The LumiraDx SARS-CoV-2 Ag 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 Ag Test (hereafter referred to as SARS-CoV-2 Ag 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 ensure that you are using the Instrument, the SARS-CoV-2 Ag Test and the Instrument correctly, read the appropriate Platform User Manual, SARS-CoV-2 Ag 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 Ag 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 Ag Quality Controls are liquid quality controls. 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 Ag 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 shall 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.
- This control contains human source material and 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.
- Refers 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 Ag Positive Control
- 2 x 0.5ml vial SARS-CoV-2 Ag Negative Control
- 24 Transfer pipettes (32uL)
- LumiraDx SARS-CoV-2 Ag Quality Control Pack Insert

Materials required but not provided with the Control Carton:
- LumiraDx Instrument
- LumiraDx SARS-CoV-2 Ag Test Strips
- LumiraDx Connect - if connectively 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 Ag Test strip(s)
- LumiraDx SARS-CoV-2 Ag Positive or Negative Quality Controls
- Transfer pipettes

Preparing the Quality Controls
The liquid controls are supplied ready to use.

Handling the LumiraDx SARS-CoV-2 Ag Test Strips:
To ensure that you are using the SARS-CoV-2 Ag Test and the Instrument correctly, read the appropriate SARS-CoV-2 Ag Test Strip Product Insert and your respective platform’s respective user manual.

Procedure/performing a test
Consult the LumiraDx Platform User Manual for instructions on how to analyze a Quality Control sample. Open the foil pouch of the SARS-CoV-2 Ag 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.