LumiraDx™ CRP Test

Quick Reference Instructions

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 CRP patient samples. Patient samples, used Test Strips and used Transfer Tubes may be potentially infectious. Proper handling and disposal methods should be established by the laboratory in accordance with local regulations. Reagents encapsulated within the Test Strip are present in extremely small amounts and where any component is of animal origin, the source is certified as free from infectious or contagious material – however, should any reagent become exposed it should be treated as potentially infectious.

The LumiraDx CRP Test is a single use fluorescence immunoassay device designed to determine the concentration of CRP in human whole blood (direct fingerstick or Lithium Heparin-venous) and Lithium Heparin-plasma specimens. The measurement of CRP provides information for the detection and evaluation of infection, tissue injury, inflammation disorders, and associated disease.

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

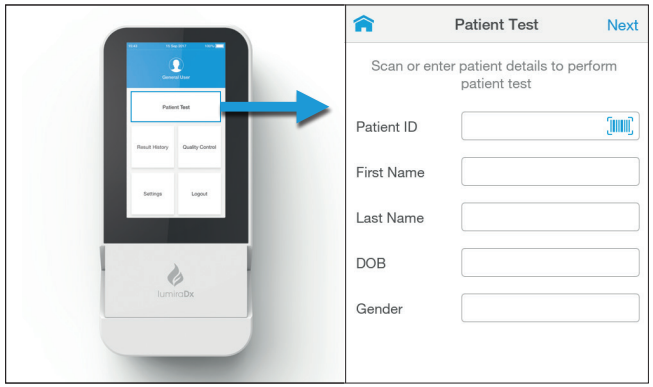
Operate the LumiraDx Platform at room temperature between 15°C and 30°C (59°F and 86°F) and 10% - 90% relative humidity. Refrigerated samples must be allowed to reach room temperature and be mixed thoroughly before testing.

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 CRP Test Strip Product Insert** for Specimen Collection, Warning and Precautions, and Limitations.

Cleaning and Disinfecting:

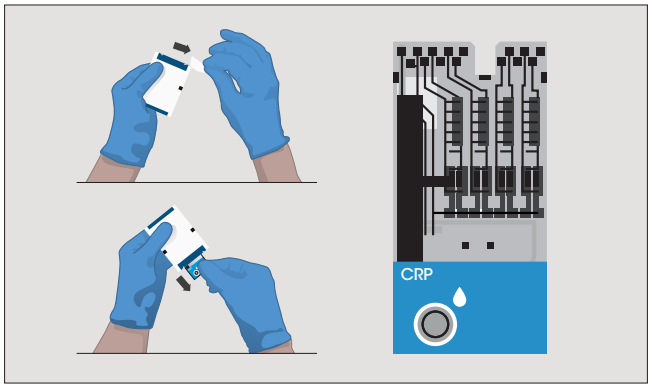
It is recommended to disinfect the Instrument after each patient sample, or if contamination is suspected. Excessive liquid may damage the Instrument. It is important for the protection of the Instrument that exposure to excess moisture is prevented. All disinfection cloths and/or wipes should only be 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 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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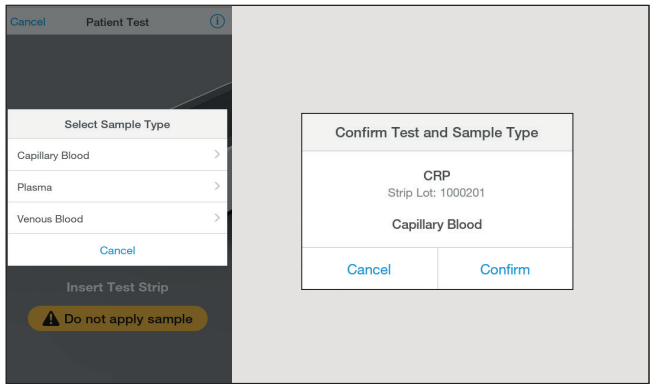
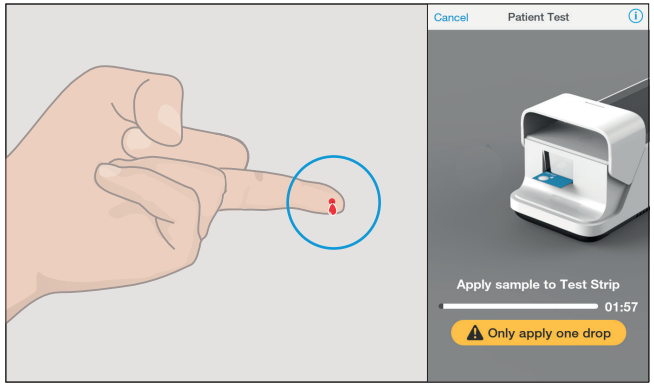


4. Select sample type

Select the appropriate sample type and confirm the test type.

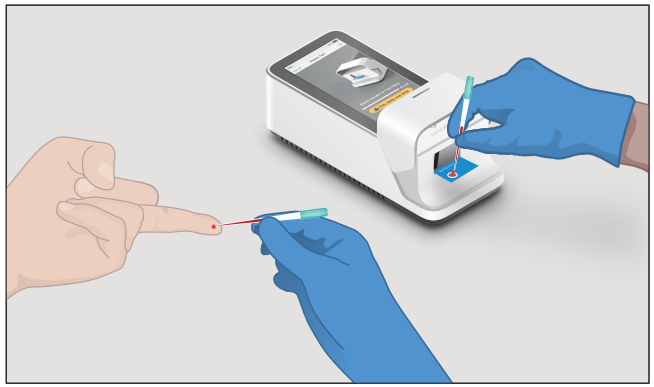


5. Create a hanging blood drop

When prompted to apply the sample by the **Instrument** use a high-flow lancet on the finger to create a hanging blood drop if using a capillary sample.

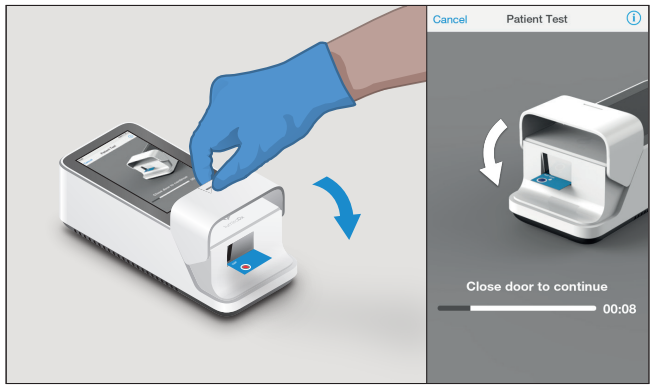
6. Apply the sample

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



7. Alternative transfer

Alternatively a 20µL Lithium Heparin Transfer Tube can be used. **See the CRP Test Strip Product Insert** for other sample types.

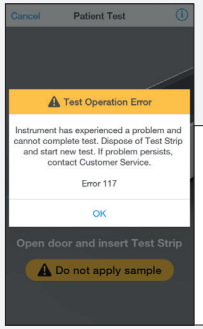


8. Close door

Close the door when prompted to continue the test.

9. Results displayed

Results are displayed 4 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*.



⚠ 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.

INTERPRETATION OF RESULTS

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.

Quality Controls

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

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