

Optimizing your Sample Application Process

For the most optimized workflow when applying a patient or Quality Control sample to the Test Strip please refer to the guidance provided in this Technical Bulletin, which is consistent with the instructions outlined in the Platform User Manual.

Applying a sample to the Test Strip

Following the insertion of a LumiraDx Test Strip, the Instrument display will prompt when to apply the sample. Apply **ONLY** one drop of the sample directly to the circular Sample Application Area on top of the Test Strip.















IMPORTANT: Sample detection and confirmation on the Instrument can take up to **15 seconds** on some Test Strips. Whilst waiting for the confirmation, **DO NOT** apply any additional sample drops. If you think you have not applied the sample correctly, cancel the test on the Instrument, remove the Test Strip, and start another test using a fresh 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 close the door once the Instrument has detected the sample.

Removing the Test Strip from the LumiraDx Instrument

The Instrument will prompt to remove the Test Strip.

Gently pull the blue label end of the Test Strip to remove and dispose.

Do NOT bend the Test Strip when removing from the instrument.









For further information refer to the "Preparation for Testing" chapter in the Platform User Manual for handling Test Strips, inserting and removing Test Strips and sample collection and application instructions.



Frequently Asked Questions

What do I do if I think I have applied too much sample to the Test Strip?

You can continue to use your Instrument. There are built-in checks to ensure the Instrument continues to operate accurately and safely. Take the Test Strip out carefully and do not bend the strip. If you have concerns, please contact Technical Services.

What do I do if I think I haven't applied enough Sample?

Sample detection and confirmation on the Instrument can take up to **15 seconds** on some Test Strips. Whilst waiting for the confirmation, **DO NOT** apply any additional sample drops. If you think you have not applied the sample correctly, cancel the test on the Instrument, remove the Test Strip, and start another test using a fresh strip.

Product Enquiries and Technical Support

Please email or call Technical Services if you have questions.

Email: technicalservices.us@lumiradx.com

Phone: 1-888-586-4721

The LumiraDx SARS-CoV-2 Ag test has not been FDA cleared or approved but has been authorized by FDA under an EUA for use by authorized laboratories. This product has been authorized only for the detection of proteins from 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.

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