LumiraDx™ SARS-CoV-2 Ag Technical Bulletin – QC Transfer Pipettes

The LumiraDx SARS-CoV-2 Ag Quality Controls (QC) are liquid quality controls used with the LumiraDx Instrument and the LumiraDx SARS-CoV-2 Ag Test. When transferring the QC material from the vial to the Test Strip, a transfer pipette is used.

Please be advised that the following transfer pipettes are acceptable for use with the LumiraDx SARS-CoV-2 Ag QC material:

- 20µL Dual-Bulb Plastic Transfer Pipettes (single use)
- 20µL Single-Bulb Plastic Transfer Pipettes (single use)
- Calibrated Laboratory Pipette (set to 20µL, with appropriate tips)

Please note that any transfer pipettes used with the LumiraDx SARS-CoV-2 Ag QC material should never contain any coatings, additives, surfactants or preservatives.

For product inquiries and technical support please contact LumiraDx Technical Support.

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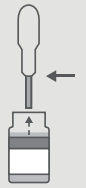
Product is not available in all countries and regions. Please check with your local LumiraDx sales representative or distributor for availability in specific markets. Available in the USA under FDA Emergency Use Authorization.

In the USA, this test has not been FDA cleared or approved; this test has been authorized by FDA under an EUA for use by authorized laboratories; use by laboratories certified under the CLIA, 42 U.S.C. §263a, that meet requirements to perform moderate, high or waived complexity tests. This test 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 proteins from SARS-CoV-2, not for any other viruses or pathogens. In the USA, this test 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.

Supplemental Instructions

Transfer Pipette Configuration	Supplemental Instructions
20µL Dual-Bulb Plastic Transfer Pipettes (single use) 	• Squeeze the upper bulb to draw up 20µL of QC material into the pipette. • Hold the pipette over the sample application area of the Test Strip and squeeze the upper bulb for a second time to dispense 20µL of QC material on to the Test Strip.
20µL Single-Bulb Plastic Transfer Pipettes (single use) 	**Note:** the tip of the pipette will be tapered. • 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. • Ensure no air bubbles are present within the pipette tip and that the whole tip of the pipette is filled with QC material. • Hold the pipette over the sample application area of the Test Strip and squeeze the bulb for a second time to dispense 20µL of QC material on to the Test Strip. **Note:** The Platform will audibly confirm that sample is detected and promptthe user to close the door.
Calibrated Laboratory Pipette (set to 20µL, with appropriate tips)	• Follow the applicable manufacturer's recommendations for correctly dispensing exactly 20µL of QC material to the Test Strip.

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S-COM-ART-00195 R4 Date of Rev 2021/05