collected municipal packaging waste); mixed packaging

#### Contaminated packaging

Handle contaminated packages in the same way as the substance itself.

### SECTION 14: Transport information

#### Land transport (ADR/RID)

<b><u>14.1. UN number:</u></b>	No dangerous good in sense of these transport regulations.
<b><u>14.2. UN proper shipping name:</u></b>	No dangerous good in sense of these transport regulations.
<b><u>14.3. Transport hazard class(es):</u></b>	No dangerous good in sense of these transport regulations.
<b><u>14.4. Packing group:</u></b>	No dangerous good in sense of these transport regulations.

#### Inland waterways transport (ADN)

<b><u>14.1. UN number:</u></b>	No dangerous good in sense of these transport regulations.
<b><u>14.2. UN proper shipping name:</u></b>	No dangerous good in sense of these transport regulations.
<b><u>14.3. Transport hazard class(es):</u></b>	No dangerous good in sense of these transport regulations.
<b><u>14.4. Packing group:</u></b>	No dangerous good in sense of these transport regulations.

#### Marine transport (IMDG)

<b><u>14.1. UN number:</u></b>	No dangerous good in sense of these transport regulations.
<b><u>14.2. UN proper shipping name:</u></b>	No dangerous good in sense of these transport regulations.
<b><u>14.3. Transport hazard class(es):</u></b>	No dangerous good in sense of these transport regulations.

#### Air transport (ICAO-TI/IATA-DGR)

<b><u>14.1. UN number:</u></b>	No dangerous good in sense of these transport regulations.
<b><u>14.2. UN proper shipping name:</u></b>	No dangerous good in sense of these transport regulations.
<b><u>14.3. Transport hazard class(es):</u></b>	No dangerous good in sense of these transport regulations.

#### **14.5. Environmental hazards**

ENVIRONMENTALLY HAZARDOUS: no

#### **14.6. Special precautions for user**

Refer to section 6-8

#### **14.7. Transport in bulk according to Annex II of Marpol and the IBC Code**

not relevant

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#### SECTION 15: Regulatory information

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

###### EU regulatory information

2010/75/EU (VOC):	No information available.
2004/42/EC (VOC):	No information available.
Information according to 2012/18/EU (SEVESO III):	Not subject to 2012/18/EU (SEVESO III)

###### Additional information

Safety Data Sheet according to Regulation (EC) No. 1907/2006 (amended by Regulation (EU) No 2019/957)  
 The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].  
 in vitro diagnosis. - 2017/746/EC  
 REACH 1907/2006 Appendix XVII, No (mixture): not relevant

###### National regulatory information

Water hazard class (D): 1 - slightly hazardous to water

##### 15.2. Chemical safety assessment

For the following substances of this mixture a chemical safety assessment has been carried out:

#### SECTION 16: Other information

##### Changes

Rev. 1.0; Initial release: 31.07.2020

##### 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)  
 AGW: Arbeitsplatzgrenzwert  
 CAS Chemical Abstracts Service  
 CLP: Classification, Labelling and Packaging of substances and mixtures  
 DNEL: Derived No Effect Level  
 d: day(s)  
 EINECS: European INventory of Existing Commercial chemical Substances  
 ELINCS: European List of Notified Chemical Substances  
 ECHA: European Chemicals Agency  
 EWC: European Waste Catalogue  
 IARC: INTERNATIONAL AGENCY FOR RESEARCH ON CANCER  
 IMDG: International Maritime Code for Dangerous Goods  
 IATA: International Air Transport Association  
 IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)  
 ICAO: International Civil Aviation Organization  
 ICAO-TI: Technical Instructions by the "International Civil Aviation Organization" (ICAO)  
 GHS: Globally Harmonized System of Classification and Labelling of Chemicals  
 GefStoffV: Gefahrstoffverordnung (Ordinance on Hazardous Substances, Germany)  
 h: hour  
 LOAEL: Lowest observed adverse effect level  
 LOAEC: Lowest observed adverse effect concentration  
 LC50: Lethal concentration, 50 percent  
 LD50: Lethal dose, 50 percent  
 NOAEL: No observed adverse effect level  
 NOAEC: No observed adverse effect concentration  
 NLP: No-Longer Polymers  
 N/A: not applicable  
 OECD: Organisation for Economic Co-operation and Development

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PNEC: predicted no effect concentration

PBT: Persistent bioaccumulative toxic

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail )

REACH: Registration, Evaluation, Authorisation of Chemicals

SVHC: substance of very high concern

TRGS: Technische Regeln für Gefahrstoffe

UN: United Nations

VOC: Volatile Organic Compounds

**Further Information**

Classification according to Regulation (EC) No 1272/2008 [CLP] - Classification procedure:

Health hazards: Calculation method.

Environmental hazards: Calculation method.

Physical hazards: On basis of test data and / or calculated and / or estimated.

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

*(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)*