ENGLISH

lumiraDx™ SARS-CoV-2 Ab Quality Controls

For Professional Use Only
For Use under Emergency Use Authorization (EUA) only
For *In Vitro* Diagnostic Use
Rx Use only

SPEC-34696 Rev1
ART-01515 Rev1 Date of Revision 2021/08

The LumiraDx SARS-CoV-2 Ab Quality Controls (hereafter referred to as Quality Controls) are liquid quality controls to be used with the LumiraDx Instrument (hereafter referred to as the Instrument) and the LumiraDx SARS-CoV-2 Test Ab Test (hereafter referred to as SARS-CoV-2 Ab Test).

Read these instructions thoroughly before using the Quality Controls.

Inspect the Quality Controls packaging and contents for damage before use. Report any damage to LumiraDx Customer Services and do not use the kit if any damage is observed to the contents.

To ensure that you are using the Instrument, the SARS-CoV-2 Ab Test and the Quality Controls correctly, read the appropriate Platform User Manual, SARS-CoV-2 Ab Test Product Insert and this entire pack insert. In addition, please watch the LumiraDx Platform Training video available at lumiradx.com. The Quality Controls are intended for healthcare professional use only.

Intended use:

The LumiraDx SARS-CoV-2 Quality Controls are intended for liquid quality control testing performed on the LumiraDx Instrument when used with the LumiraDx SARS-CoV-2 Ab Test Strip. The Quality Controls provide users with assurance that the device is performing within specification.

Summary and explanation of the test:

The LumiraDx SARS-CoV-2 Ab Quality Controls are normal human plasma-based reagents:

The controls are specifically formulated and manufactured to ensure performance of the test and are used to verify the user's ability to properly perform the test and interpret the results.

It is the responsibility of each laboratory or healthcare setting using the LumiraDx SARS-CoV-2 Ab Test to establish an adequate quality assurance program to ensure the performance of the device under its specific locations and conditions of use. Quality control requirements should be followed in conformance with local, state, and federal regulations or accreditation requirements and the user laboratory's standard quality control procedures.

Warnings and precautions:

- For *in vitro* diagnostic use.
- For Emergency Use Authorization only.
- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.
- This product is authorized for use with a test authorized only for detecting the presence of total antibodies to SARS CoV 2, not for any other viruses or pathogens.
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID 19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb 3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
- This control contains human source material that was tested and found nonreactive for the Human Immunodeficiency Virus (HIV 1 and 2) antibody, Hepatitis B Surface Antigen (HbsAg) and Hepatitis C Virus (Anti-HCV) at the donor stage. This product, as with all human based specimens, should be treated as potentially infectious and handled with proper laboratory safety procedures to minimize the risk of transmission of infectious disease.
- All components of this kit can be discarded as Biohazard waste according to the local guidelines.
- Refer to the product safety data sheet for risk and safety phrases and disposal information. The product safety data sheet is available for users upon request.
- Requirements of the appropriate licensing or accrediting body should be incorporated into your quality control program.
- Exercise the normal precautions required for handling all laboratory reagents.

Storage and stability:

- Store controls between 2°C and 8°C (36 - 46°F).
- Unopened controls that are stored between 2°C and 8°C (36 and 46°F) can be used until the expiration date. Do not use kits or components beyond the expiration date given on the label.
- Once opened, the vial has a 30 day expiry.
- Open the Control Vials only when you are performing tests.
- Recap and store the Control Vials in their original container at 2°C and 8°C (36 and 46°F) after use.

Carton contents:

- 2 x 0.5ml vial SARS-CoV-2 Ab Positive Quality Control: heat-treated convalescent plasma positive for antibodies to SARS-CoV-2 in human plasma matrix with 5% 1,2,3-propanetriol, 0.1% Sodium Azide and 0.1% ProClin 950
- 2 x 0.5ml vial SARS-CoV-2 Ab Negative Quality Control: heat-treated SARS-CoV-2 antibody negative plasma matrix containing 5% 1,2,3-propanetriol, 0.1% sodium azide and 0.1% ProClin 950
- 40 Transfer pipettes (20µl)
- LumiraDx SARS-CoV-2 Ab Quality Control Pack Insert

Materials required but not provided with the Control Carton:

- LumiraDx Instrument
- LumiraDx SARS-CoV-2 Ab Test Strips
- LumiraDx Connect– if connectivity required (refer to LumiraDx Connect User Manual)

Getting ready to test:

You will need the LumiraDx Instrument and the following supplies:

- LumiraDx SARS-CoV-2 Ab Test strip(s)
- LumiraDx SARS-CoV-2 Ab Positive or Negative Quality Controls
- Transfer pipette

Preparing the Quality Controls:

The liquid controls are supplied ready to use.

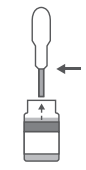
Handling the LumiraDx SARS-CoV-2 Ab Test Strips:

To ensure that you are using the SARS-CoV-2 Ab Test and the Instrument correctly, read the appropriate SARS-CoV-2 Ab Test Strip Product Insert and Platform User Manual.

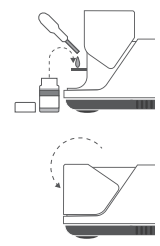
Procedure/Performing a Test:

Consult the LumiraDx Platform User Manual for instructions on how to analyse a Quality Control sample. Open the foil pouch of the SARS-CoV-2 Ab Test Strip just before use and insert the Test Strip into the LumiraDx Instrument. The Instrument will indicate when ready for the sample to be applied.

1. Draw up the **Quality Control solution into the Transfer pipette**. **For single bulb pipettes** squeeze the bulb, drawing up QC material to where the tip of the pipette tapers as indicated by the arrow on the diagram. Take care to fill only the tip of the pipette to collect approximately 20µL of QC material.



2. **Apply the Quality Control solution to the already inserted SARS-CoV-2 Ab Test Strip.** Hold the pipette over the Sample Application Area of the Test Strip and dispense the Quality Control solution. The LumiraDx Instrument will indicate sample is detected with an audible alert (if the Instrument sounds are enabled). The screen of the LumiraDx Instrument will request the user to close the door. Dispose of pipette.



3. **Do not open the door while the test is in progress.** The touch-screen will indicate test progress.

4. **The Result** will appear on the touch-screen within 11 minutes of applying the Quality Control solution and starting the test. The results will be displayed as a **PASS** or **FAIL** QC result on the instrument screen.

5. **NOTE**: If you need to repeat a test, use a new Test Strip.

Expected results:

The Instrument displays the result as Pass or Fail. The result is automatically saved in the memory of the Instrument. The system is working properly and all handling has been done correctly when the test results obtained are displayed as a **PASS**.

If the LumiraDx Antibody 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 on telephone number 1-888-586-4721.

Symbols glossary:

Symbol	Meaning
	Temperature limitation
	Manufacturer
IVD	For *In Vitro* Diagnostic Use Only
REF	Catalogue Number
	Indicates that potential biological risks are associated with the Quality Control material.
Rx Only	Prescription Use Only
LOT	Lot Number
	Use-by Date – indicates the date after which the unopened IVD/Quality Control Material cannot be used
	Refer to instructions for use
CONTROL –	Indicates a negative control
CONTROL +	Indicates a positive control
EUA	Emergency Use Authorization

LumiraDx customer services:

For product inquiries please contact LumiraDx Customer Services by email: customerservices.US@lumiradx.com or telephone 1-888-586-4721.

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.US@lumiradx.com or at lumiradx.com.

For return policy:

If there is a problem with the **LumiraDx SARS-CoV-2 Ab Quality Controls Pack** 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 Ab Quality Controls Pack – As per shelf life.

Unused Test 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 Ab Quality Controls Pack 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, UK.
Registration Number: 09206123

LumiraDx US Office:

221 Crescent St, Suite 502, Waltham, MA 02453. Telephone: (617) 621-9775

In the USA, this product has not been FDA cleared or approved; but has been authorized by FDA under an EUA for use by authorized laboratories; use by laboratories certified under the CLIA that meet requirements to perform moderate, high or waived complexity tests. This product is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. This test has been authorized only for the detection of antibodies to SARS-CoV-2, not for any other viruses or pathogens. In the USA, this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.