Quick Reference Instructions
HbA1c Test

For *in vitro* diagnostic use

The LumiraDx HbA1c test is a single use fluorescence immunoassay designed to measure HbA1c in human whole blood. The measurement of HbA1c allows physicians and pharmacists to monitor patients with diabetes, or as an aid to screen and identify those at risk for developing diabetes.

Study the LumiraDx Platform User Manual and LumiraDx HbA1c 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.

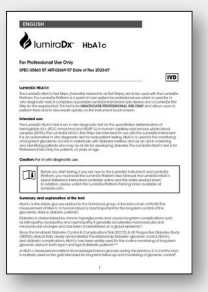
Check expiration date on outer test carton and each individual test package before using. Do not use any test components beyond its expiration date. Refer to the LumiraDx HbA1c Test Strip Product Insert for Specimen Collection, Warnings and Precautions, and Limitations.

Warnings and Precautions

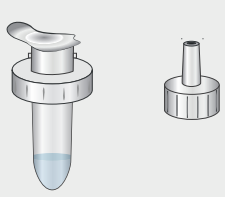
All kit components can be discarded as Biohazard waste according to local guidelines. Refer to the product safety data sheet for risk and safety phrases and disposal information. The product safety data sheet is available at lumiradx.com. Exercise the normal precautions required for handling all laboratory reagents. Proper laboratory safety techniques should be followed at all times when working with HbA1c patient samples. Patient samples, used Test Strips and used Lysis Devices 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 – however, should any reagent become exposed it should be treated as potentially infectious.

1. What's in the Box

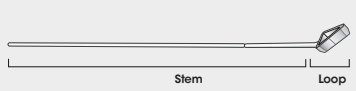
Test Strips



Product Insert



Lysis Buffer Tube & Dropper Lid

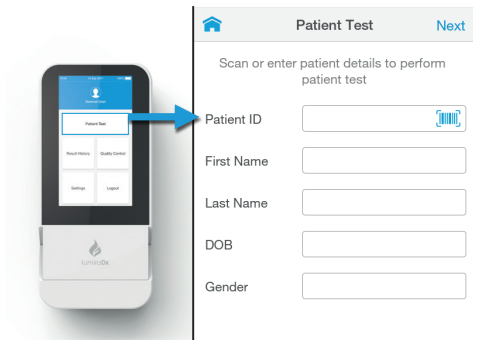


Transfer Device

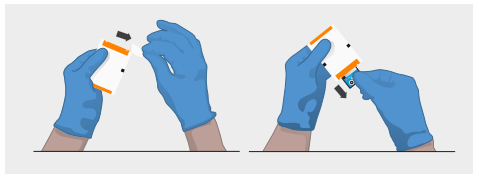
2. Performing a patient test

1. **Press *Patient Test* on the Home Screen and enter patient details.**

Always follow the on-screen prompts.

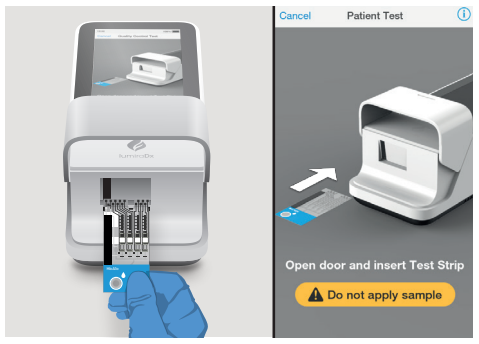


2. **Remove the Test Strip from its pouch and hold by gripping only the blue portion.**



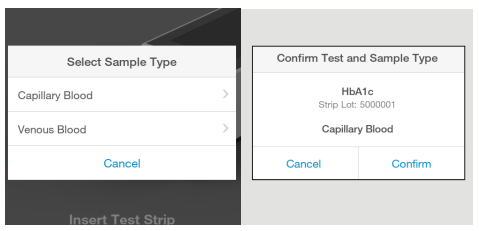
*Do **NOT** bend the Test Strip or touch any part other than the blue portion.*

3. **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 or close the door until prompted by the Instrument.*
- *The Instrument will prompt the user to install the Lot Calibration file only when a new test strip lot is used. If no Lot Calibration File is required then you can proceed with the test normally. To install the Lot Calibration file follow the on screen instructions or refer to section 2.8 of the Platform User Manual.*

4. **Choose the appropriate sample type and confirm the test type.**

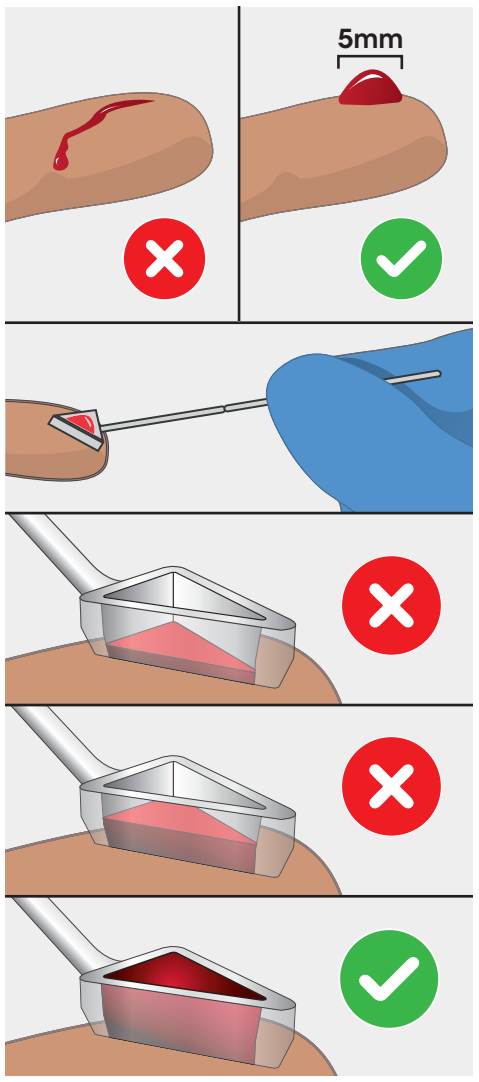


5. **For capillary samples use a high flow lancet on the selected finger to obtain a large beaded blood sample, roughly 5mm wide (15µL).**

It is recommended to use a lower numbered gauge (G) high flow lancet to extract the appropriate blood drop size.

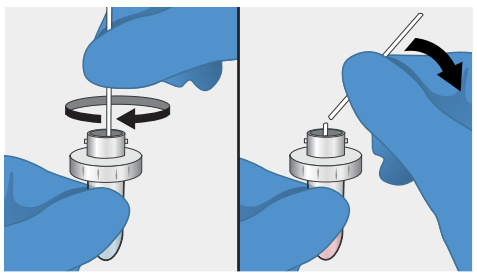
6. **Once a large, beaded drop has formed, lightly press and hold the loop of the Transfer Device against the blood drop until the loop is full.**

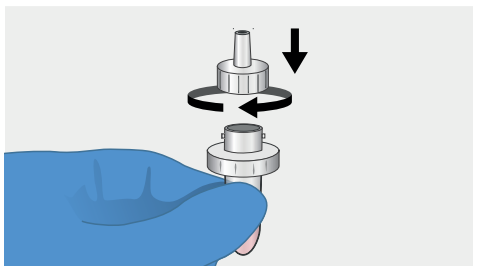
Completely fill the Transfer Device before transferring to the Buffer Tube.



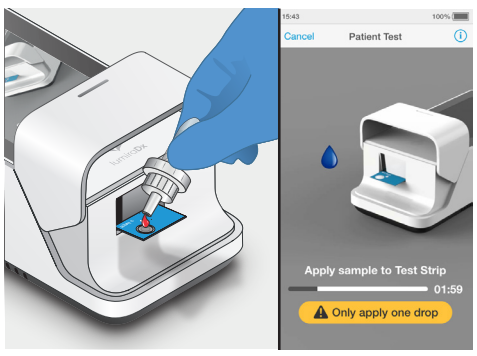
2. Performing a patient test (continued)

7. **Place the Transfer Device into the Lysis Buffer Tube and roll the Transfer Device 10 times between the index finger and thumb to lyse the blood. Directing the tube away from the face, snap the Transfer Device stem at the breakpoint, leaving the loop in the tube. Dispose of the upper part of the stem. Place the Dropper Lid on the tube.**

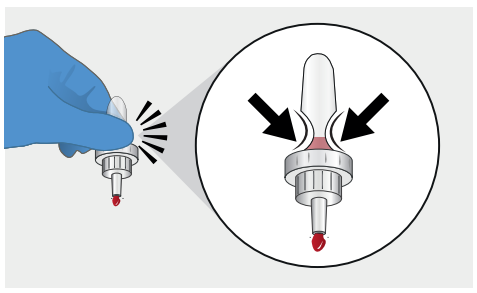




8. **Add *only one whole drop* of lysed sample to the Sample Application Area of the Test Strip when prompted.**



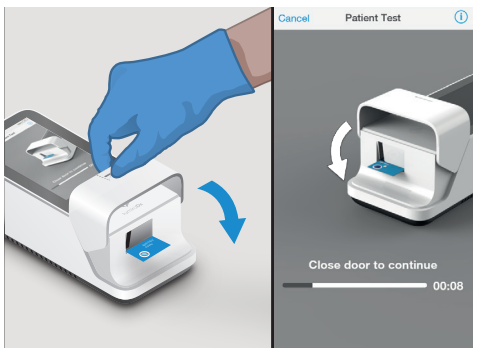
> *Do **NOT** apply more than one drop of sample.*



- *Once the sample is applied it may take up to **15 seconds** before the sample is detected.*
- *Do **NOT** touch the Test Strip until the test has finished and the result is displayed.*

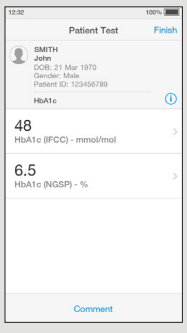
9. **For venous whole blood samples (EDTA) *please see the HbA1c Test Strip Product Insert* for instructions.**

10. **When prompted, close the door immediately to continue the test.**

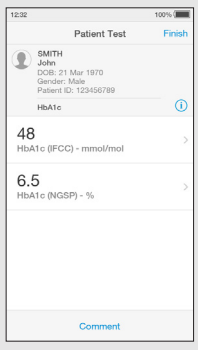
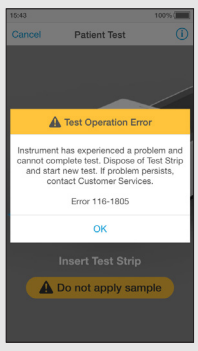


- *Do **NOT** open the door or move the Instrument during the test.*
- *The countdown timer is only displayed for a few seconds. It is important to close the door quickly when prompted to avoid test errors.*

11. **Results are displayed within <7 minutes of applying the sample. Tap *Finish* to complete the test or tap *Comment* to leave a comment or to reject the test. All test results must be read using the LumiraDx Instrument.**



3. Interpretation of results

Display on screen	Interpretation
	Each HbA1c result is reported on screen in mmol/mol and/or % HbA1c units of measurement. Please refer to the Results section of the HbA1c Test Strip Product Insert for more information on interpretation of results.
	If an issue occurs, a message will be displayed on the Instrument. Error messages include a ⚠ symbol. All messages will contain a description of the error and an instruction. Follow the instructions to start a new test. If the problem persists, contact LumiraDx Customer Services via lumiradx.com or customerservices@lumiradx.com

4. Additional Information

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.

Quality Controls

To complete Quality Control assessment of the LumiraDx Instrument and HbA1c Test Strips, you must use the LumiraDx HbA1c Quality Controls which are available separately. If the LumiraDx HbA1c 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.

Manufacturer Information

CE 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

Customer Support

If the LumiraDx HbA1c test or the LumiraDx Instrument do not perform as expected, contact LumiraDx Customer Services via lumiradx.com or customerservices@lumiradx.com