WHO Emergency Use Assessment SARS-CoV-2 IVDs
PUBLIC REPORT

Product: LumiraDx SARS-CoV-2 Ag Test
Manufacturer: LumiraDx UK Ltd
EUL Number: EUL 0578-234-00
Outcome: Accepted

The EUL process is intended to expedite the availability of in vitro diagnostics needed in public health emergency situations and to assist interested UN procurement agencies and Member States in determining the acceptability of using specific products in the context of a Public Health Emergency of International Concern (PHEIC), based on an essential set of available quality, safety and performance data. The EUL procedure includes the following:

- Quality Management Systems Review and Plan for Post-Market Surveillance: a desktop review of the manufacturer's Quality Management System documentation and specific manufacturing documents.
- Product Dossier Review: assessment of the documentary evidence of safety and performance. This evaluation of limited scope is to verify critical analytical and performance characteristics.

LumiraDx SARS-CoV-2 Ag Test with product codes L016000110012, L016000110024, and L016000110048, CE mark regulatory version manufactured by LumiraDx UK Ltd located at Dumyat Business Park Alloa, FK10 2PB, United Kingdom of Great Britain and Northern Ireland, was listed as eligible for WHO procurement on 13 May 2022.

This public report has since been amended. Amendments may have arisen because of changes to the prequalified product for which the WHO has been notified and has undertaken a review. Amendments to the report are summarised in the following table, and details of each amendment are provided below.

Version	Summary of amendment	Date of report amendment
2.0	Updated the IFU in the public report.	14 September 2023

Intended use

According to the claim of intended use from LumiraDx UK Ltd, " *the LumiraDx SARS-CoV-2 Ag test is a rapid microfluidic immunofluorescence assay for use with the LumiraDx Platform intended for the qualitative detection of the nucleocapsid protein antigen to SARS-CoV-2 in nasal swab samples. Samples are collected from individuals suspected of COVID-19 infection within the first twelve days of symptom onset or from asymptomatic individuals. The Test aids in the diagnosis of current SARS-CoV-2 infection by detection of SARS-CoV-2 antigen.*
Positive results indicate the presence of viral antigens from infective virus, but clinical correlation with individual's history and other diagnostic information is necessary to confirm infection status.
Negative results do not rule out SARS-CoV-2 infection and should be considered in the context of an individual's recent exposures, history and presence of clinical signs and symptoms consistent with COVID-19.

Results should not be used as the sole basis for treatment or case management decisions, including infection control decisions. The LumiraDx SARS-CoV-2 Ag test is intended for use by individuals trained in point of care settings and proficient in performing tests using the LumiraDx Platform."

Specimen type that was validated: Nasal swab specimens.

Assay description

According to the claim of assay description from LumiraDx UK Ltd, " *the LumiraDx SAR-CoV-2 Ag test is a single use fluorescence immunoassay device designed to detect the presence of the nucleocapsid protein antigen from SARS-CoV-2 in nasal swab samples.*
The test procedure involves collecting a nasal swab sample using a recommended swab which is eluted into a vial containing Extraction Buffer. A single drop of the sample in Extraction Buffer is added to the Test Strip using the vial dropper cap provided. The LumiraDx Instrument is programmed to perform the test protocol using the dried reagents contained within the strip. The test result is determined from the amount of fluorescence the Instrument detects within the measurement zone of the Test Strip. The concentration of the analyte in the sample is proportional to the fluorescence detected. The results are displayed on the Instrument touchscreen within 12 minutes from the addition of the sample."

Test kit contents

Component	12 tests/kit (product code L016000110012	24 tests (product code L016000110024)	48 tests/kit (product code L016000110048)
LumiraDx Test Strips packed individually in sealed desiccant foil pouches.	12	24	48
LumiraDx Test Product Insert	1	1	1
RFID (Radio frequency ID) Tag held inside the Test Strip carton	1	1	1
Quick Reference Instructions	1	1	1
Extraction Buffer Vials	12	24	48
Dropper Lids	12	24	48

Items required but not provided

- LumiraDx Instrument – Product code: L001000330001,
- LumiraDx SARS-CoV-2 Ag Quality Controls (as required to meet local and organisational compliance) – Product code: L016080101002,
- LumiraDx Connect if connectivity required (refer to LumiraDx Connect User Manual) – Product code: L002040201001,
- Standard nasal swab collection equipment. Below is a list of commercially available swabs recommended by LumiraDx. The use of nasal swab collection kits that are not listed in the list below is not recommended by LumiraDx.

Validated nasal swabs

- Copan Nasal FLOQSwab Regular (Supplier Product Code: 502CS01)
- Copan eSwab (Supplier Product Code: 490CE.A)
- Copan Regular PL/Swab NY/VEL Drytube (Supplier Product Code: 552C)
- Copan REGULAR APPL.NYLON PF100 (Supplier Product Code: 519CS01)
- Copan FLOQswab Regular Tip (Supplier product code: 519C)
- Puritan HydraFlockSterile Standard Flock Swab(Supplier Product Code:25-3306-H)
- Puritan HydraFlock Sterile Standard Flock Swab(Supplier Product Code:25-3506-H)
- Aspen Surgical Polyester Swab (supplier product code: 20200062)
- SteriPack Sterile Polyester Spun Swab (Supplier Product Code: 60564REVA)
- mwe medical wire DrySwab Rayon Swab (Supplier Product Code: MW112)
- Kang Jian Virus Collection Swab (Supplier Product Code: KJ502-19)
- Nerbe Plus dry swab (Supplier Product Code: 09-511-5017)

- Nerbe Plus PS Stick (Supplier Product Code: 09-812-8053)
- Plast Labor 06913 Swab Haste Plastica Ponta Rayon Estéril Embalagem Indv (Supplier Product Code: 50X100)
- Citotest Citoswab (Supplier Product Code: 2122-0008)
- Gongdong Disposable Sterile Swab (Supplier Product Code: G1029FT77)
- OPT Industries InstaSwab Nasal (Anterior) (Supplier Product Code: INS-T4BAA)

Storage
The test kit should be stored at 2 to 30°C.

Shelf-life upon manufacture
6 months (real-time stability studies are ongoing).

Warnings/limitations
Please refer to the attached instructions of use (IFU).

Product dossier assessment

LumiraDx UK Ltd submitted a product dossier for the LumiraDx SAR-CoV-2 Ag Test as per the "*Instructions for Submission Requirements: In vitro diagnostics (IVDs) Detecting SARS-CoV-2 nucleic acid or antigen (PQDx_0347)"*. The information (data and documentation) submitted in the product dossier was reviewed by WHO staff and an external assessor appointed by WHO.

Post listing Commitments for EUL

As a requirement to listing, the manufacturer is required to:

1. When available, submit a Limit of Detection (LoD) study report using the WHO SARS-CoV-2 antigen International Standard.
2. Partaking in an independent performance evaluation conducted by a laboratory commissioned by WHO. Any such performance evaluation testing will be conducted using the protocol and technical criteria established by WHO.
3. Submit interim and final stability study reports by 30 June 2022 and 30 June 2023, respectively.

The risk-benefit assessment conclusion is acceptable.

Quality Management Systems Review

To establish the eligibility for WHO procurement, LumiraDx UK Ltd was asked to provide up-to-date information about the status of their quality management system.

Based on the review of the submitted quality management system documentation by WHO staff and external technical experts (assessors), it was established that LumiraDx UK Ltd provided sufficient information to fulfil the requirements described in the "*Instructions for Submission Requirements: In vitro diagnostics (IVDs) Detecting SARS-CoV-2 nucleic acid or antigen(PQDx_ 347) "*.

The quality management documentation assessment conclusion is acceptable.

Plan for Post-Market Surveillance

Post-market surveillance, including monitoring all customer feedback, detecting and acting on adverse events, product problems, non-conforming goods and processes is a critical component of minimising the potential harm of an IVD listed for emergency use.

The following post-prequalification activities are required to maintain the prequalification status:
1. Notification to WHO of any planned changes to a prequalified product, in accordance with "*WHO procedure for changes to a WHO prequalified in vitro diagnostic" (document number PQDx_121*); and
2. Post-market surveillance activities, in accordance with "*Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics* " (ISBN 978-92-4-001531-9).

LumiraDx UK Ltd is also required to report complaints related to the product. There are certain categories of complaints and changes to the product that must be notified immediately to WHO, as per the above-mentioned documents.

The manufacturer has committed to ensuring that post-emergency use listing safety, quality and performance monitoring activities are in place, per WHO guidance "*Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics."*[1]

[1] https://www.who.int/publications/i/item/9789240015319

Scope and duration of procurement eligibility

The LumiraDx SARS-CoV-2 Ag Test with product codes L016000110012, L016000110024 and L016000110048, manufactured by LumiraDx UK Ltd, is considered to be eligible for WHO procurement for 12 months from the day of listing. The assay may detect Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) antigen. This listing does not infer that the product meets WHO prequalification requirements and does not mean that the product is listed as WHO-prequalified.

As part of the ongoing requirements for listing as eligible for WHO procurement, LumiraDx UK Ltd must engage in post-market surveillance activities to ensure that the product continues to meet safety, quality and performance requirements. LumiraDx UK Ltd is required to notify WHO of any complaints, including adverse events related to the use of the product, within 7 days and any changes made to the product.

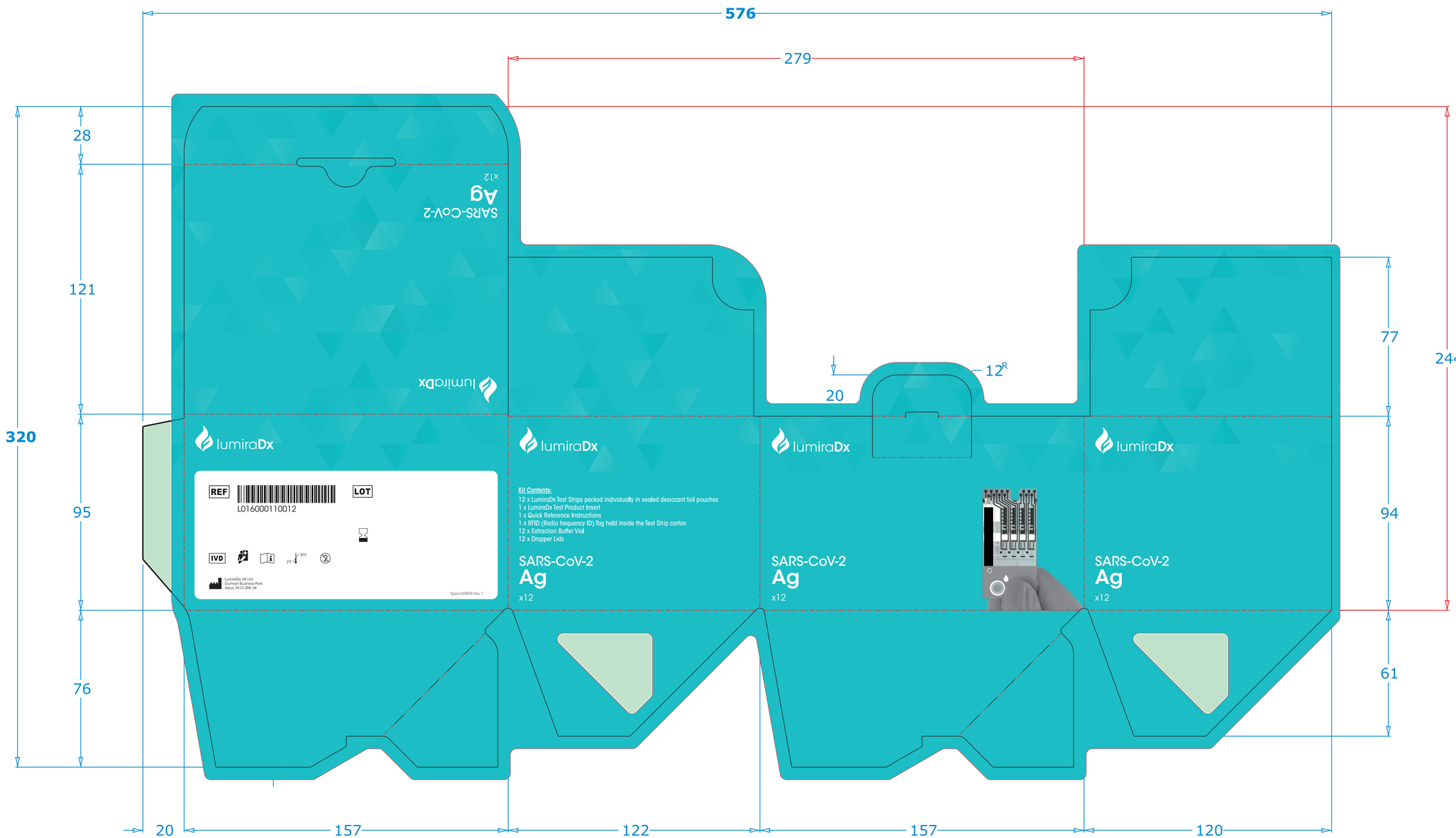
WHO reserves the right to rescind eligibility for WHO procurement if additional information on the safety, quality, and performance during post-market surveillance activities and if new data becomes available to WHO that changes the risk-benefit balance.

Labelling

1. **Labels**
2. **Instructions for use**

1.0 Labels

1.1 Kit box


576
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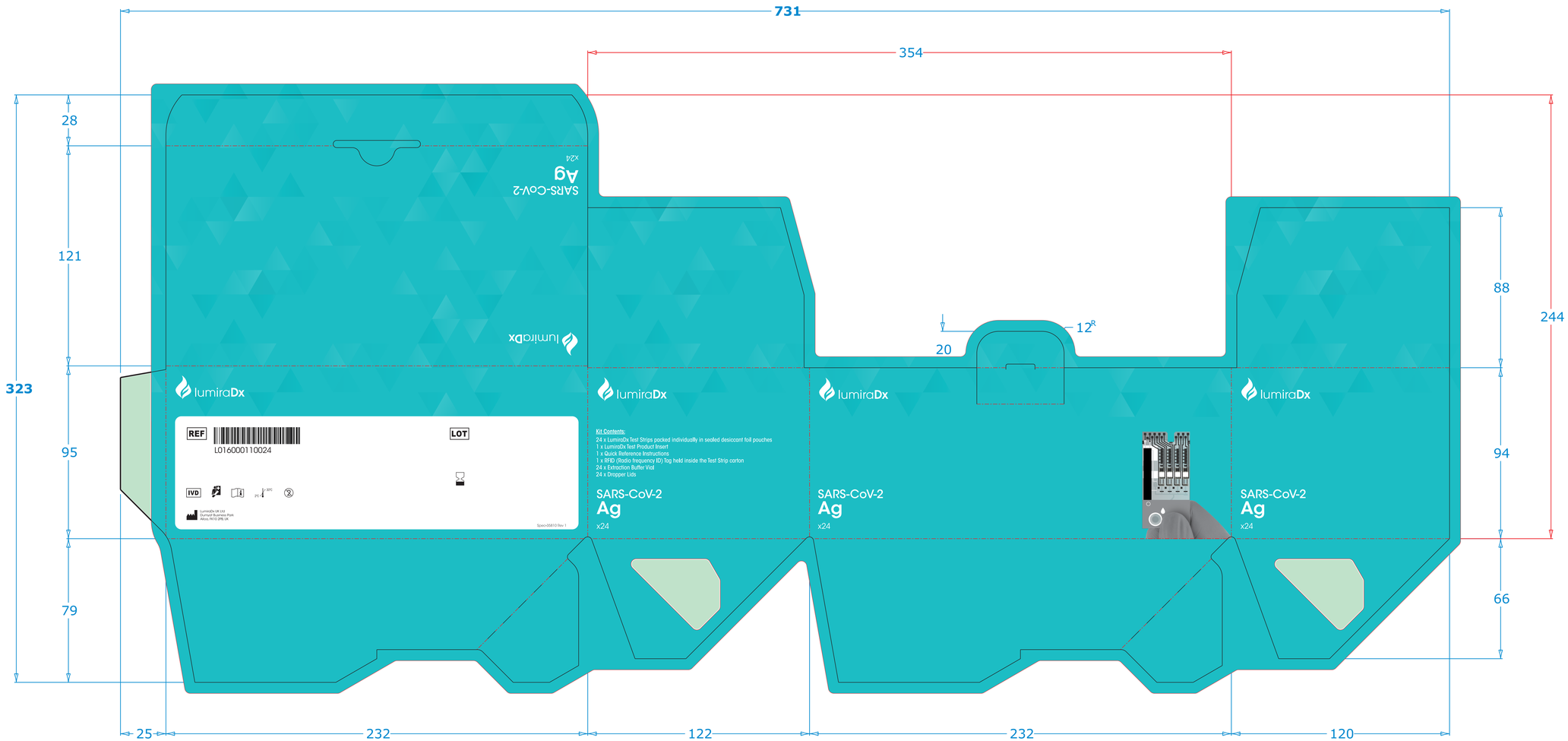
lumiraDx
SARS-CoV-2
Ag
x12
REF
LOT
L016000110012
IVD
2°C 30°C
LumiraDx UK Ltd
Dumyat Business Park
Alloa, FK10 2PB, UK
Spec-35809 Rev 1
Kit Contents:
12 x LumiraDx Test Strips packed individually in sealed desiccant foil pouches
1 x LumiraDx Test Product Insert
1 x Quick Reference Instructions
1 x RFID (Radio frequency ID) Tag held inside the Test Strip carton
12 x Extraction Buffer Vial
12 x Dropper Lids
SARS-CoV-2
Ag
x12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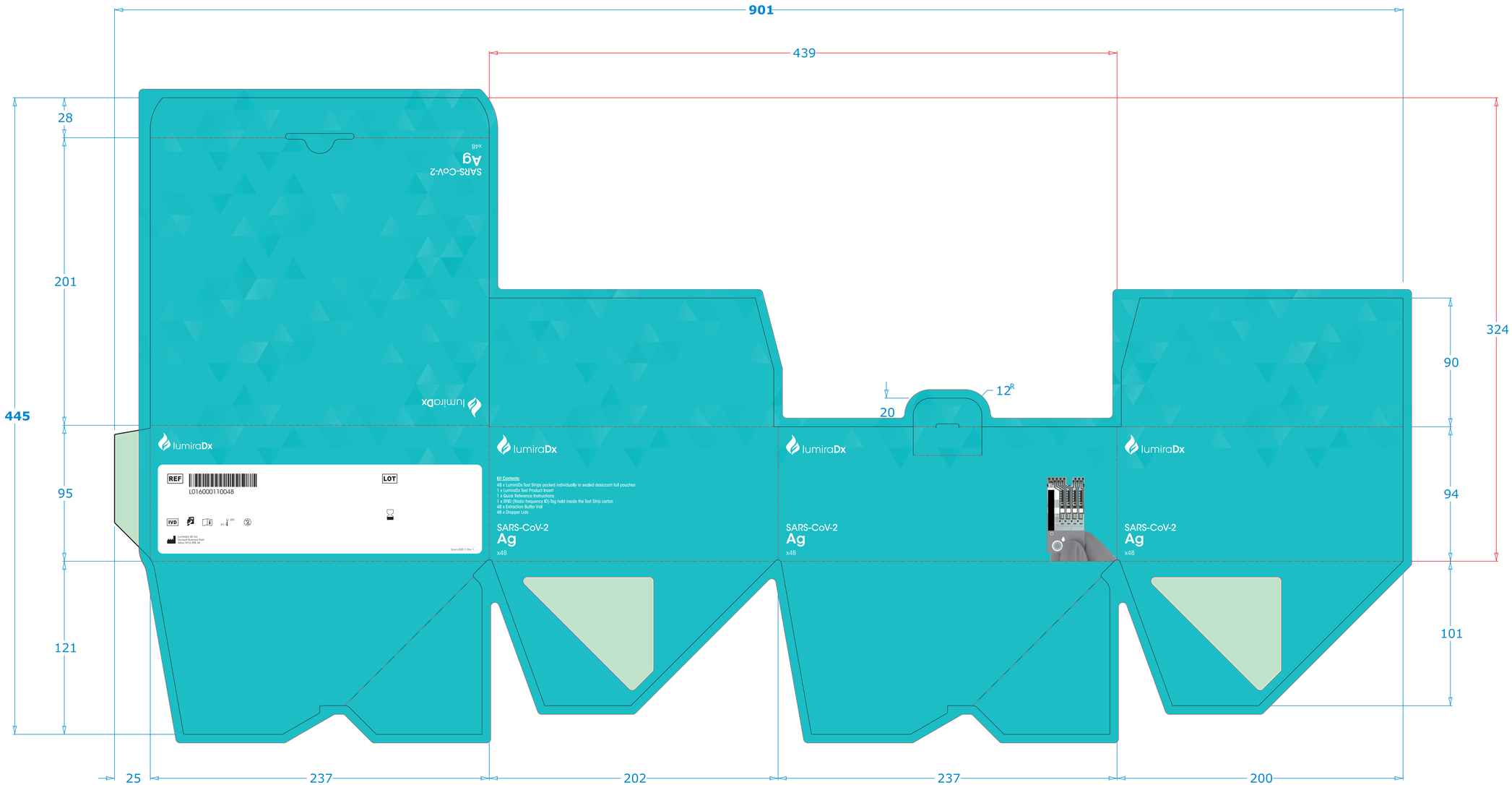
79
323
88
94
66
244
20
12R
lumiraDx
SARS-CoV-2
Ag
x24
REF
L016000110024
LOT
IVD
Kit Contents:
24 x LumiraDx Test Strips packed individually in sealed desiccant foil pouches
1 x LumiraDx Test Product Insert
1 x Quick Reference Instructions
1 x RFID (Radio frequency ID) Tag held inside the Test Strip carton
24 x Extraction Buffer Vial
24 x Dropper Lids
Spec-55810 Rev 1
25
232
122
232
120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439
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12R
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202
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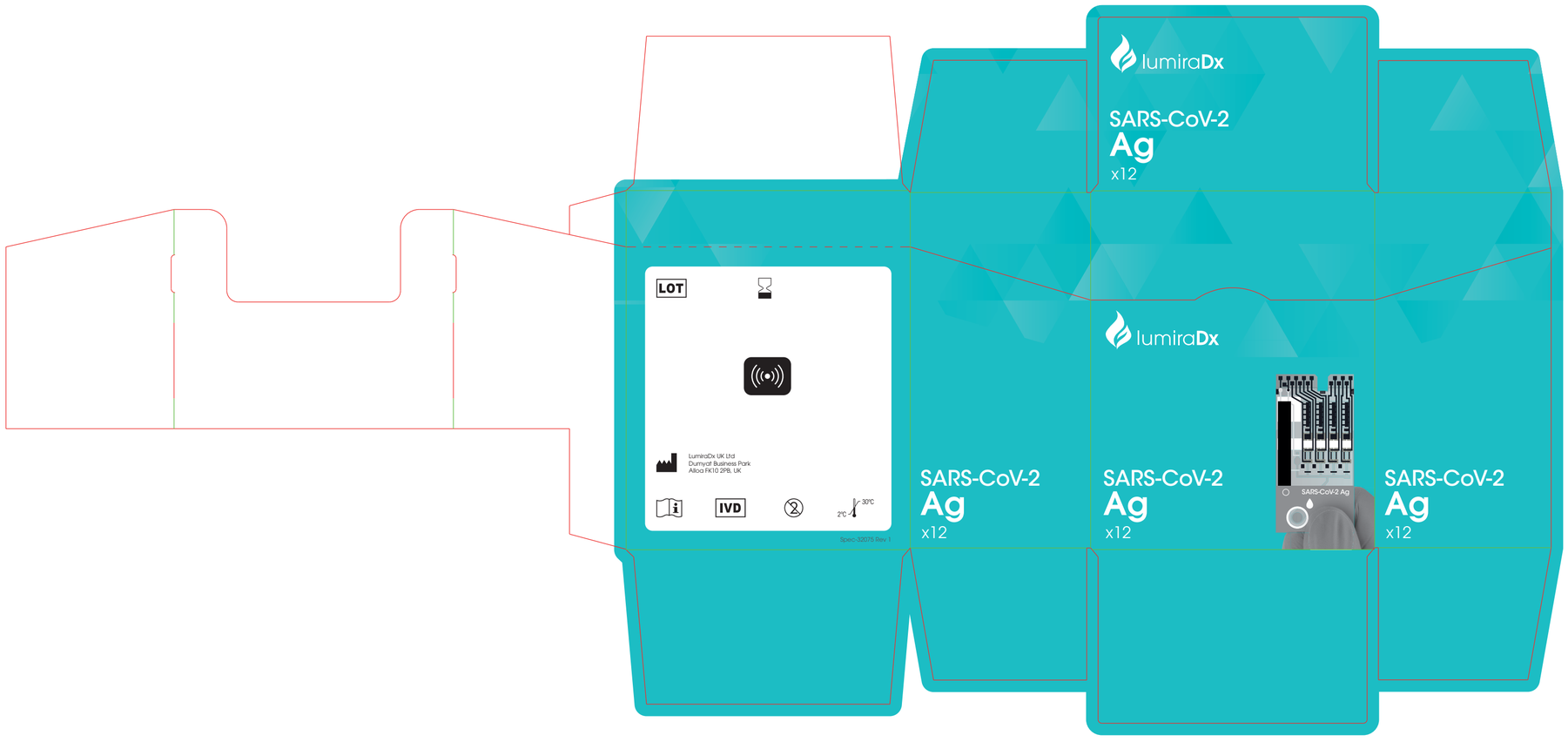
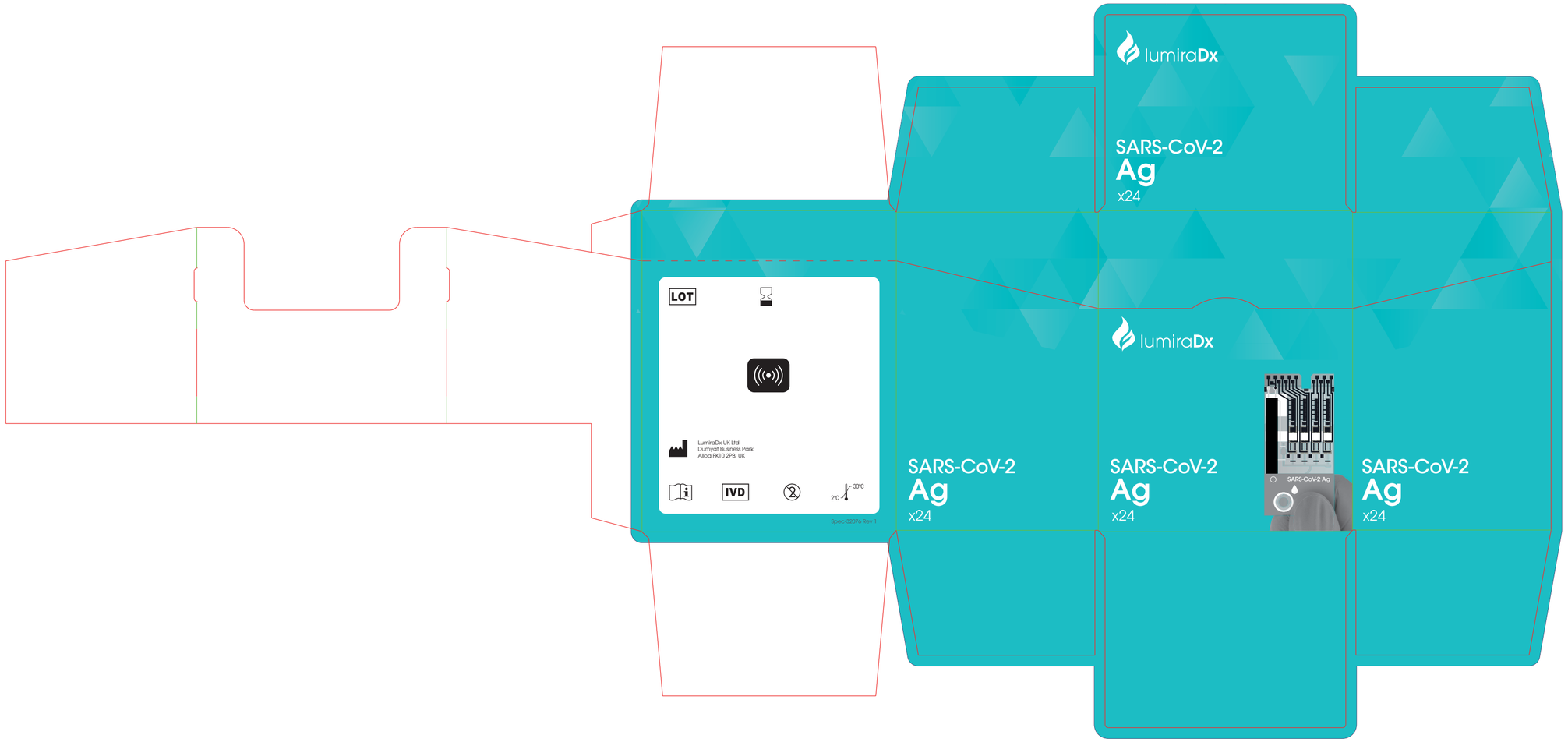
200
SARS-CoV-2
Ag
x48
lumiraDx
REF
L016000110048
LOT
IVD
Kit Contents:
48 x LumiraDx Test Strips packed individually in sealed desiccant foil pouches
1 x LumiraDx Test Product Insert
1 x Quick Reference Instructions
1 x RPID (Radio frequency ID) Tag held inside the Test Strip carton
48 x Extraction Buffer Vial
48 x Dropper Lids
SARS-CoV-2
Ag
x48


LOT
LumiraDx UK Ltd
Dunnyat Business Park
Alloa FK10 2PB, UK
IVD
2°C
30°C
Spec-32075 Rev 1
lumiraDx
SARS-CoV-2
Ag
x12
lumiraDx
SARS-CoV-2
Ag
x12
SARS-CoV-2
Ag
x12
SARS-CoV-2 Ag
SARS-CoV-2
Ag
x12


LumiraDx
SARS-CoV-2
Ag
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LumiraDx UK Ltd
Dumyat Business Park
Alloa FK10 2PB, UK
IVD
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30°C
Spec-32076 Rev 1
LumiraDx
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SARS-CoV-2
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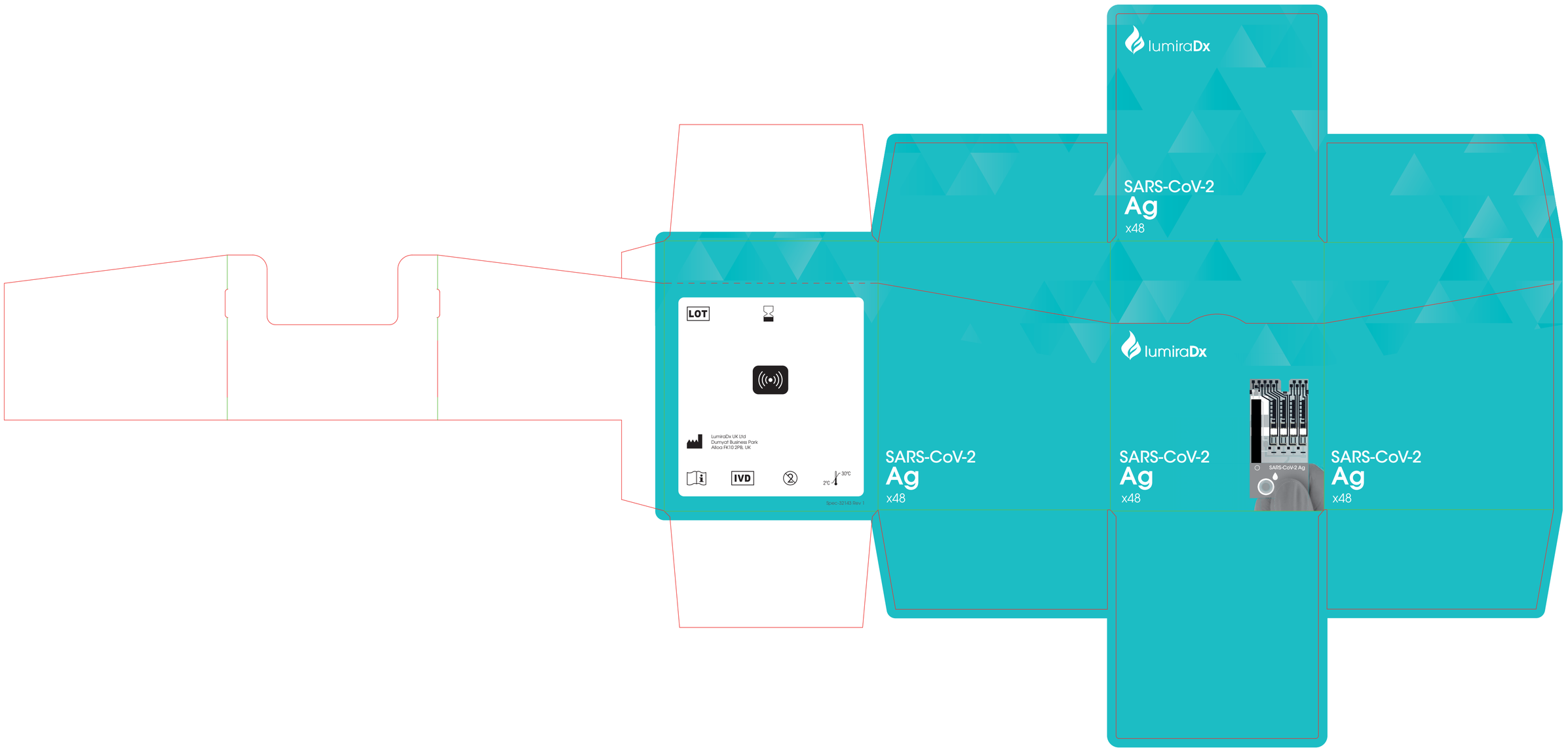
SARS-CoV-2
Ag
x24


lumiraDx
SARS-CoV-2
Ag
x48
LOT
LumiraDx UK Ltd
Dumyat Business Park
Alloa FK10 2PB, UK
IVD
2°C
30°C
Spec-32143 Rev 1
SARS-CoV-2 Ag

1.2 Test strip carton label

SARS-CoV-2
Ag

LOT IVD EC REP 2°C 30°C

LumiraDx AB Västra Vägen 5A
16961 Solna Sweden
SPEC-32058 Rev 2 Rev date 2020-11

LumiraDx UK Ltd
Dumyat Business Park
Alloa FK10 2PB, UK

SARS-CoV-2
Ag

LOT IVD EC REP 2°C 30°C

LumiraDx AB Västra Vägen 5A
16961 Solna Sweden
SPEC-32058 Rev 2 Rev date 2020-11

LumiraDx UK Ltd
Dumyat Business Park
Alloa FK10 2PB, UK

SARS-CoV-2
Ag

LOT IVD EC REP 2°C 30°C

LumiraDx AB Västra Vägen 5A
16961 Solna Sweden
SPEC-32058 Rev 2 Rev date 2020-11

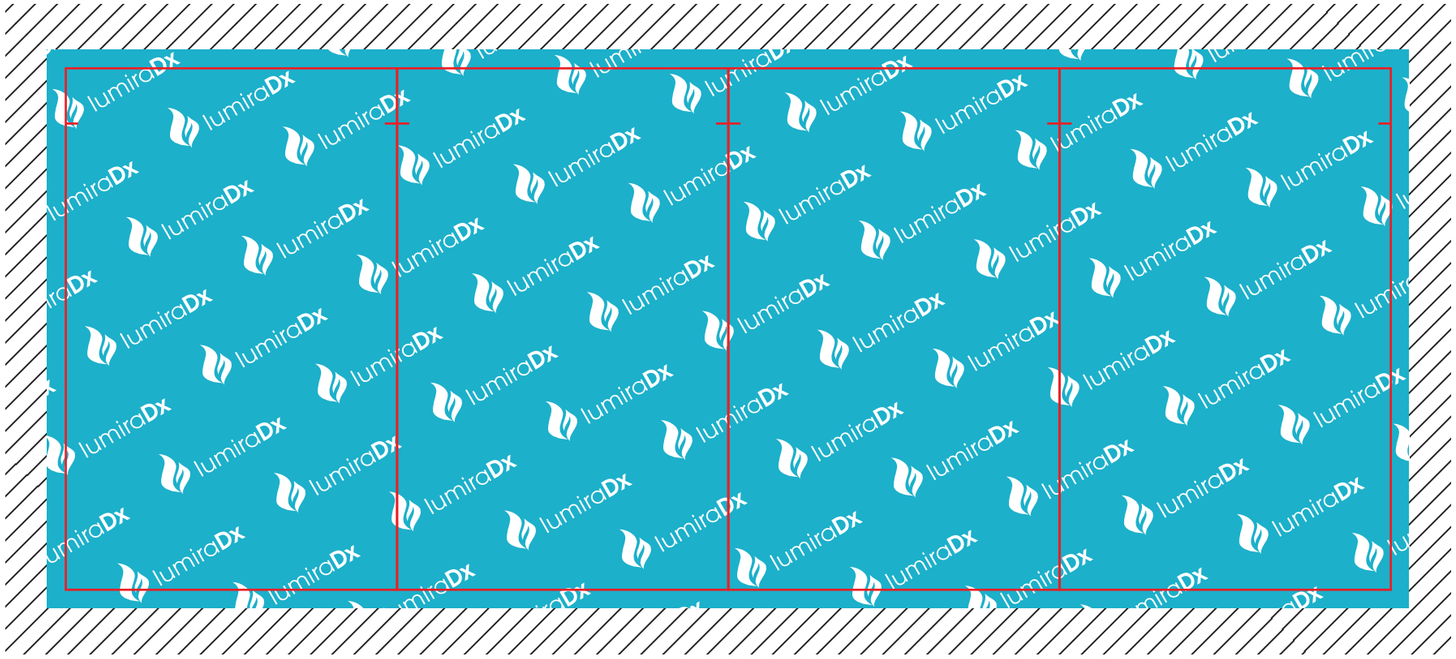
LumiraDx UK Ltd
Dumyat Business Park
Alloa FK10 2PB, UK

SARS-CoV-2
Ag

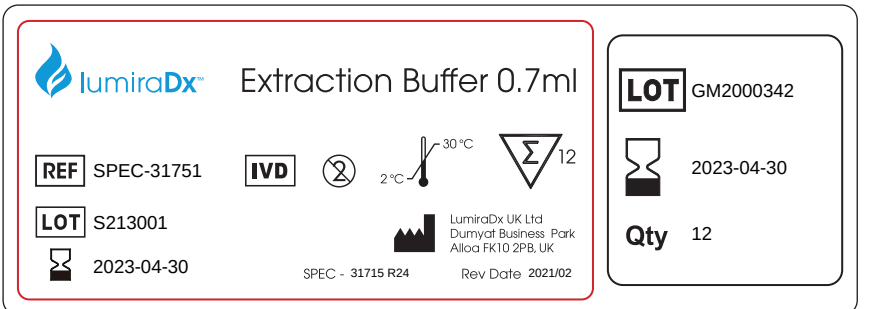
LOT IVD EC REP 2°C 30°C

LumiraDx AB Västra Vägen 5A
16961 Solna Sweden
SPEC-32058 Rev 2 Rev date 2020-11

LumiraDx UK Ltd
Dumyat Business Park
Alloa FK10 2PB, UK


lumiraDx

1.3 Foil pouch label


LumiraDx
Extraction Buffer 0.7ml
REF SPEC-31751
LOT S213001
2023-04-30
IVD
2 °C
30 °C
12
LumiraDx UK Ltd
Dumyat Business Park
Alloa FK10 2PB, UK
SPEC - 31715 R24
Rev Date 2021/02
LOT GM2000342
2023-04-30
Qty 12

1.4 Extraction buffer carton label

lumiraDx

Extraction Buffer

REF SPEC-31751

LOT 2023-04-30

S213001

Spec
Rev date

Extraction Buffer 0.7ml

REF SPEC-32381

IVD

2 °C 30 °C

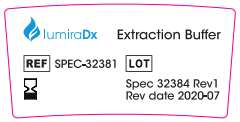
Σ 12

LOT

LumiraDx UK Ltd
Dumyat Business Park
Alloa FK10 2PB, UK

SPEC - 32383 Rev1 Rev Date 2020/07

1.5 Extraction buffer vial label


LumiraDx
Extraction Buffer
REF SPEC-32381 LOT
Spec 32384 Rev1
Rev date 2020-07

2.0 Instructions for use (IFU)[2]

2.1 IFU

[2] English version of the IFU was assessed by WHO. It is the responsibility of the manufacturer to ensure correct translation into other languages.

LumiraDx™ SARS-CoV-2 Ag - WHO

For Professional Use Only
For *In Vitro* Diagnostic Use Only **IVD**

SPEC-35850 R2 ART-02655 R2 Date of Rev 06/2022

Product Name	Product Description	REF	Σ
LumiraDx SARS-CoV-2 Ag Test Strip Kit WHO	(12 Tests / EN, FR, PT(EU))	L016000110012	12
LumiraDx SARS-CoV-2 Ag Test Strip Kit WHO	(24 Tests / EN, FR, PT(EU))	L016000110024	24
LumiraDx SARS-CoV-2 Ag Test Strip Kit WHO	(48 Tests / EN, FR, PT(EU))	L016000110048	48

ENGLISH 01 - 21

ENGLISH

LumiraDx™ SARS-CoV-2 Ag - WHO

For Professional Use Only
For *In Vitro* Diagnostic Use Only **IVD**

SPEC-35850 R2 ART-02655 R2 Date of Rev 06/2022

LumiraDx SARS-CoV-2 Ag Test

The LumiraDx Severe Acute Respiratory Syndrome (SARS) CoV-2 Antigen (Ag) Test Strips (hereafter referred to as Test Strips) are to be used with the LumiraDx Platform. The LumiraDx Platform is a point of care system for professional use which is used for *in vitro* diagnostic tests. It comprises a portable LumiraDx Instrument and a LumiraDx Test Strip for the required test. This test is for **HEALTHCARE PROFESSIONAL USE ONLY** and allows users to perform tests using small sample volumes and to view results quickly on the Instrument touchscreen.

Intended use:

The LumiraDx SARS-CoV-2 Ag test is a rapid microfluidic immunofluorescence assay for use with the LumiraDx Platform intended for the qualitative detection of the nucleocapsid protein antigen to SARS-CoV-2 in nasal swab samples. Samples are collected from individuals suspected of COVID-19 infection within the first twelve days of symptom onset or from asymptomatic individuals. The Test aids in the diagnosis of current SARS-CoV-2 infection by detection of SARS-CoV-2 antigen.

Positive results indicate the presence of viral antigens from infective virus, but clinical correlation with individual's history and other diagnostic information is necessary to confirm infection status.

Negative results do not rule out SARS-CoV-2 infection and should be considered in the context of an individual's recent exposures, history and presence of clinical signs and symptoms consistent with COVID-19.

Results should not be used as the sole basis for treatment or case management decisions, including infection control decisions.

The LumiraDx SARS-CoV-2 Ag test is intended for use by individuals trained in point of care settings and proficient in performing tests using the LumiraDx Platform.

Caution: For *in vitro* diagnostic use.

Before you start testing, if you are new to the LumiraDx Instrument and LumiraDx Platform, you must read the LumiraDx Platform User Manual, the LumiraDx SARS-CoV-2 Ag Test Quick Reference Instructions and this entire Product Insert. In addition, please watch the LumiraDx Platform Training Video. All these materials are available at **lumiradx.com.**

Summary and explanation of the Test:

The World Health Organisation (WHO) have named the disease caused by SARS-CoV-2 virus as coronavirus 2019 or COVID-191. The most common symptoms of COVID-19 are fever, tiredness, and dry cough. Some patients may have aches and pains, nasal congestion, headache, conjunctivitis, sore throat, diarrhoea, loss of taste or smell, or a rash on skin or discoloration of fingers or toes. These symptoms are usually mild and begin gradually. Some people become infected but do not develop any symptoms and do not feel unwell. However, the disease can develop rapidly and have high morbidity in certain populations, especially those with underlying health conditions. The disease can spread from person to person through small droplets from the nose or mouth which are spread when a person with COVID-19 coughs or exhales. Most estimates of the incubation period for COVID-19 range from 2-14 days2.

The use of a LumiraDx SARS-CoV-2 Ag Test will enable the physician to verify infection quickly, begin proper treatment and to initiate isolation precautions helping prevent further spread of infection.

Principle of the assay:

The LumiraDx SAR-CoV-2 Ag test is a single use fluorescence immunoassay device designed to detect the presence of the nucleocapsid protein antigen from SARS-CoV-2 in nasal swab samples.

The test procedure involves collecting a nasal swab sample using a recommended swab which is eluted into a vial containing Extraction Buffer. A single drop of the sample in Extraction Buffer is added to the Test Strip using the vial dropper cap provided. The LumiraDx Instrument is programmed to perform the test protocol using the dried reagents contained within the strip. The test result is determined from the amount of fluorescence the Instrument detects within the measurement zone of the Test Strip. The concentration of the analyte in the sample is proportional to the fluorescence detected. The results are displayed on the Instrument touchscreen within 12 minutes from the addition of the sample.

Material Provided	L016000110012 -LumiraDx SARS-CoV-2 Ag Test Strip Kit WHO (12 Tests / EN, FR, PT(EU))	L016000110024 - LumiraDx SARS-CoV-2 Ag Test Strip Kit WHO (24 Tests / EN, FR, PT(EU))	L016000110048 - LumiraDx SARS-CoV-2 Ag Test Strip Kit WHO (48 Tests / EN, FR, PT(EU))
LumiraDx Test Strips packed individually in sealed desiccant foil pouches.	12	24	48
LumiraDx Test Product Insert	1	1	1
RFID (Radio frequency ID) Tag held inside the Test Strip carton	1	1	1
Quick Reference Instructions	1	1	1
Extraction Buffer Vials	12	24	48
Dropper Lids	12	24	48

Materials required but not provided with the Test Strip carton:

- LumiraDx Instrument – Product code: L001000330001
- LumiraDx SARS-CoV-2 Ag Quality Controls (as required to meet local and organisational compliance) – Product code: L016080101002
- LumiraDx Connect if connectivity required (refer to LumiraDx Connect User Manual) – Product code: L002040201001
- Standard nasal swab collection equipment. Below is a list of commercially available swabs recommended by LumiraDx. The use of nasal swab collection kits that are not listed in this product insert are not recommended by LumiraDx

Nasal Swabs:

- Copan Nasal FLOQSwab™ Regular (Supplier Product Code: 502CS01)
- Copan eSwab (Supplier Product Code: 490CE.A)
- Copan Regular PL/Swab NY/VEL Drytube (Supplier Product Code: 552C)
- Copan REGULAR APPL.NYLON PF100 (Supplier Product Code: 519CS01)
- Copan FLOQswab Regular Tip (Supplier product code: 519C)
- Puritan HydraFlock™ Sterile Standard Flock Swab(Supplier Product Code:25-3306-H)
- Puritan HydraFlock™ Sterile Standard Flock Swab(Supplier Product Code:25-3506-H)
- Aspen Surgical Polyester Swab (supplier product code: 20200062)
- SteriPack™ Sterile Polyester Spun Swab (Supplier Product Code: 60564REVA)
- mwe medical wire DrySwab™ Rayon Swab (Supplier Product Code: MW112)
- Kang Jian™ Virus Collection Swab (Supplier Product Code: KJ502-19)
- Nerbe Plus dry swab (Supplier Product Code: 09-511-5017)
- Nerbe Plus PS Stick (Supplier Product Code: 09-812-8053)
- Plast Labor 06913 Swab Haste Plastica Ponta Rayon Estéril Embalagem Indv (Supplier Product Code: 50X100)
- Citotest Citoswab (Supplier Product Code: 2122-0008)
- Gongdong Disposable Sterile Swab (Supplier Product Code: G1029FT77)
- OPT Industries InstaSwab™ Nasal (Anterior) (Supplier Product Code: INS-T4BAA)

Warnings and precautions

- For *in vitro* diagnostic use only
- Do not open the test strip until ready for immediate use.
- Discard and do not use any damaged or dropped Test Strips or other materials.
- Inadequate or inappropriate sample collection, storage, and transport can result in incorrect results.
- The test cannot be visually interpreted; the LumiraDx Instrument must be used to generate results.
- Do not use the kit components beyond the expiration date
- Do not reuse any kit components.
- Samples must be processed as indicated in the Sample Extraction and Performing a Test sections of this Product Insert. Failure to follow the instructions for use can result in inaccurate results.
- All components of this kit should be discarded as Biohazard waste according to local regulations and procedures.

- Exercise the normal precautions required for handling all laboratory reagents. Wear protective clothing such as laboratory coats, masks, disposable gloves, and eye protection when samples are collected and evaluated.
- Proper laboratory safety techniques should be followed at all times when working with SARS-CoV-2 patient samples. Patient swabs, used Test Strips and used Extraction Buffer vials may be potentially infectious. Proper handling and disposal methods should be established by the laboratory in accordance with local regulations and procedures.
- Do not mix and match components from other test kits
- For additional information on safety, handling, and disposal of the components within this kit, please refer to the Safety Data Sheet (SDS) located at lumiradx.com.

Storing the Test Strips:

Store the Test Strips in their original carton. You can store the Test Strips at a temperature between 2°C and 30°C (36°F and 86°F). Avoid freezing or storing in any area that could exceed 30°C. When stored properly, the Test Strips can be used until the expiration date printed on the Test Strip foil pouch and the Test Strip carton. Discard the Test Strips if they are passed the expiration date.

Handling the Test Strips:

When you are ready to perform a test, open the Test Strip carton, take out a Test Strip, and remove it from the foil pouch. After removing the Test Strip from the foil pouch, it should be used immediately. Do not use the Test Strip if there are any visible signs of damage to the foil pouch such as tears or holes.

Sample material:

The following samples can be used with the LumiraDx SARS-CoV-2 Ag Test Strip:

- Nasal Swab Sample (NS)

The Test device contains:

- Rabbit and mouse monoclonal antibodies
- Fluorescent particles
- Magnetic particles
- Buffer and stabilising agents

Preparing the Instrument to perform a Test:

Power on the Instrument by pressing the power button at the rear of the Instrument. You will hear the Instrument powering on, and the display will be a blank black screen for several seconds before starting up. If the screen is just dimmed tap the touch-screen to wake up the Instrument.

Refer to the section on **Performing a Test** in this Product Insert for information on how to test a Patient sample. The LumiraDx Quick Reference Instructions (QRI) provide an illustrated step-by-step procedure on how to run a Test. Operate the LumiraDx Platform at room temperature between 15°C and 30°C (59°F and 86°F) and 10% - 75% relative humidity.

The Instrument will prompt to install the Lot Calibration File when inserting a new Test Strip Lot. Once installed, the Instrument will have all the information required to process the test, and any future tests from the same Lot of Test Strips.

Lot Calibration File installation

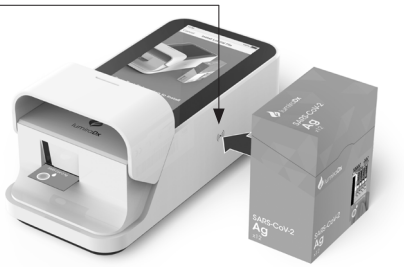
Lot Calibration Files are required to provide the instrument with the information needed to perform diagnostics tests. This only needs to be completed once for each Test Strip Lot. The instrument will prompt to install the Lot Calibration File when inserting a new Test Strip Lot.

RFID strip code reader

Locate ((•)) symbol on Instrument.

Installation

Touch back of Test Strip Carton ((•)) symbol to install.



The Instrument will sound and a confirmation message will be displayed.

When indicated by the touchscreen, open the foil pouch just before use and insert the LumiraDx Test Strip into the LumiraDx Instrument. The Instrument will indicate when it is ready for the sample to be applied.

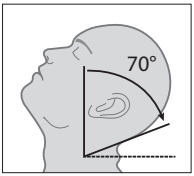
The LumiraDx SARS-CoV-2 Ag test results should be evaluated by a Healthcare Professional in the context of all available clinical and laboratory data.

Instructions for sample collection:

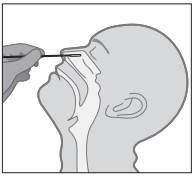
When collecting any type of sample, follow universal collection precautions and guidelines according to your organization. For collection of nasal swabs, follow appropriate Swab Collection Guidelines and swab manufacturers' recommendations. Users should be trained in appropriate sample collection and handling procedures.

The steps that follow apply to a nasal swab.

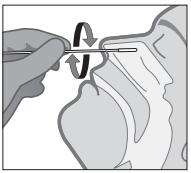
Sampling from a nasal swab:



1. Tilt patient's head back 70°



2. A swab sample is needed from both nostrils, and this is taken using the same swab. While gently rotating the swab, insert swab less than one inch into the first nostril until resistance is met at Turbinates. (Turbinates are the small structures inside the nose).

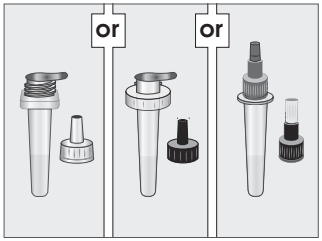


3. Rotate the swab several times against the nasal wall. Remove and repeat this process by using the same swab into the second nostril. Place swab in a dry, clean, and sterile tube or process the swab directly in the extraction buffer vial as per instructions for sample extraction of samples outlined below

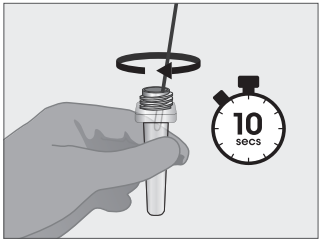
After patient swabbing, process the Swab in the Extraction Vial as soon as possible or place in a clean, dry and sterile tube for up to 1 hour before processing the extraction buffer.

Do not place the swab back into the swab packaging sleeve after sample collection.

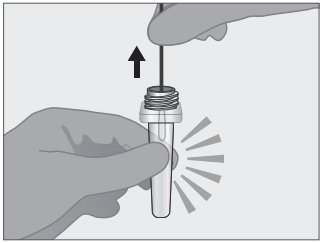
Instructions for sample extraction:



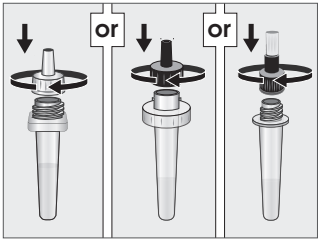
1. **Remove the seal or blue screw cap** from the top of the Extraction Vial containing the Extraction Buffer.



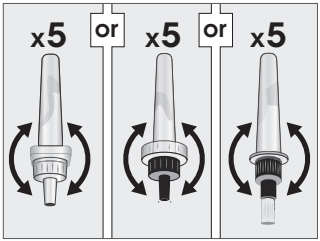
2. **Place and soak the Patient Swab** in the Extraction Buffer for 10 seconds and then stir well by rotating the swab against the side of the vial 5 times.



3. **Squeeze Swab** Remove the Patient Swab while squeezing the middle of the Extraction Vial to remove the liquid from the swab. Discard the swab in biohazard waste.



4. **Firmly attach the clear or purple Dropper Lid** to the top of the Extraction Vial. The extracted sample must be used within 5 hours of preparation when stored at room temperature. Extracted nasal swab samples may be frozen at -80°C and used up to 5 days after freezing.



5. **Gently invert the Extraction Vial** five times just before applying the sample to the Test Strip.

Performing a Test (refer to the Quick Reference Instruction to make sure that your instrument has been prepared before starting this step). If using a frozen sample, the sample must be at room temperature before testing.

1. **Gently invert** the Extraction Vial five times (5x) just before applying the sample to the Test Strip.
2. **Apply the extracted sample from the Extraction Vial** onto the Sample Application Area of the inserted Test Strip. To do this gently press the sides of the extraction vial until **one whole drop** is visible and allow it to touch the Sample Application Area of the Test Strip. The sample will then be drawn by capillary action into the Test Strip. When the sample is detected the Instrument will sound (if sounds are enabled) and a confirmation message will be displayed. The touchscreen of the LumiraDx Instrument will request the user to **immediately close the door (Note: you have 10 seconds only to close the door).**
3. **Do not add more than one drop of sample.** Do not open the door while the test is in progress. The touchscreen will indicate test progress.
4. **The result** will appear on the Instrument touchscreen within 12 minutes of applying the sample and starting the test. The results will be displayed as a **positive** or **negative result SARS-CoV-2 Ag** on the Instrument screen. (see Fig 1 and Fig 2).
5. **Dispose** of the swab, Extraction Vial and Test Strip in the appropriate clinical waste.
6. **Disinfection** of the Instrument with LumiraDx approved materials is recommended if contamination is suspected. Details of approved disinfecting materials are available at lumiradx.com. Allow the Instrument to air dry before testing the next sample. The disinfectant should remain in contact for at least 1 minute.
7. **If you need to retest,** you will use a new Test Strip. Use the same extraction vial and repeat the test. The extracted sample must be used within 5 hours of preparation when stored at room temperature. Extracted nasal swab samples may be frozen at -80°C and used up to 5 days after freezing.

Result interpretation:

The results will be displayed on the Instrument screen - **examples of result screen display:**

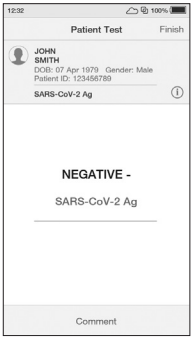


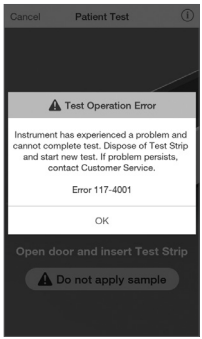
Fig 1: Negative result for SARS-CoV-2 Ag

Fig 2: Positive result for SARS-CoV-2 Ag

NOTE: A negative result, from patients with symptoms onset beyond twelve days, should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed.

Invalid test results

If an issue occurs, a message will be displayed on the Instrument touch-screen. Alert messages include useful information and are highlighted by an orange banner. Error messages also include a ⚠ symbol. All messages will contain a description of the Instrument status or error and an instruction. Error messages contain an identifying code that may be used for further troubleshooting purposes. Refer to the LumiraDx Platform User Manual if an error message is displayed on the LumiraDx Instrument touch-screen and contact LumiraDx Customer Services on customerservices@lumiradx.com



Example of an error screen:

If the On-Board Control (OBC) fails, an error message will be shown and no test result will be returned. Follow the on screen instructions to dispose of the Test Strip and start a new test. If the problem persists, contact Customer Services.

Built-in controls:

The instrument reads the 2D bar code on each Test Strip and can identify if the strip has exceeded the expiry date for use, and if the strip Lot Calibration file has not yet been loaded, at which point it will request it.

The LumiraDx Instrument and LumiraDx SARS-CoV-2 Ag test strips have several quality control functions integrated to ensure validity of each test run. These checks ensure that the volume of sample added is sufficient and the assay sequence of the Test Strip is as expected. The checks also ensure that the Test Strip has not been damaged or used previously. If these checks are not verified, the test run will be rejected and an error message displayed on the Instrument touchscreen.

The LumiraDx Instrument ensures the quality of test results obtained through the following features:

- Automated checks of the correct functioning of the Instrument at power on and during operation.
- This includes electrical component operation, heater operation, battery charge state, mechanical actuators and sensors and optical system performance.
- Monitoring of Test Strip performance and controls during test runtime.
- Ability to perform Quality Control Tests using LumiraDx Quality Control solutions to meet regulatory compliance requirements.

External Quality Controls:

External liquid Quality Controls for SARS-CoV-2 Ag are available from LumiraDx and may be used to demonstrate that the Test is functioning properly by demonstrating the expected Quality Control results and correct test performance by the operator.

External Quality Control requirements should be established in accordance with local, state, and federal regulations or accreditations requirements and/or by the user's quality control procedures. It is recommended that external control testing be performed with each new operator and before using a new lot or shipment of the LumiraDx SARS-CoV-2 Ag Test. Refer to the LumiraDx SARS-CoV-2 Ag Quality Controls pack insert available at lumiradx.com for detailed instructions.

LumiraDx SARS-CoV-2 Ag Quality Controls are purchased separately.

If the LumiraDx SARS-CoV-2 Ag Quality Controls do not perform as expected, repeat the QC Test and if the problems persists, do not report patient results and contact LumiraDx Customer Services.

Cleaning and disinfection

Cleaning and disinfection of the Instrument should follow and be performed according to established site protocols and schedules.

To clean the Instrument wipe the external surfaces with a soft, slightly damp cloth when it appears visibly dirty.

It is recommended to clean and disinfect the Instrument at least once per day if in use, or if contamination is suspected. Details of LumiraDx approved disinfectant materials can be found at lumiradx.com. Allow the Instrument to air dry before testing the next sample. The disinfectant should remain in contact for at least 1 minute.

Excessive liquid may damage the Instrument. It is important for the protection of the Instrument that exposure to excess moisture is prevented. All disinfection cloths and/or wipes should only be slightly damp, with any excess liquid being manually removed from the cloth before use.

Avoid USB ports and power inlet. Do not spray or pour solution directly onto the Instrument. Do not put any objects or cleaning materials into the Test Strip slot.

Limitations

- This test detects both viable (live) and non-viable, SARS-CoV and SARS-CoV-2. Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.
- Failure to follow the instructions for use may adversely affect test performance and/or invalidate the test result.
- Test results should be considered in the context of all available clinical and diagnostic information, including patient history and other test results.
- Positive test results do not differentiate between SARS-CoV and SARS-CoV-2.
- Negative test results are not intended to rule in other non-SARS viral or bacterial infections.
- Negative results, from patients with symptom onset beyond twelve days, should be treated as presumptive and confirmation with a molecular assay, if necessary for patient management, may be performed.
- If the differentiation of specific SARS viruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.
- Clinical performance was established on frozen samples and performance may be different with fresh clinical samples.
- Users should test samples as quickly as possible after sample collection.
- Extracted nasal samples may be frozen at -80°C and used up to 5 days after freezing. Samples may be used once after thawing.
- Swab samples and Extraction Buffer must be at room temperature before testing.
- Positive test results do not rule out co-infection with other pathogens
- A false negative result may occur if the level of viral antigen in a sample is below the detection limit of the test or if the sample was collected inappropriately, therefore a negative test result does not rule out the possibility of SARS-CoV-2 infection.
- The amount of antigen in a sample may decrease as the duration of illness increases. Samples collected after 12 days are more likely to be negative compared to RT-PCR.
- The contents of this kit are for qualitative detection of SARS-CoV-2 antigens from nasal swab samples only.

Clinical performance – Nasal Swab Subjects

The performance of the LumiraDx SARS-CoV-2 Ag test was established with 257 direct nasal swabs prospectively collected from individual subjects during the 2020 COVID-19 pandemic. Samples were collected from sequentially enrolled subjects who presented with symptoms of COVID-19 (159) or key workers (98) at increased risk of infection. No positive results were observed from patients without symptoms or beyond 12 days of symptom onset. Dual nasal swabs were simultaneously collected and then randomly allocated to testing with the LumiraDx test or the Roche Cobas 6800. Samples were collected from 6 sites across the United States (5) and United Kingdom (1), including four sites in which minimally trained operators collected and tested fresh samples.

Swabs were collected and extracted into the LumiraDx Extraction Buffer without transport media. Samples were tested fresh or frozen within 1h of collection and stored until tested. Samples were thawed and sequentially tested according to the Product Insert, with operators blinded to the PCR result. The performance of the LumiraDx SARS-CoV-2 Ag test was compared to the results from nasal swabs collected into 3ml universal transport medium (UTM) and tested with the Roche Cobas 6800 PCR method.

Patient demographics

Patient demographics (gender, age, time elapsed since onset of symptoms) are available for the 257 samples used in the study. The table below shows the positive results broken down by age of the patient:

Age	LumiraDx SARS-CoV-2 Ag		
	Total #	Positive	Prevalence
≤ 5 years	13	0	N/A
6 to 21 years	29	6	20.7%
22 to 59 years	200	70	35.0%
≥ 60 years	15	5	33.3%

Positive results broken down by days since symptom onset:

Days since symptom onset	Cumulative RT-PCR Positive(+)	Cumulative LumiraDx Positive(+)	PPA	95% Confidence interval	
				LCI	UCI
0	6	6	100.0%	61.0%	100.0%
1	12	12	100.0%	75.8%	100.0%
2	28	28	100.0%	87.9%	100.0%
3	37	37	100.0%	90.6%	100.0%
4	55	54	98.2%	90.4%	99.7%
5	61	60	98.4%	91.3%	99.7%
6	67	66	98.5%	92.0%	99.7%
7	73	72	98.6%	92.6%	99.8%
8	75	74	98.7%	92.8%	99.8%
9	75	74	98.7%	92.8%	99.8%
10	77	76	98.7%	93.0%	99.8%
11	80	79	98.8%	93.3%	99.8%
12	83	81	97.6%	91.6%	99.3%

Final data analysis is presented below:

Reference RT-PCR Assay							95% Wilson Score CI	
							LCI	UCI
LumiraDx SARS-CoV-2 Ag Test		POS	NEG	Total	PPA	97.6%	91.6%	99.3%
	POS	81	6	87	NPA	96.6%	92.7%	98.4%
	NEG	2	168	170	PPV	93.1%	85.8%	96.8%
	TOTAL	83	174	257	NPV	98.8%	95.8%	99.7%
					Prevalence	32.3%	26.9%	38.2%
					OPA	96.9%	94.0%	98.4%

100% positive agreement* was achieved with samples with cycle threshold values (ct) < 33 (*Roche Cobas 6800 SARS-CoV-2 reference method).

Evidence[3] suggests that patients with Ct values above 33-34 are no longer contagious. Published literature shows that RT- PCR Ct values from symptomatic and asymptomatic subjects are similar[4,5].

PPA - Positive Percent Agreement (Sensitivity)

NPA – Negative Percent Agreement (Specificity)

PPV – Positive Predictive Value
NPV- Negative Predictive Value
OPA – Overall Percent Agreement
CI - Confidence Interval
LCI – Lower Confidence Interval
UCI – Upper Confidence Interval

Clinical Performance –Asymptomatic Subjects

Clinical studies were continued to include asymptomatic and symptomatic positive individuals across sites in the United Kingdom, the United States and Norway*

The performance of the LumiraDx SARS-CoV-2 Ag test was established with direct nasal swabs prospectively collected from asymptomatic and symptomatic individual subjects during the 2020 COVID-19 pandemic. Samples were collected from 782 subjects in the US, UK and Norway (176 positive by PCR). Dual nasal swabs were simultaneously collected and then randomly allocated to testing with the LumiraDx test or the RT-PCR reference. Swabs were collected and extracted into the LumiraDx Extraction Buffer and tested fresh or frozen within 1h of collection and stored until tested. The performance of the LumiraDx SARS-CoV-2 Ag test was compared to the results from nasal swabs collected into 3ml universal transport medium (UTM) and tested with RT-PCR. Ct range = 15-38.

* SKUP (Scandinavian evaluation of laboratory equipment for point of care testing) independent evaluation of the LumiraDx SARS-CoV-2 Ag test. www.skup.org.

Grouping	Nasal Swabs				
	N	PPA	95% CI	NPA	95% CI
All Subjects	**782**	**93.8%**	**89.2-96.5**	**98.8%**	**97.6-99.4**
DSSO* ≤ 12	473	95.0%	90.4-97.4	98.4%	96.3-99.3
DSSO ≤ 10	465	95.4%	90.9-97.8	98.4%	96.3-99.3
DSSO ≤ 7	451	95.3%	90.6-97.7	98.3%	96.2-99.3
Ct < 33 (all)**	146	97.9%	94.1-99.3	-	-
Ct < 30 (all)	129	99.2%	95.7-99.9	-	-
Ct < 25 (all)	91	100%	95.9-100	-	-
Asymptomatic	309	82.4%	59.0-93.8	99.3%	97.5-99.8
Ct < 33 (asymptomatic)	13	100%	77.2-100	-	-

* DSSO = Days Since Symptom Onset

** Ct < [X] (all) = includes all subjects in the study (symptomatic and asymptomatic)

Analytical performance

Limit of Detection - LoD (Analytical sensitivity):

Limit of Detection (LoD) studies determined the lowest detectable concentration of SARS-CoV-2 at which 100% of all (true positive) replicates test positive. The LoD for the LumiraDx SARS-CoV-2 Ag test was established using limiting dilutions of gamma-irradiated SARS-CoV-2 (BEI Resources NR-52287). The NR-52287 is a preparation of SARS-Related Coronavirus 2 (SARS-CoV2), isolate USA WA1/2020, that has been inactivated by gamma-irradiation at 5 x 106 RADs. The material was supplied frozen at a concentration of 2.8 x 10^5 $TCID_{50}$/mL.

Limit of Detection (LoD) screening

An initial LoD screening study was performed using a 5-fold serial dilutions (six dilutions in total) of the gamma-irradiated virus made in pooled negative human nasal matrix starting at a test concentration of 2 x 10^4 $TCID_{50}$/mL (as shown in table below) and processed for each study as described above. These dilutions were tested in triplicate. The lowest concentration at which all (3 out of 3 replicates) were positive was chosen for LoD Range finding. This was 32 $TCID_{50}$/mL.

SARS-CoV-2 tested ($TCID_{50}$/mL)	Test result
20000	3/3 positive
4000	3/3 positive
800	3/3 positive
160	3/3 positive
32	3/3 positive
6.4	0/3 positive

Limit of Detection range finding:

Using the 32 $TCID_{50}$/mL concentration, the LoD was further refined using a 2-fold dilution series (four dilutions in total) of the gamma-irradiated SARS-CoV-2 virus made in pooled negative human nasal matrix.These dilutions were tested in triplicate. The lowest concentration at which all (3 out of 3 replicates) were positive was treated as the tentative LoD for the LumiraDx SARS-CoV-2 Ag test. This was 32 $TCID_{50}$/mL.

SARS-CoV-2 tested ($TCID_{50}$/mL)	Test result
32	3/3 positive
16	0/3 positive
8	1/3 positive
4	0/3 positive

Limit of Detection (LoD) confirmation:

The LoD of the LumiraDx SARS-CoV-2 Ag test was then confirmed by testing 20 replicates with concentrations at the tentative Limit of Detection. The final LoD of the LumiraDx SARS-CoV-2 Ag test was determined to be the lowest concentration resulting in positive detection of twenty (20) out of twenty (20) replicates. Based on this testing the LoD for nasal swab samples was confirmed as: 32 $TCID_{50}$/mL.

Starting Material Concentration	Estimated LoD	No. Positive/Total	% Positive
2.8 x 105 $TCID_{50}$/mL	32 $TCID_{50}$/mL	20/20	100

Cross-reactivity (analytical specificity) and microbial interference studies

Cross-reactivity and interference of the LumiraDx SARS-CoV-2 Ag test was evaluated by testing a panel of related pathogens, high prevalence disease agents and normal or pathogenic flora including various microorganisms and viruses and negative matrix that are reasonably likely to be encountered in the clinical sample and could potentially cross-react or interfere with the LumiraDx SARS CoV-2 Ag test. Each organism and virus were tested in the absence or presence of heat inactivated SARS-CoV-2 at 3 x LoD.

Microorganism	Source	Concentration	Cross-reactivity (Yes/No)	Interference (Yes/No)
Human coronavirus 229E	Zeptometrix	1 x 105 PFU/mL	No (3/3 negative)	No (3/3 positive)
Human coronavirus OC43	Zeptometrix	1 x 105 PFU/mL	No (3/3 negative)	No (19/20 positive)
Human coronavirus NL63	Zeptometrix	9.87 x 103PFU/mL	No (3/3 negative)	No (3/3 positive)
MERS coronavirus	Zeptometrix	7930 PFU/mL	No (2/2 negative)	No (3/3 positive)
Adenovirus (e.g. C1 Ad. 71)	Zeptometrix	1 x 105 PFU/mL	No (3/3 negative)	No (3/3 positive)
Human Metapneu-movirus (hMPV)	Zeptometrix	1 x 105 PFU/mL	No (3/3 negative)	No (3/3 positive)
Parainfluenza virus Type 1	Zeptometrix	1 x 105 PFU/mL	No (3/3 negative)	No (3/3 positive)
Parainfluenza virus Type 2	Zeptometrix	1 x 105 PFU/mL	No (3/3 negative)	No (3/3 positive)
Parainfluenza virus Type 3	Zeptometrix	1 x 105 PFU/mL	No (3/3 negative)	No (3/3 positive)
Parainfluenza virus Type 4a	Zeptometrix	1 x 105 PFU/mL	No (3/3 negative)	No (3/3 positive)
Influenza A H3N2 (Wisconsin/67/05)	Zeptometrix	8.82 x 104 PFU/mL	No (3/3 negative)	No (3/3 positive)
Influenza A H1N1	Zeptometrix	1 x 105 PFU/mL	No (3/3 negative)	No (3/3 positive)

Influenza B (Malaysia/2506/04)	Zeptometrix	2.92 x 104 PFU/mL	No (3/3 negative)	No (19/20 positive)
Enterovirus	Zeptometrix	1 x 105 PFU/mL	No (3/3 negative)	No (3/3 positive)
Respiratory syncytial virus	Zeptometrix	1 x 105 PFU/mL	No (3/3 negative)	No (3/3 positive)
Rhinovirus	Zeptometrix	4.17 x 105 PFU/mL	No (3/3 negative)	No (3/3 positive)
Haemophilus influenzae	Zeptometrix	1 x 106 CFU/mL	No (3/3 negative)	No (3/3 positive)
Streptococcus pneumoniae	Zeptometrix	1 x 106 CFU/mL	No (3/3 negative)	No (3/3 positive)
Streptococcus pyogenes	Zeptometrix	1 x 106 CFU/mL	No (3/3 negative)	No (3/3 positive)
Candida albicans	Zeptometrix	1 x 106 CFU/mL	No (3/3 negative)	No (3/3 positive)
Pooled human nasal wash	LumiraDx	14% v/v	No (3/3 negative)	No (3/3 positive)
Bordetella pertussis	Zeptometrix	1 x 106 CFU/mL	No (3/3 negative)	No (3/3 positive)
Mycoplasma pneumoniae	ATCC	1 x 106 CFU/mL	No (3/3 negative)	No (3/3 positive)
Chlamydia pneumoniae	ATCC	1 x 106 CFU/mL	No (3/3 negative)	No (3/3 positive)
Legionella pneumophila	Zeptometrix	1 x 106 CFU/mL	No (3/3 negative)	No (3/3 positive)
Mycobacterium tuberculosis	Zeptometrix	1 x 106 CFU/mL	No (3/3 negative)	No (3/3 positive)
Pneumocystis jirovecii	Zeptometrix	1 x 106 CFU/mL	No (3/3 negative)	No (3/3 positive)
Pseudomonas Aeruginosa	Zeptometrix	1 x 106 CFU/mL	No (3/3 negative)	No (3/3 positive)
Staphylococcus Epidermidis	Zeptometrix	1 x 106 CFU/mL	No (3/3 negative)	No (3/3 positive)
Streptococcus Salivarius	Zeptometrix	1 x 106 CFU/mL	No (3/3 negative)	No (3/3 positive)

To estimate the likelihood of cross-reactivity with SARS-CoV-2 of organisms that were not available for wet testing, *in silico* analysis using the Basic Local Alignment Search Tool (BLAST) managed by the National Center for Biotechnology Information (NCBI) was used to assess the degree of protein sequence homology.

- For Human Coronavirus HKU1, homology exists between the SARS-CoV-2 nucleocapsid protein and Human Coronavirus HKU1. BLAST results showed 30 sequence IDs, all nucleocapsid protein, showing homology. Sequence ID AGW27840.1 had the highest alignment score and was found to be 39.1% homologous across 76% of the sequences, this is relatively low but cross-reactivity cannot be fully ruled out.
- For SARS-Coronavirus, high homology exists between the SARS-CoV-2 nucleocapsid protein and SARS-Coronavirus. BLAST results showed 68 sequence IDs, mostly nucleocapsid protein, showing homology. Sequence ID AAR87518.1, had the highest alignment score isolated from a human patient and was found to be 90.76% homologous across 100% of the sequence. This is high and cross-reactivity is likely.
- For MERS-Coronavirus, high homology exists between the SARS-CoV-2 nucleocapsid protein and MERS-Coronavirus. BLAST results showed at least 114 sequence IDs, mostly nucleocapsid protein, showing homology. Sequence IDs AHY61344.1 and AWH65950.1, had the highest alignment scores isolated from a human patient and were found to be 49.4% and 50.3% homologous across 88% of the sequence. Whilst this potentially represents moderate cross-reactivity testing of the MERS virus at 7930 PFU/mL showed no reactivity (see table above).

Endogenous interference studies

A study was performed to demonstrate that potentially interfering substances that may be found in the upper respiratory tract in symptomatic subjects (including over the counter medications) do not cross-react or interfere with the detection of SARS-CoV-2 in the LumiraDx SARS-CoV-2 Ag test. Each substance was tested in triplicate in the absence or presence of SARS-CoV-2 at 3 x LoD.The final concentration of the substances tested are documented in the following table.

Interfering substance	Concentration	Interference (Yes/No)
Benzocaine	150 mg/dL	No (3/3 Negative, 3/3 Positive)
Blood (human)	5%	No (3/3 Negative, 3/3 Positive)
Mucin	5 mg/mL	No (3/3 Negative, 3/3 Positive)
Naso GEL (NeilMed)	5% v/v	No (3/3 Negative, 3/3 Positive)
CVS Nasal Drops (phenylephrine)	15% v/v	No (3/3 Negative, 3/3 Positive)
Afrin (Oxymetazoline)	15% v/v	No (3/3 Negative, 3/3 Positive)
CVS Nasal Spray (Cromolyn)	15% v/v	No (3/3 Negative, 3/3 Positive)
Zicam Cold Remedy	5% v/v	No (3/3 Negative, 3/3 Positive)
Homeopathic (Alkalol)	10 % v/v	No (3/3 Negative, 3/3 Positive)
Sore Throat Phenol Spray	15% v/v	No (3/3 Negative, 3/3 Positive)
Tobramycin	3.3 mg/dL	No (3/3 Negative, 3/3 Positive)
Mupirocin	0.15 mg/dL	No (3/3 Negative, 3/3 Positive)
Fluticasone	0.000126 mg/dL	No (5/5 Negative, 4/4 Positive)
Tamiflu (Oseltamivir phosphate)	500 mg/dL	No (3/3 Negative, 3/3 Positive)
Budesonide	0.00063 mg/dL	No (3/3 Negative, 3/3 Positive)
Biotin	0.35 mg/dL	No (3/3 Negative, 3/3 Positive)
Methanol	150 mg/dL	No (19/20 Negative, 3/3 Positive)
Acetylsalicylic Acid	3 mg/dL	No (3/3 Negative, 3/3 Positive)
Diphenhydramine	0.0774 mg/dL	No (3/3 Negative, 3/3 Positive)
Dextromethorphan	0.00156 mg/dL	No (19/20 Negative, 3/3 Positive)
Dexamethasone	1.2 mg/dL	No (3/3 Negative, 3/3 Positive)
Mucinex	5%	No (3/3 Negative, 3/3 Positive)

High dose hook effect

High Dose Hook Effect studies determine the level at which false negative results can be seen when very high levels of target are present in a tested sample. To determine if the LumiraDx SARS-CoV-2 Ag test suffers from any high dose hook effect, increasing concentrations of gamma-irradiated SARS-CoV-2 virus (BEI Resources NR-52287) were tested up to a concentration of 1.4 x 105 $TCID_{50}$/mL. In this study, the starting material was spiked into a volume of pooled human nasal matrix obtained from healthy donors and confirmed negative for SARS-CoV-2. At each dilution, 50 µL samples were added to swabs and the swabs processed for testing on the LumiraDx SARS-CoV-2 Ag test as per the Product Insert using the procedure appropriate for patient nasal swab samples.

No impact on test performance or high dose hook effect was observed up to 1.4 x 105 $TCID_{50}$/mL of gamma-irradiated SARS-CoV-2 with the LumiraDx SARS-CoV-2 Ag test.

Test Dilution	Concentration ($TCID_{50}$/mL)	Mean Signal (ADC Units)
1	0	495
2	62.5	26100.6
3	250	63013.8
4	1000	83451.8
5	1.4×10^5	86220

Point of Care Use

The LumiraDx SARS-CoV-2 Ag test was used by 8 untrained users in 4 sites across the United States. Untrained users tested 132 patients and ran 148 tests.

References:

1. World Health Organisation www.who.int
2. Centers for Disease Control and Prevention www.cdc.gov
3. La Scola B, Le Bideau M, Andreani J, et al. Viral RNA load as determined by cell culture as a management tool for discharge of SARS-CoV-2 patients from infectious disease wards. *Eur J Clin Microbiol Infect Dis.* 2020;39(6):1059-1061
4. Kissler, SM., et al., Viral dynamics of SARS-CoV-2 infection and 1 the predictive value of repeat testing https://www.medrxiv.org/content/10.1101/2020.10.21.20217042v1
5. Lavezzo E., et al., Suppression of a SARS-CoV-2 outbreak in the Italian municipality of Vo'. Nature 584, 2020: 425–429

Symbols glossary

Symbol	Meaning
	Temperature limitation
	Manufacturer
	*In vitro* diagnostic medical device
	Catalogue Number
	Lot Number
	Use-by Date – indicates the date after which the unopened IVD/Quality Control Material cannot be used
	Refer to Instructions for Use
	Do Not Re-use
	For near patient testing
	"CE Mark ".This product fulfils the requirements of the European Directive 98/79/EC on *in vitro* diagnostic medical devices.
	Indicates the presence of the Radio Frequency Identification (RFID) reader/ tag.
	Contains sufficient for 12 **or** 24 **or** 48 Tests
	Indicates a carrier that contains unique device identifier information.

LumiraDx customer services:

For product enquiries please contact LumiraDx Customer Services at customerservices@lumiradx.com or find telephone contact details at lumiradx.com.

Any adverse results experienced with the use of this product, and/or quality problems should also be reported to LumiraDx Customer Services by email: customerservices@lumiradx.com or at lumiradx.com.

For return policy

If there is a problem with the **LumiraDx SARS-CoV-2 Ag test strips** you may be asked to return them. Before returning tests please obtain a return authorization number from LumiraDx Customer Services. This return authorization number must be on the shipping carton for return. For ordinary returns following purchase, please contact LumiraDx Customer Services for terms and conditions.

Limited warranty

LumiraDx SARS-CoV-2 Ag test strips – As per shelf life.

Unused strips must be stored according to the required storage conditions as printed in this product insert and they can be used only up to the expiry date printed on the Test Strip pouch and Test Strip box. For the applicable warranty period, LumiraDx warrants that each product shall be (i) of good quality and free of material defects, (ii) function in accordance with the material specifications referenced in the product insert, and (iii) approved by the proper governmental agencies required for the sale of products for their intended use (the "limited warranty"). If the product fails to meet the requirements of the limited warranty, then as customer's sole remedy, LumiraDx shall either repair or replace, at LumiraDx's discretion, the Test Strips. Except for the limited warranty stated in this section, LumiraDx disclaims any and all warranties, express or implied, including but not limited to, any warranty of merchantability, fitness for a particular purpose and non-infringement regarding the product. LumiraDx's maximum liability with any customer claim shall not exceed the net product price paid by the customer. Neither party shall be liable to the other party for special, incidental or consequential damages, including, without limitation, loss of business, profits, data or revenue, even if a party receives notice in advance that these kinds of damages might result. The Limited Warranty above shall not apply if the customer has subjected the LumiraDx SARS-CoV-2 Ag test to physical abuse, misuse, abnormal use, use inconsistent with the LumiraDx Platform User Manual or Product Insert, fraud, tampering, unusual physical stress, negligence or accidents. Any warranty claim by Customer pursuant to the Limited Warranty shall be made in writing within the applicable Limited Warranty period.

Intellectual property:

The LumiraDx Instrument, Test Strips and all provided LumiraDx documentation ('Products') are protected by law. The Intellectual Property of the LumiraDx Products remains at LumiraDx. Details of relevant Intellectual Property regarding our products can be found at lumiradx.com/IP.

Legal notices:

Manufacturer information:

LumiraDx UK Ltd
Dumyat Business Park, Alloa
FK10 2PB, United Kingdom
Registration number: 09206123

CE Mark applies to LumiraDx Instrument, Test Strips, Quality Controls, and Connect Hub only

EC REP LumiraDx AB, Västra Vägen 5A, 16961 Solna, Sweden

SPEC-35850 R2 ART-02655 R2 Date of rev 06/2022

2.2 Quick Reference Instructions

lumiraDx™ SARS-CoV-2 Ag Test

WHO Quick Reference Instructions

For *in vitro* diagnostic use

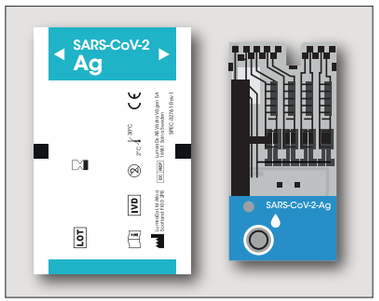
ART-02654 R1 SPEC-35849 R1 Date of rev 06/2022

Product Name	Product Description	REF	▽
LumiraDx SARS-CoV-2 Ag Test Strip Kit WHO	(12 Tests / EN, FR, PT(EU))	L016000110012	12
LumiraDx SARS-CoV-2 Ag Test Strip Kit WHO	(24 Tests / EN, FR, PT(EU))	L016000110024	24
LumiraDx SARS-CoV-2 Ag Test Strip Kit WHO	(48 Tests / EN, FR, PT(EU))	L016000110048	48

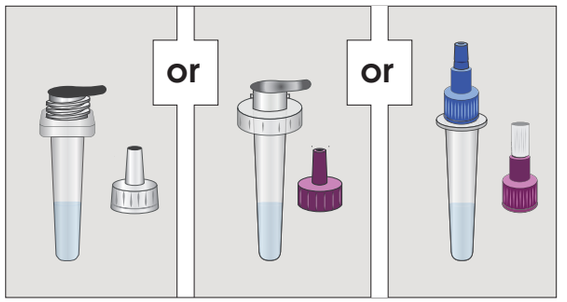
Warning and Precautions:
All kit components can be discarded as biohazard waste according to local guidelines. Refer to the product safety data sheet for risk and safety phrases and disposal information. The product safety data sheet is available at lumiradx.com. Exercise the normal precautions required for handling all laboratory reagents. Proper laboratory safety techniques should be followed at all times when working with SARS-CoV-2 patient samples. Patient swabs, used Test Strips and used extraction buffer vials may be potentially infectious. Proper handling and disposal methods should be established by the laboratory in accordance with local, state and federal regulations.

LumiraDx SARS-CoV-2 Ag Test Kit Components

Test Strip



Extraction Vial and Dropper Lids



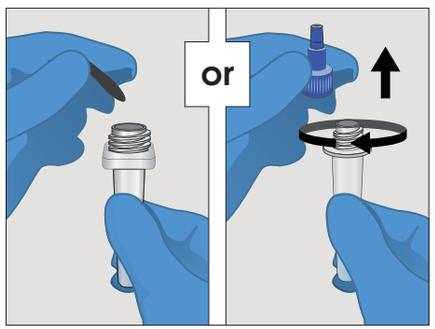
The LumiraDx SARS-CoV-2 Ag test is a rapid microfluidic immunofluorescence assay for use with the LumiraDx Platform intended for the qualitative detection of the nucleocapsid protein antigen to SARS-CoV-2 in nasal swab samples. Samples are collected from individuals suspected of COVID-19 infection within the first twelve days of symptom onset or from asymptomatic individuals. The Test aids in the diagnosis of current SARS-CoV-2 infection by detection of SARS-CoV-2 antigen.

Study the **LumiraDx Platform User Manual** and **LumiraDx SARS-CoV-2 Ag Product Insert** thoroughly before using these **Quick Reference Instructions** or performing a test. This is not a complete package insert.

Operate the LumiraDx Platform at room temperature between 15°C and 30°C (59°F and 86°F) and 10% - 75% relative humidity. The extracted sample must be used within 5 hours of preparation when stored at room temperature. Extracted nasal swab samples may be frozen at -80°C and used up to 5 days after freezing. Samples may be used once after thawing. Samples and extraction buffer must be at room temperature before testing. Check expiration date on outer test kit carton and each individual test package before using. **Do not use any test beyond its expiration date.** Refer to the LumiraDx SARS-CoV-2 Ag Product Insert for Sample Collection, Warning and Precautions, and Limitations.

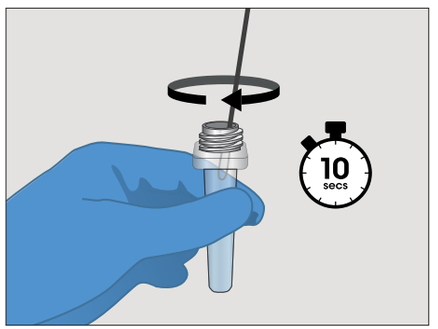
Preparing the sample

Collect a patient swab sample before following steps 1 – 4 of **Running the Test.**
Sample Collection and Handling: Proper sample collection and handling of nasal swabs is required to ensure accurate results (refer to product insert). Additional training or guidance is recommended if operators are not experienced with sample collection and handling procedures.



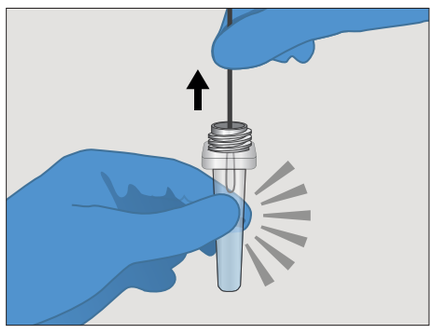
Remove seal

Remove the seal or blue screw cap from top of **Extraction Vial** containing the **Extraction Buffer**.



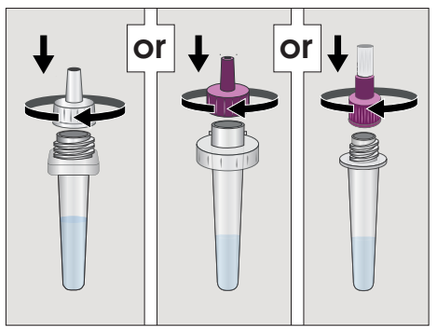
Soak Swab

Place and soak the **Patient Swab** in the **Extraction Buffer** for 10 seconds, then stir well by rotating the swab against the side of the vial 5 times.



Squeeze Swab

Remove the **Patient Swab** while squeezing the **Extraction Vial** to remove the liquid from the swab. Discard the swab in biohazard waste.



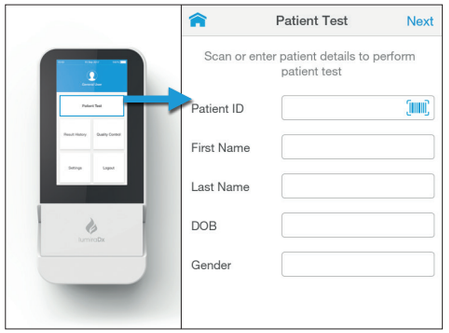
Attach Dropper Lid

Firmly attach the clear or purple **Dropper Lid** to the top of the **Extraction Vial. The extracted sample must be used (see Step 5 and 6 below) within 5 hours when stored at room temperature.**

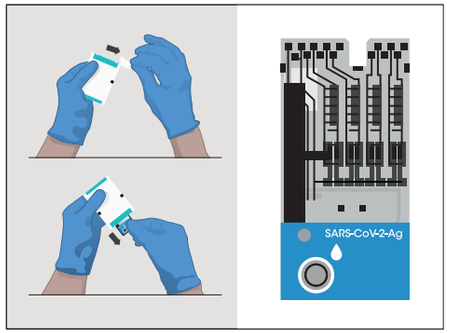
Cleaning and Disinfecting

Wipe the external surfaces of the LumiraDx Instrument with a soft, slightly damp cloth when it appears visibly dirty. It is recommended to clean and disinfect the Instrument if contamination is suspected and at least once per day when in use with LumiraDx approved materials. Details of LumiraDx approved disinfectant materials can be found at lumiradx.com. Allow the Instrument to air dry before testing the next sample. The disinfectant should remain in contact for at least 1 minute. **Avoid USB ports and power inlet. Do not spray or pour solution directly onto the Instrument. Do not put any objects or cleaning materials inside the Test Strip slot.**

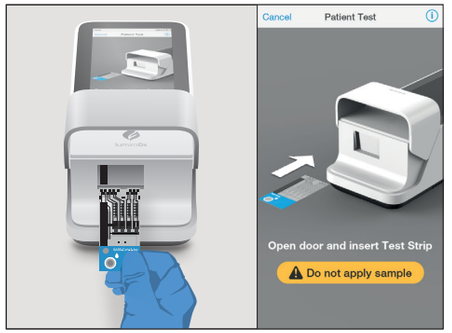
Running the Test



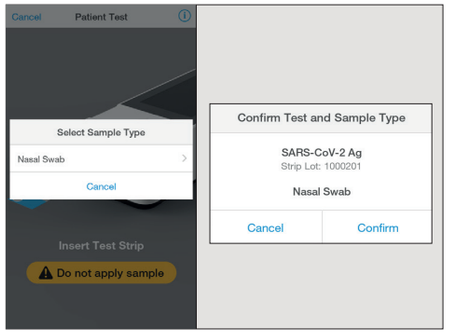
1. Select *Patient Test* from the **Instrument** *Home Screen* and enter patient details using the **Keyboard** or **Barcode Scanner**. See section 10 of the **Platform User Manual** for instructions on using the **Barcode Scanner.**



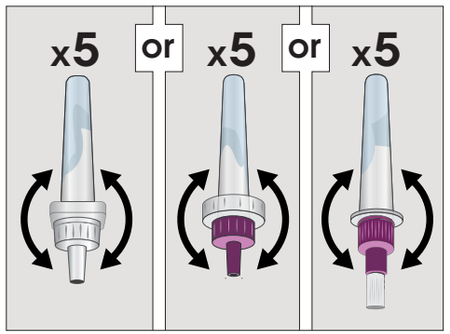
2. Remove the **Test Strip** from its pouch and hold by gripping only the blue portion. **Do not bend the Test Strip or touch any part other than the blue portion.**



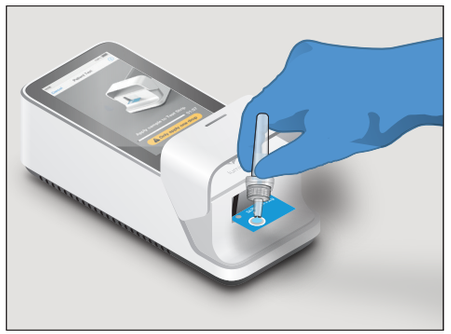
3. When prompted, open the **Instrument** door and gently insert the **Test Strip** as far as it will go. The thick black alignment rib on the **Test Strip** should be on the left and line up with the black line on the **Instrument. Do not apply the sample until prompted.** Install the Lot Calibration file if using a new **Test Strip Lot** for the first time. See section 2.8 of the **Platform User Manual.**



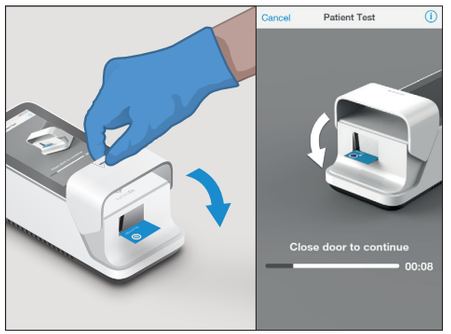
4. Select the appropriate sample type and confirm the test type.



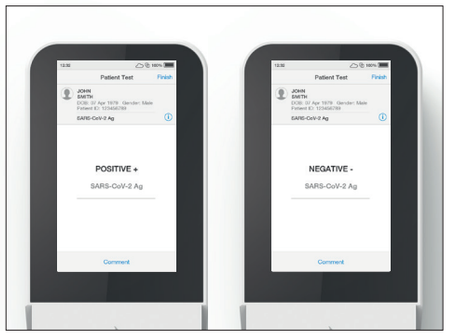
5. Gently invert the **Extraction Vial** five times before applying the sample to the **Test Strip**.



6. Apply **one whole drop** of the sample onto the **Test Strip Sample Application Area** when prompted by the **Instrument.**



7. Close the door when prompted to continue the test.



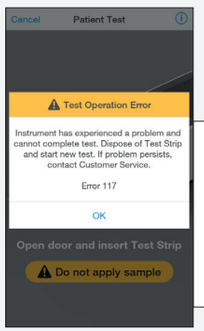
8. Results are displayed within 12 minutes of applying the sample. The left-hand image here shows a positive result for SARS-CoV-2 Ag and the right-hand image shows a negative result for SARS-CoV-2 Ag. Tap *Finish* to complete testing or tap *Comment* to leave a comment or to reject the Test, then follow prompts to return to the *Home Screen*. All test results must be read using the LumiraDx Instrument.

INTERPRETATION OF RESULTS

Positive results indicate the presence of viral antigens from infective virus, but clinical correlation with individual's history and other diagnostic information is necessary to confirm infection status.

Negative results do not rule out SARS-CoV-2 infection and should be considered in the context of an individual's recent exposures, history and presence of clinical signs and symptoms consistent with COVID-19.

Invalid results – If an issue occurs, a message will be displayed on the Instrument touch-screen. Alert messages include useful information and are highlighted by an orange banner. Error messages also include a ⚠ symbol. All messages will contain a description of the Instrument status or error and an instruction. Error messages contain an identifying code that may be used for further troubleshooting purposes.



⚠ **Example of an error screen:**
If the On Board Control (OBC) fails, an error message will be shown and no test result will be returned. Follow the on screen instructions to dispose of the Test Strip and start a new test. If the problem persists, contact Customer Services.

Quality Controls

To complete Quality Control assessment of the LumiraDx Instrument and SARS-CoV-2 Ag Test Strips, you must use the LumiraDx SARS-CoV-2 Ag Quality Control Pack which are available separately. If the LumiraDx Antigen Quality Controls do not perform as expected, do not report patient results. Retest using a new Test Strip – if problems persist contact LumiraDx Customer Services.

Customer Services

If the **LumiraDx SARS-CoV-2 Ag Test** or the **LumiraDx Instrument** do not perform as expected, contact LumiraDx Customer Services via **lumiradx.com** or **customerservices@lumiradx.com**

Manufacturer Information

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Registration Number: 09206123