NHS SUPPLY CHAIN FRAMEWORK AGREEMENT FOR THE SUPPLY OF GOODS AND SERVICES

Order Form

Pathology and Point of Care Testing, Associated Equipment, Instruments, Consumables, Accessories, and Managed Services Framework.

OJEU REF - 2019/S 212-519575

Contract number/reference/date: C102500/9th September 2022

The Parties:

(1) LumiraDx UK Limited registered in the United Kingdom no. 09206123 and having its registered office at Unit 2, 22 East Muirlands Road, Arbroath, DD11 3ES (the "**Supplier**"); and

(2) The Secretary of State for Health and Social Care as part of the Crown acting through the UK Health Security Agency, Nobel House, 17 Smith Square, London, SW10 3HX (the "**Authority**").

Whereas:

(A) The Parties hereto have entered into the Contract.

(B) This Schedule is entered into pursuant to the Contract.

It is agreed:

1. Contract

The Contract shall comprise the following terms in the following order of precedence:

1. This Order Form and its appendices;
2. The terms set out at the front end of this Contract;
3. The Call-off Terms and Conditions which are appended to the Framework Agreement (Pathology and Point of Care Testing, Associated Equipment, Instruments, Consumables, Accessories, and Managed Services. OJEU REF - 2019/S 212-519575) (including its Schedules) as Appendix 3a;
4. The Specification; and
5. The Framework Agreement (including its Schedules).

Any purchase order issued by the Authority in respect of this Contract does not form part of this Contract.

2. The Goods

2.1 The Authority shall be entitled to buy the goods set out below (the "Goods") subject to ordering of Goods as set out in Section 7 of this Order Form.

Pricing Product Code	Product Description
L0160000101048	LumiraDx SARS-CoV-2 Ag Test Strip Kits (48 tests per kit)
L019000201048	LumiraDx SARS-CoV-2 & Flu A/B Test Strip Kits (48 tests per kit)
L016000502048	LumiraDx SARS-CoV-2 Ag Ultra (48 tests per kit)
L016080101002	LumiraDx SARS-COV-2 Liquid Control Solution (2 sets/pack)

2.2 The Goods shall be supplied in accordance with their respective specifications as set out in Appendix C ("**Supplier**

Specifications").

3. Contract Period and Termination

3.1 This Contract shall be deemed to have commenced on 19 September 2022 (the **"Commencement Date"**) and shall, unless terminated earlier, or extended, in accordance with its terms, expire on 31st March 2023 (the **"Term"**).

3.2 Without prejudice to any other right of termination set out in this Contract, the Authority shall be entitled to pause or terminate this contract, in whole or in part, for convenience by giving the Supplier not less than four (4) weeks' notice in writing.

4 Price of Goods

4.1 Subject to Clause 7.3, the maximum value of the Goods that can be ordered under this Contract is eight million two hundred and seventy-five thousand and thirty-five pounds (£8,275,035) (the **"Contract Price"**).

4.2 Unit prices for the Goods are contained in Appendix A of this Order Form. For the avoidance of doubt the Authority is only committed to pay part of the Contract Price as set out in section 7.

4.3 The Contract Price excludes VAT at the applicable rate but is inclusive of freight and delivery charges.

5 Delivery and Risk:

5.1 The Supplier shall deliver agreed quantities of the goods to locations as detailed at Appendix B or as otherwise directed by the Authority (the "**Delivery Locations**")

5.2 All planned deliveries shall be pre-advised by the Supplier to the Authority's primary delivery contact and the additional delivery contact stated below (individually or collectively being known as the "**Delivery Contact**") not less than 48 hours prior to shipping:

5.2.1 Primary delivery [redacted]

5.2.2 Additional delivery contact: [redacted]

5.3 The Supplier shall provide the following data when notifying the Delivery Contact:

5.3.1 Supplier name;

5.3.2 Authority's PO number;

5.3.3 Item reference, Supplier's part code, description and quantity;

5.3.4 Item / pallet / carton reference for multi-pallet / carton shipments; and

5.3.5 Full detailed despatch / pack list at item level and any special instructions originally entered for Authority's Order (e.g. project).

5.4 The Delivery Contact will confirm:

5.4.1 Booking reference number;

5.4.2 Date and time of delivery slot (where applicable); and

5.4.3 Delivery address.

5.5 The Supplier shall ensure that all Goods are labelled with the, product description, part number, volume, batch number, storage requirements and barcode.

5.6 Delivery of the Goods shall be considered to have occurred when the Delivery Contact or other authorised

representative of the Authority at the Authority's nominated location has signed the delivery note confirming receipt.

5.7 Risk will pass to the Authority on the Goods in accordance with clause 2 (Delivery of the Goods and passing of risk and ownership of the Goods) of the Call Off Terms and Conditions.

5.8 Time is of the essence as to any delivery dates under the Contract and if the Supplier fails to meet any delivery date this shall be deemed to be a breach incapable of remedy for the purposes of Clause 15.4 of the Call-Off Terms and Conditions.

5.9 The Authority may refuse unscheduled deliveries. In such event, the Supplier shall rearrange delivery utilising the delivery process set out in this Clause 5.

6 Return Conditions

The Return Conditions shall be as follows:

6.1 The Supplier is responsible for collecting the Goods.

6.2 The Supplier is responsible for the costs of returning/collecting the Goods.

6.3 Return Conditions shall be in accordance with Schedule 2 - clause 3 (Inspection, rejection, return and recall of the Goods) of the Call Off Terms and Conditions.

7 Supplementary Conditions and Key Provisions

7.1 In the event that Goods are deemed to be Defective Goods by the Authority, the Authority, at its sole discretion, shall provide a written request or written notice to the Supplier in accordance with Schedule 2, clause 4.7 of the Call-Off Terms and Conditions.

7.2 **Ordering Process:**

7.2.1 Following execution of the Contract, the Authority shall submit to the Supplier a purchase order for the sum of (£8,275,035 Excl. VAT), the amount of which shall be the maximum value of Goods which can be ordered during the Contract Period (the **"Purchase Order"**). Thereafter, the Goods shall be called off by the Authority against the Purchase Order in accordance with the ordering process in this Clause 7.2. The Purchase Order shall not form part of the Contract.

7.2.2 The Parties agree that the period of 4 WEEKS is adequate notice.

7.2.3 Where the Authority provides the Supplier with an order pursuant to clause 7.2.2. above with notice that is not less than the period specified in clause 7.2.3 above then the Supplier shall fulfil such call off order. The Authority shall use the committed spend set out in clause 7.2.2 paragraph 1 in full prior to utilising the non-committed spend solely at the Authority's option).

7.2.4 Where the Authority provides the Supplier with a call off order pursuant to clause 7.2.2. above with notice that is less than the period specified in clause 7.2.3 above then the Supplier shall use its reasonable endeavours to fulfil such call off order in whole, and where the Supplier is not able to fulfil in whole in part, in the timeframe specified by the Authority.

7.2.5 Where the Authority's call off order made pursuant to clause 7.2.5. has been in the Supplier's possession for a period not less than that set out in clause 7.2.3. above the Supplier shall treat such call off order as if the Authority had submitted it pursuant to clause 7.2.4. accordingly.

7.2.6 The Supplier shall, as per the Authority's request, deliver the allocated amount to the relevant designated laboratory or laboratories on the specified Delivery Date(s).

7.2.7 The Supplier shall provide [redacted] with the delivery notes on dispatch of each allocated amount with unique reference numbers.

7.2.8 The Supplier shall provide [redacted] with a consolidated summary of the delivered allocated amounts on a monthly basis to allow verification of invoices and proof of delivery at each Delivery Location.

7.2.9 The Supplier shall not accept any requests under this Contract, made directly to the Supplier, by the Delivery Locations, including but not limited to any variance to the weekly delivery.

7.2.10 The Supplier shall provide monthly delivery information, as defined by the Authority, of all Delivery Sites via spreadsheet and, in line with the Authority's requirement of all Suppliers.

7.2.11 In the event of an error of the system that results in the loss of Goods that is not a result of Authority operator negligence the Supplier shall replace lost materials free of charge.

7.2.12 Subject to Clauses of this Order Form, the Authority shall be entitled to order the Goods, and the Supplier shall provide the Goods. The Supplier shall deliver to such call off requirements unless otherwise agreed with the Authority.

7.2.13 At the Contract Management meeting organised by the Authority every week, the Parties shall hold a call to determine the Authority's current demand for the Goods and delivery schedule. At such meetings, the Parties shall:

(i) review the volume of Goods to be delivered for the following week
(ii) review current inventory levels for Goods and
(iii) discuss such other matters as the Parties may consider appropriate.

7.2.14 If the Authority requires additional Goods the total number of Goods set out in this order form, under the same terms set out in this Contract, the Authority will do this by submitting a new order form. The Supplier shall use its best endeavours to fulfil any Authority orders for such additional Goods in the timescales required.

7.2.15 The Supplier shall ensure that ambient Goods are packaged suitably so as not to cause loss or damage during shipment to a Delivery Location;

7.2.16 In the event that the Supplier is unable to deliver the agreed order in full, the Supplier shall inform the Authority of the actual number of Assays and Consumables to be shipped prior to shipment, explaining the reasons for non-compliance with the agreed order and inform the Authority of when such missing Goods will be delivered. The Supplier shall, using its best endeavours, deliver such missing Goods at the earliest possible time;

7.2.17 The Supplier shall provide [redacted] with the delivery notes on dispatch of the Goods with unique reference numbers;

7.2.18 The Supplier shall provide [redacted] with a summary of the delivered

Goods on a monthly basis to allow verification of invoices and proof of delivery at each Delivery Location.

7.2.19 The Supplier shall inform the Authority of any requests, made directly to the Supplier, by the Delivery Locations, to vary the weekly delivery to: [redacted] who will approve or reject such requests.

7.2.20 The Parties reserve the right to modify the above process, by written agreement of both Parties, as necessary during the Term of this Contract

7.2.21 In the event of the Contract's expiry or earlier termination for whatever reason, the Supplier shall only invoice for the stock that has been shipped and not previously invoiced.

7.2.22 The Parties agree that notwithstanding submission of the Purchase Order to the Supplier, but subject to Clause 7.2 of this Order Form, the Authority is only committed to purchasing the quantities of the Goods that have been agreed by the Authority as part of this order form.

LumiraDx Platform Instrument including installation and access to Connect Manager (the Supplier's software) and a barcode reader per instrument ("Instruments")

7.2.23 As at the date of this Contract, the Supplier holds 732 Instruments at its own warehouses. Such instruments are owned by the Authority. The Authority has paid the Supplier in full for such Instruments and therefore title to the Instruments sits with the Authority. The Supplier shall continue holding such Instruments on behalf of the Authority at no cost to the Authority. Risk in such Instruments shall sit with the Supplier who shall insure these Instruments under its own policies. The Supplier shall store such Instruments until directed by the Authority in writing to deliver them to a specified location(s).

7.3 **Invoicing Terms**

7.3.1 Payment terms are net 30 days from receipt of a valid invoice.

7.3.2 Following receipt of the Supplier's countersigned copy of the Contract, the Authority will send a unique purchase order (the **"PO"**) number. The Supplier must be in receipt of a valid PO number before submitting an invoice.

7.3.3 The Supplier shall provide a consolidated monthly invoice to the Authority for all Goods delivered to and accepted by the Authority each month.

7.3.4 All invoices must be sent for approval and shall include the proof of delivery to the Authority's designated finance mailbox e-mail: [redacted] nd their agreed representative before being submitted for payment.

7.3.5 All invoices must be sent quoting a valid purchase order number. The Supplier shall provide a current statement of accounts on a monthly basis; this is a standard commercial process and should show all invoices raised and amounts outstanding.

7.3.6 The Supplier shall provide compliant invoices that include, as a minimum, a valid PO number, PO line item number (if applicable), PO line description, and the details (name and telephone number) of the Authority's authorised representative. Non-compliant invoices will be sent back to the Supplier, which may lead to a delay in a payment.

7.3.7 In support of Goods delivered the Supplier shall provide to the Authority a signed delivery note confirming receipt of the Goods at the Authority's nominated Delivery Locations by email to [redacted]

7.3.8 Supplier queries regarding payment must be forwarded to the Authority's Accounts Payable section by email to: [redacted].

7.3.9 The Authority shall have the right to audit Supplier stock at any time on not less than 5 business days' notice. The Parties shall be responsible their own expenses or costs that occur as part of any of these audits.

8 Authority Obligations

The Authority shall accept or reject such Goods promptly following the Supplier's delivery to the Authority.

9 Contract Managers

The Supplier's Contract Manager is:

[redacted]

The Authority's Contract Manager is:

[redacted]

10 Frequency of meetings

10.1 The Authority's Contract Manager (or their delegate) and Supplier's Contract Manager shall meet weekly (or such other frequency as reasonably requested by the Authority) to discuss the Supplier's performance and other matters connected to the delivery of the Contract.

10.2 At the Authority's request, and within five (5) Working Days of such request, the Supplier shall provide such management information to the Authority as the Authority may reasonably requests from time to time (including without limit any information about the Supplier's supply chain and its compliance in relation to sustainability requirements). The Contract Managers shall meet no less than monthly to discuss the operation of this Contract.

10.3 Contract management meeting will be set up to monitor the following:

- Delivery on time and in full;
- Stock Level held by the Supplier at the Authority's request;
- Issues;
- Invoicing; and
- Discuss such other matters as the Parties may consider appropriate including but not limited to the below KPIs:.
  - Quantity of delivery correct against the relevant Order (including deliveries in excess and shortfall of the Order quantity)

- Quality of delivery in accordance with the Framework Agreement and Contracts (including delivery presentation in accordance with the Framework Agreement and Contracts (the delivery must be presented in such a way that it can be unloaded safely and in a ready for use condition taking into consideration the Framework Agreement and Contract requirements) and damaged Goods (the Goods must be in a condition that is new and ready to use)
- Timely and accurate administration (including booking/amending delivery times and Orders and invoices, delivery advice notes and labels being in accordance with the requirements of the Framework Agreement and Contracts)
- The Supplier shall provide any management information required in accordance with the ORS (including, for the avoidance of doubt, monthly statements) and as The Authority may request from time to time within seven (7) Business Days of the date of the request.

11 Quality Assurance Standards for the Goods

11.1 The quality assurance standards set out in the Supplier's Specification set out Clause 2 of this Order Form shall apply to the manufacture and supply of the Goods.

12 Requirements for Use by Dates

12.1 The Supplier shall ensure that the Goods have an expiry date of at least six (6) months following the date of delivery by the Supplier.

13 Data Protection Protocol

13.1 The Supplier shall Process Personal Data under or in connection with this Contract in accordance with the Data Protection Protocol as supplied by the Authority to the Supplier as part of this Order Form (if any).

This Contract has been entered into on the day and date given below:

Signed by for and on behalf of the Supplier

[redacted]

Full Name: [redacted]

Job Title/Role:

Date Signed: 13th September 2022

Signed by for and on behalf of the Authority

[redacted]

Full Name: [redacted]

Job Title/Role:

Date Signed: 13/09/22

NHS SUPPLY CHAIN FRAMEWORK AGREEMENT FOR THE SUPPLY OF GOODS AND SERVICES

Appendix A

Goods Information and Pricing

Pricing Product Code	Product Description	Price per kit/pack (ex VAT)
L0160000101048	LumiraDx SARS-CoV-2 Ag Test Strip Kits (48 tests per kit)	[redacted]
L019000201048	LumiraDx SARS-CoV-2 & Flu A/B Test Strip Kits (48 tests per kit)	
L016000502048	LumiraDx SARS-CoV-2 Ag Ultra (48 tests per kit)	
L016080101002	LumiraDx SARS-COV-2 Liquid Control Solution (2 sets/pack)	

NHS SUPPLY CHAIN FRAMEWORK AGREEMENT FOR THE SUPPLY OF GOODS AND SERVICES

Appendix B

Delivery Locations

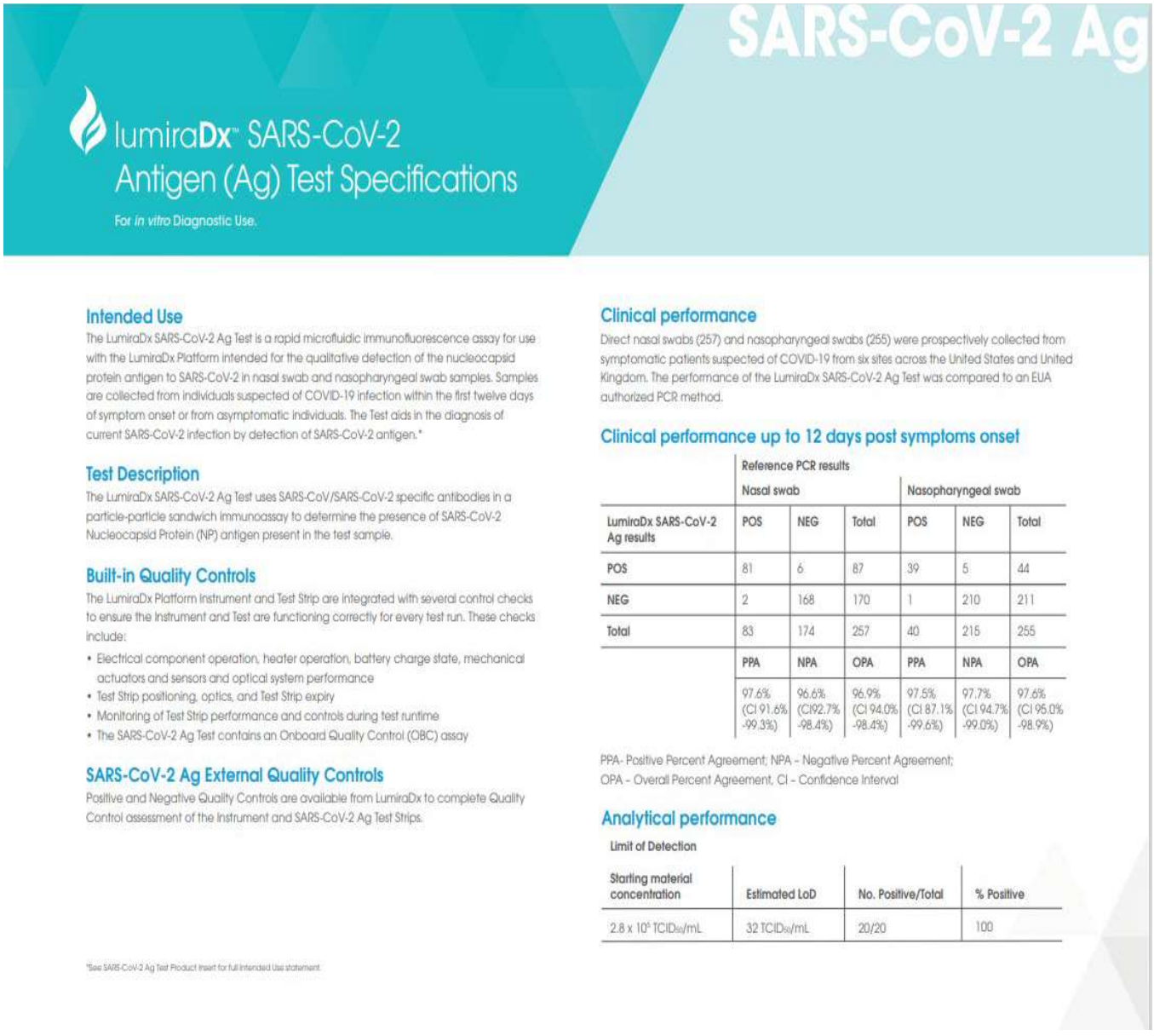
Region	Network	Trust	Trust Code	Site name
London	London 1	Imperial College Healthcare NHST		Charing Cross Hospital
London	London 2	North Middlesex University Hospital NHS Trust	RAP	North Middlesex Hospital
London	London 2	Royal Free London NHS Foundation Trust	RAL	Barnet Hospital
North East and Yorkshire	North 1	The Newcastle Upon Tyne Hospitals NHS Foundation Trust	RTD	Freeman Hospital
North East and Yorkshire	North 1	The Newcastle Upon Tyne Hospitals NHS Foundation Trust	RTD	The Royal Victoria Infirmary
North East and Yorkshire	North 2	Mid Yorkshire Hospitals NHS Trust	RXF	Pinderfields General Hospital
South West	South 1	Royal Cornwall Hospitals NHS Trust	REF	Royal Cornwall Hospital (Treliske)
South East	South 5	Frimley Health NHS Foundation Trust	RDU	Frimley Park Hospital
South East	South 5	Royal Surrey County Hospital NHS Foundation Trust	RA2	Royal Surrey County Hospital
Northern Ireland	South 6	Isle of Wight NHS Trust	R1F	St Mary's Hospital
South East	South 7	Surrey and Sussex Healthcare NHS Trust	RTP	East Surrey Hospital
Northern Ireland		Western HSC Trust		Altnagelvin Area Hospital Laboratories
Northern Ireland		Northern HSC Trust		Antrim Hospital Laboratories
Northern Ireland		Southern HSC Trust		Bio Lab Craigavon Area Hospital
Northern Ireland		Southern HSC Trust		Regional Virus Laboratory
Northern Ireland		South Eastern HSC Trust		Ulster Hospital
Scotland	West of Scotland Specialist Virology Centre	Glasgow Royal Infirmary		Ward 119
Scotland	NHS Lothian	Western General Hospital		CAU Reception, Edinburgh Cancer Centre, Oncology

Scotland	NHS Lothian	St Johns Hospital		St Johns Hospital
Scotland	NHS Lothian	East Lothian Community Hospital		Endoscopy and Minor Procedure Unit
Scotland	NHS Lothian	Leith Community Treatment Centre		Leith Community Treatment Centre
Scotland	NHS Lothian	Royal Infirmary Edinburgh		Royal Infirmary Edinburgh
Scotland	NHS Lothian	St John's Hospital		St John's Hospital
Scotland	NHS Lothian	Western General Hospital		Western General Hospital
Scotland	NHS Lothian	Building 9 Edinburgh Bioquarter		POCT
Scotland	NHS Lothian	RHCYP		RHCYP Melville Unit (Mental Health)
Scotland	NHS Lothian	Astley Ainslie Hospital		LEAP
Scotland	NHS Lothian	Royal Edinburgh Hospital		Ritson Clinic
Scotland	NSS	Glasgow Royal Infirmary		Specialist Virology Centre
Scotland	NSS	Glasgow Royal Infirmary		Specialist Virology Centre
East of England	Mid 6	West Suffolk NHS Foundation Trust	RGR	Cumberland Infirmary
Scotland	NSS			Western Isles Hospital
Scotland	NSS	NHS Borders		Borders General Stores
Scotland	NSS	NHS Grampian		Medical Microbiology, Aberdeen Royal Infirmary
Midlands	Mid 1	The Shrewsbury and Telford Hospital NHS Trust	RXW	The Princess Royal University Hospital Hospital
Midlands	Mid 2	University Hospitals of Leicester NHS Trust	RWE	Leicester Royal Infirmary
Midlands	Mid 2	University Hospitals of Leicester NHS Trust		Glenfield Hospital
South West	South 1	Northern Devon Healthcare NHS Trust	RBZ	North Devon District Hospital
South East	South 5	Ashford and St Peter's Hospitals NHS Foundation Trust	RTK	St Peter's Hospital
Midlands	Mid 2	United Lincolnshire Hospitals NHS Trust	RWD	Pilgrim
East of England	Mid 6	East Suffolk and North Essex NHS Foundation Trust	RDE	Colchester General Hospital
East of England	Mid 6	West Suffolk NHS Foundation Trust	RGR	West Suffolk Hospital

North East and Yorkshire	North 1	Gateshead Health NHS Foundation Trust	RR7	Queen Elizabeth Hospital
North East and Yorkshire	North 1	North Tees and Hartlepool NHS Foundation Trust	RVW	University Hospital of North Tees
North West	North 3	Lancashire Teaching Hospitals NHS Foundation Trust	RXN	Royal Preston Hospital
South West	South 2	Yeovil District Hospital NHS Foundation Trust	RA4	Yeovil District Hospital
East of England	Mid 6	East Suffolk and North Essex NHS Foundation Trust	RDE	Ipswich Hospital
South East	South 7	Western Sussex Hospitals NHS Foundation Trust		St Richard's Hospital
South East	South 7	Western Sussex Hospitals NHS Foundation Trust		Worthing Hospital
London	London 5	St George's University Hospitals NHS Foundation Trust	RJ7	St George's Hospital (Tooting)

Appendix C

Specifications



SARS-CoV-2 Ag

lumiraDx™ SARS-CoV-2 Antigen (Ag) Test Specifications

For *in vitro* Diagnostic Use.

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 and nasopharyngeal 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.*

Test Description

The LumiraDx SARS-CoV-2 Ag Test uses SARS-CoV/SARS-CoV-2 specific antibodies in a particle-particle sandwich immunoassay to determine the presence of SARS-CoV-2 Nucleocapsid Protein (NP) antigen present in the test sample.

Built-in Quality Controls

The LumiraDx Platform Instrument and Test Strip are integrated with several control checks to ensure the Instrument and Test are functioning correctly for every test run. These checks include:

- Electrical component operation, heater operation, battery charge state, mechanical actuators and sensors and optical system performance
- Test Strip positioning, optics, and Test Strip expiry
- Monitoring of Test Strip performance and controls during test runtime
- The SARS-CoV-2 Ag Test contains an Onboard Quality Control (OBC) assay

SARS-CoV-2 Ag External Quality Controls

Positive and Negative Quality Controls are available from LumiraDx to complete Quality Control assessment of the Instrument and SARS-CoV-2 Ag Test Strips.

*See SARS-CoV-2 Ag Test Product Insert for full Intended Use statement.

Clinical performance

Direct nasal swabs (257) and nasopharyngeal swabs (255) were prospectively collected from symptomatic patients suspected of COVID-19 from six sites across the United States and United Kingdom. The performance of the LumiraDx SARS-CoV-2 Ag Test was compared to an EUA authorized PCR method.

Clinical performance up to 12 days post symptoms onset

	Reference PCR results					
	Nasal swab			Nasopharyngeal swab		
LumiraDx SARS-CoV-2 Ag results	POS	NEG	Total	POS	NEG	Total
POS	81	6	87	39	5	44
NEG	2	168	170	1	210	211
Total	83	174	257	40	215	255
	PPA	NPA	OPA	PPA	NPA	OPA
	97.6% (CI 91.6% -99.3%)	96.6% (CI92.7% -98.4%)	96.9% (CI 94.0% -98.4%)	97.5% (CI 87.1% -99.6%)	97.7% (CI 94.7% -99.0%)	97.6% (CI 95.0% -98.9%)

PPA- Positive Percent Agreement; NPA – Negative Percent Agreement; OPA – Overall Percent Agreement, CI – Confidence Interval

Analytical performance

Limit of Detection

Starting material concentration	Estimated LoD	No. Positive/Total	% Positive
2.8 x 10^5 $TCID_{50}$/mL	32 $TCID_{50}$/mL	20/20	100

Cross reactivity

SARS-CoV-2 Ag Test was found not to cross-react with a panel of organisms and viruses including several human coronaviruses. See LumiraDx SARS-CoV-2 Ag Test Product Insert for full details.

Specifications

Sample type	Nasal and nasopharyngeal swabs
Time to result	12 minutes
Result display	Qualitative - positive or negative
Storage temperature	2-30 °C (36-86 °F)
Operating temperature	15-30 °C (59-86 °F)
Interferences	See LumiraDx SARS-CoV-2 Ag Test Product Insert for details
Onboard control	Onboard Quality Control (OBC) assay and sample processing control
Quality control material	Positive and Negative external liquid controls
Validated swabs	See swabs technical bulletin at lumiradx.com

ENGLISH

LumiraDx™ SARS-CoV-2 Ag Test

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

SPEC-32312 R7 ART-00571 R13

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 and nasopharyngeal 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-19[1]. 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 days[2].

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 and nasopharyngeal swab samples.

The test procedure involves collecting a nasal swab or nasopharyngeal 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.

Materials provided:

- LumiraDx Test Strips packed individually in sealed desiccant foil pouches.
- LumiraDx Test Product Insert
- RFID (Radio frequency ID) Tag held inside the Test Strip carton
- Extraction Buffer Vials
- Dropper Lids

Materials required but not provided with the Test Strip carton:

- LumiraDx Instrument
- Standard nasal swab and nasopharyngeal swab collection equipment. Please refer to the Limitations section of this product insert for information on recommended swabs.
- LumiraDx SARS-CoV-2 Ag Test Quick Reference Instructions
- LumiraDx SARS-CoV-2 Ag Quality Controls (as required to meet local and organisational compliance)
- LumiraDx Connect if connectivity required (refer to LumiraDx Connect User Manual)

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.

ENGLISH

lumiraDx™ SARS-CoV-2 Ag Ultra

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

SPEC-35816 R1 ART-02554 R1 Date of Rev 2022/07

LumiraDx SARS-CoV-2 Ag Ultra

The LumiraDx Severe Acute Respiratory Syndrome (SARS) CoV-2 Antigen (Ag) Ultra 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 Ultra test is an automated rapid microfluidic immunofluorescence assay for use with the LumiraDx Platform, for near-patient testing, intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 directly from anterior nasal swab samples collected from individuals suspected of COVID-19 by their healthcare provider within the first twelve days of symptom onset or from individuals without symptoms or other epidemiological reasons to suspect COVID-19.

The LumiraDx SARS-CoV-2 Ag Ultra test does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in anterior nasal swab samples during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

Negative results should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and presence of clinical signs and symptoms consistent with COVID-19.

The LumiraDx SARS-CoV-2 Ag Ultra test is intended for use by healthcare professionals trained in point of care settings, and proficient in performing tests using the LumiraDx Instrument.

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 Ultra test Quick Reference Instructions, available online, and this entire Product Insert. In addition, please watch the LumiraDx Platform Training Video 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-19[1]. 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 days[2].

The use of a LumiraDx SARS-CoV-2 Ag Ultra 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 SARS-CoV-2 Ag Ultra test is a single use fluorescence immunoassay device designed to detect the presence of the nucleocapsid protein antigen from SARS-CoV-2 in anterior nasal swab samples, without transport media.

The test procedure involves collecting an anterior nasal swab sample (using a recommended swab or a swab supplied with specific product codes) 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 5 minutes from the addition of the sample.

Materials provided:

- LumiraDx Test Strips packed individually in sealed desiccant foil pouches.
- LumiraDx Product Insert
- RFID (Radio frequency ID) Tag held inside the Test Strip carton
- Extraction Buffer Vials
- Dropper Lids
- Individually packaged sterile nasal collection swabs (provided only with product codes L016000501024, L016000501048, L016000502024, L016000502048, L016000504024, L016000504048, L016000505024, L016000505048, L016000508024, L016000508048,)

SARS-CoV-2 & Flu A/B Specifications

Specifications

Sample Type	Nasal swabs
Time to Result	12 minutes
Result Display	Qualitative – Positive or Negative
Storage Temperature	2-30°C (36-86°F)
Operating Temperature	15-30°C (59-86°F)
Relative Humidity	10% - 75%
Interferences	See LumiraDx SARS-CoV-2 & Flu A/B Product Insert for details
Onboard Control	Onboard Quality Control (OBC) assay and sample processing control
Quality Control Material	Positive and Negative external liquid controls