LumiraDx™ INR Test

Quick Reference Instructions

For *in vitro* diagnostic use

Warnings and Precautions:
All kit components can be discarded as Biohazard waste according to local guidelines. Refer to the product safety data sheet for risk and safety phrases and disposal information. The product safety data sheet is available at lumiradx.com. Exercise the normal precautions required for handling all laboratory reagents. Proper laboratory safety techniques should be followed at all times when working with INR patient samples. Used lancets, used Test Strips and used Transfer Tubes may be potentially infectious. Proper handling and disposal methods should be established by the care setting in accordance with local regulations. Reagents encapsulated within the Test Strip are present in extremely small amounts however, should any reagent become exposed it should be treated as potentially infectious.

The LumiraDx INR Test is a point of care test that measures quantitative prothrombin time, reported as International Normalised Ratio (INR), in fresh capillary whole blood – taken by finger-stick or via non-anticoagulated transfer tube. It is used for the monitoring of oral anticoagulation therapy with Vitamin K Antagonist (VKA) drugs.

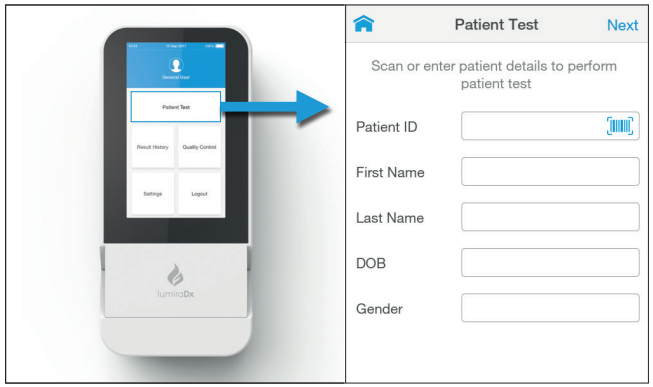
Study the **LumiraDx Platform User Manual** and **LumiraDx INR Test Strip Product Insert** thoroughly before using these **Quick Reference Instructions** or performing a test. This is not a complete product insert.

Operate the LumiraDx Platform at room temperature between 15°C and 30°C (59°F and 86°F) and 10% - 90% relative humidity. Check expiration date on outer test carton and each individual test package before using. **Do not use any test components beyond its expiration date.** Refer to the **LumiraDx INR Test Strip Product Insert** for Sample Collection, Warning and Precautions, and Limitations.

Cleaning and Disinfecting:

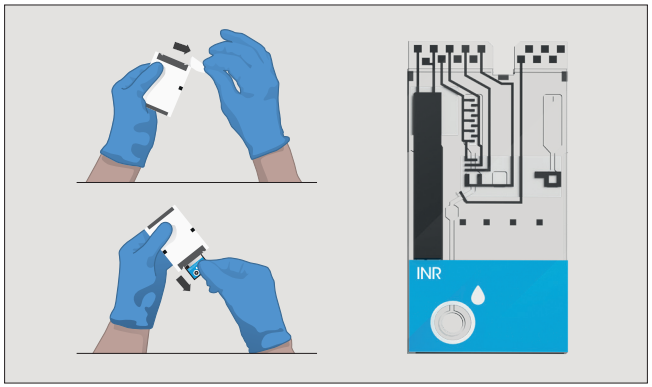
It is recommended to disinfect the Instrument after each patient sample, or if contamination is suspected. Excessive liquid may damage the Instrument. It is important for the protection of the Instrument that exposure to excess moisture is prevented. All disinfection cloths and/or wipes should only be slightly damp, with any excess liquid being manually removed from the cloth before use. Alcohol wipes alone are not sufficient to disinfect the Instrument for blood-based samples, due to the potential presence of bloodborne pathogens. For more information, or for the full procedure on cleaning and disinfection, please refer to the Technical Bulletin Platform Disinfection Procedure at **www.lumiradx.com.**

Running the Test



1. Enter patient details

Select *Patient Test* from the **Instrument** *Home Screen* and enter patient details using the **Keyboard** or **Barcode Scanner.** See section 10 of the **Platform User Manual** for instructions on using the **Barcode Scanner.**



2. Remove Test Strip from pouch

Remove the **Test Strip** from its pouch and hold by gripping only the blue portion. **Do not touch the Test Strip Sample Application Area. Do not bend the Test Strip or touch any part other than the blue portion.**

3. Insert Test Strip

When prompted, open the **Instrument** door and gently insert the **Test Strip** as far as it will go. The thick black alignment rib on the **Test Strip** should be on the left and line up with the black line on the **Instrument. Do not apply the sample until prompted.** Install the Lot Calibration file if using a new **Test Strip lot** for the first time. See section 2.8 of the **Platform User Manual.**

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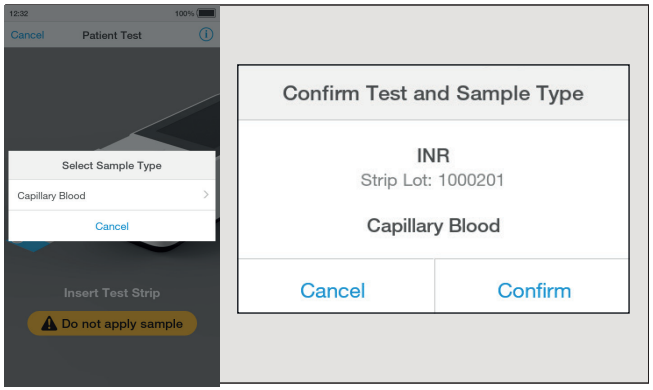
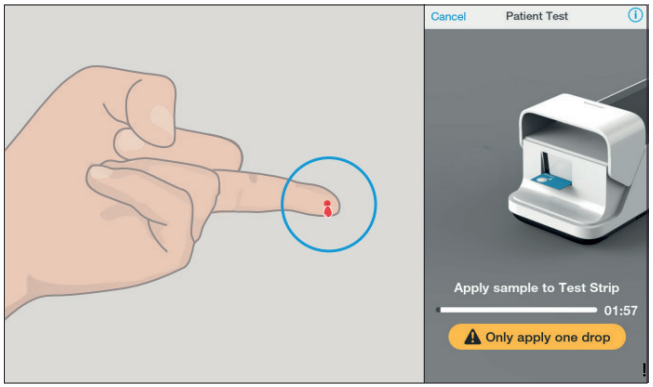


4. Select sample type

Select "Capillary Blood" and confirm the test type.

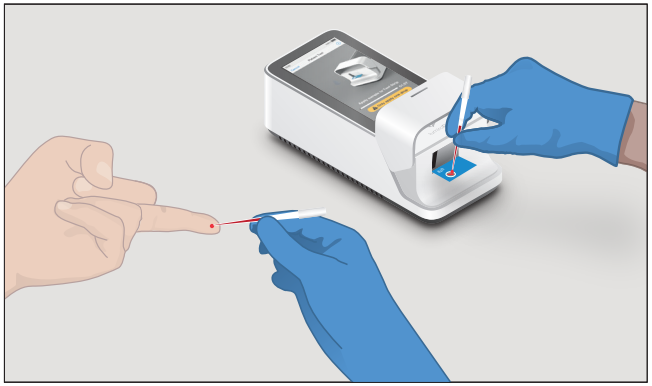


5. Create a hanging blood drop

When prompted to apply the sample by the **Instrument** use a lancet on the finger to create a hanging blood drop.

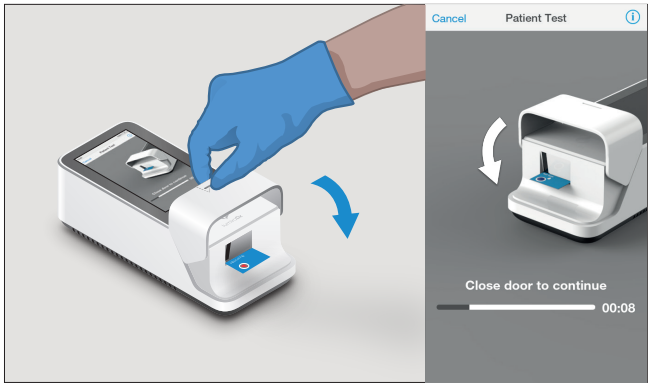
6. Apply the sample

Apply **one whole drop** of blood onto the **Test Strip Sample Application Area** directly from the hanging blood drop.



7. Alternative transfer

Alternatively a non-anticoagulated Transfer Tube can be used.



8. Close door

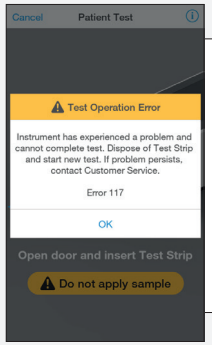
Close the door when prompted to continue the test.

9. Results displayed

Results are displayed within 3 minutes from applying the sample. Tap *Finish* to complete testing or tap *Comment* to leave a comment or to reject the Test, then follow prompts to return to the *Home Screen*.

Invalid results

If an issue occurs, a message will be displayed on the Instrument touch-screen. Alert messages include useful information and are highlighted by an orange banner. Error messages also include a ⚠ symbol. All messages will contain a description of the Instrument status or error and an instruction. Error messages contain an identifying code that may be used for further troubleshooting purposes.



⚠ **Example of an error screen:** If the Onboard Control (OBC) fails, an error message will be shown and no test result will be returned. Follow the on- screen instructions to dispose of the Test Strip and start a new test. If the problem persists, contact Customer Services.

Quality Controls

To complete Quality Control assessment of the LumiraDx Instrument and INR Test Strips, you must use the LumiraDx INR Quality Controls which are available separately. If the LumiraDx INR 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.

Customer Service

If the **LumiraDx INR Test** or the **LumiraDx Instrument** do not perform as expected, contact LumiraDx Customer Services via **lumiradx.com** or **customerservices@lumiradx.com**

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Manufacturer Information
LumiraDx UK Ltd, Dumyat Business Park, Alloa, FK10 2PB, UK
Registration Number: 09206123

Authorized Representative in the European Community:
LumiraDx AB, Västra Vägen 5A, 16961 Solna, Sweden

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