



Home » LumiraDx » IumiraDx OS-04282-01 Test Strip User Manual



Contents [hide]

- 1 Optimizing your Sample Application Process
- 2 Frequently Asked Questions
- 3 Documents / Resources
 - 3.1 References

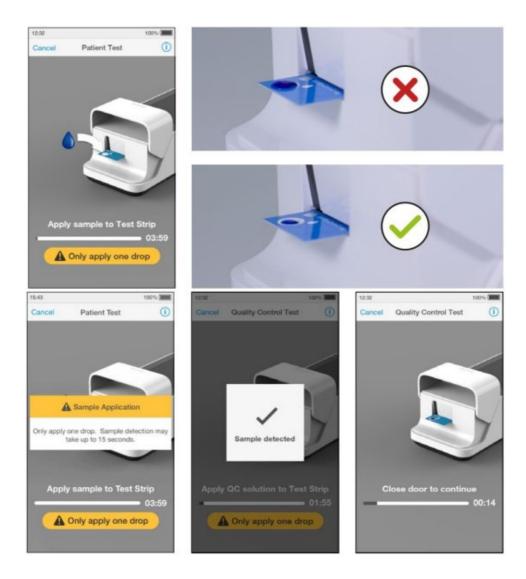
Optimizing your Sample Application Process

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 samples?

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

p style="text-align: justify">The LumiraDx SARS-CoV-2 Ag test has not been FDA cleared or approved, but has been authorized by the 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.

Copyright © 2023 LumiraDx UK LTD. All rights reserved worldwide.

LumiraDx and Flame logo are trademarks of LumiraDx International LTD. Full details of these and other registrations of LumiraDx can be found at lumiradx.com/IP. All other trademarks are the property of their respective owners.

Content should be used for the use of the LumiraDx products only and in line with the instructions provided. You may not, except with our express written permission, distribute or commercially exploit the content. Nor may you transmit it or store it in any other form of electronic retrieval system other than for the purpose of use of the LumiraDx Instrument, LumiraDx Instrument Base, or LumiraDx Test Strips. Information provided is subject to change without notice.

<

p>Manufactured by:

LumiraDx UK Ltd, Dumyat Business Park, Alloa, FK10 2PB, UK

S-COM-ART-03373 R3 2023/11

<

p style="text-align: center">OS-04282-01

APPROVED FOR USE IN THE US.

EMERGENCY USE AUTHORIZED ONLY.



Documents / Resources



<u>lumiraDx OS-04282-01 Test Strip [pdf]</u> User Manual OS-04282-01, OS-04282-01 Test Strip, Test Strip, Strip

References

• User Manual

ul>

- LumiraDx, OS-04282-01, OS-04282-01 Test Strip, strip, Test
- LumiraDx Strip

Leave a comment

Your email address will not be published. Required fields are marked*

Comment *

Name

Email

Website

☐ Save my name, email, and website in this browser for the next time I comment.

Post Comment

Search:

e.g. whirlpool wrf535swhz

Search

Manuals+ | Upload | Deep Search | Privacy Policy | @manuals.plus | YouTube

This website is an independent publication and is neither affiliated with nor endorsed by any of the trademark owners. The "Bluetooth®" word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. The "Wi-Fi®" word mark and logos are registered trademarks owned by the Wi-Fi Alliance. Any use of these marks on this website does not imply any affiliation with or endorsement.