

LumiraDx HbA1c – Optimising your Workflow

Introduction

The innovative, easy to use LumiraDx Platform was designed to have a simple and standardised workflow. Whereas the LumiraDx INR, D-Dimer, CRP, NT-proBNP & SARS-CoV-2 Antibody tests* are direct fingerstick assays, the LumiraDx HbA1c Test requires a lysis step prior to sample application, making the workflow unique relative to our other blood-based assays. This Technical Bulletin provides a closer look at how it all works.

Key points to remember:

- Always use a **high flow lancet**.

Note: the needles or blades within the lancets come in a variety of sizes, which are measured in gauges (G), blade widths and puncture depths. Higher gauge (G) numbers indicate smaller, lower-flow needles, while lower gauge numbers indicate larger, higher-flow needles. Higher width numbers indicate a larger, higher flow blade. When running the LumiraDx HbA1c Test, it is recommended to use a **high flow lancet** to get an adequate 15µL drop of blood. Please ensure to select the appropriate gauge (G) number, blade width and/or puncture depth when sourcing lancets.

- Wait for the blood drop to form **in the shape of a small bead, about 5mm in diameter**, before trying to collect the sample with the transfer device. Ideally, the drop that forms should be beaded. If the blood drop runs down the finger, the sample won't collect properly in the loop of the transfer device. Refer to the below images for examples of an ideal blood drop.

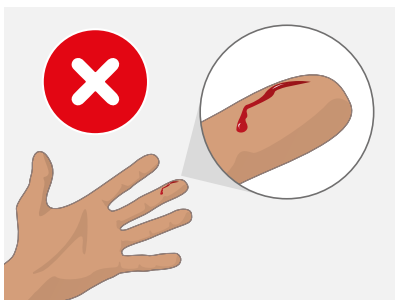


Image 1.
Incorrect – the blood drop is running down the finger

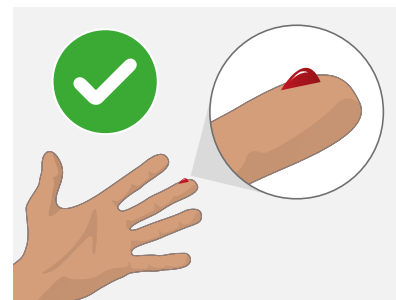


Image 2.
Correct – the blood drop is beaded and about 5mm in diameter

- Only try to collect the sample **once**. It's important to wait for the beaded blood drop to form to be large enough in size before trying to collect the sample with the transfer device. If you try to collect the sample multiple times to fill the sample loop, bubbles may form, causing underfilling of the transfer device.
- Ensure that the **sample loop is completely full**. To do so, hold the sample loop on the beaded blood drop until the loop is completely full. Refer to the below images for further guidance.

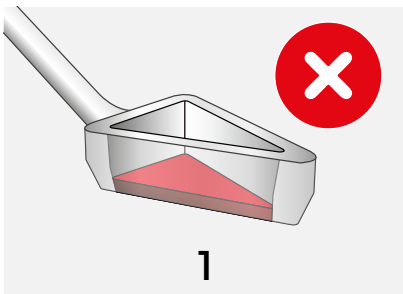


Image 1.
Incorrect – the loop is only about 25% filled

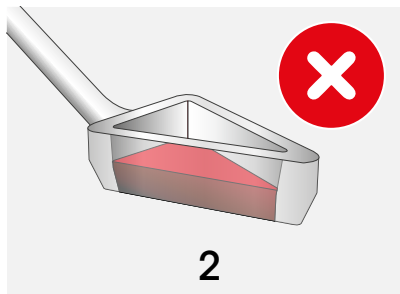


Image 2.
Incorrect – the loop is only about 50% filled

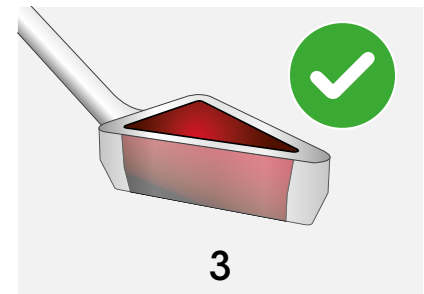


Image 3.
Correct – the loop is completely filled

Note: Inadequate or inappropriate sample collection can result in incorrect results.

- Once you place the transfer device into the lysis buffer, you must **mix the sample thoroughly** to create a hemolysate, or a solution where all of the red blood cells have lysed. To do this, roll the stem of the transfer device between the thumb and index finger quickly at least 10 times. The resulting hemolysate solution should be a uniform, pink colour.

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- When you break the top of the transfer device off from the bottom part, ensure to **point the tube and contents away from your face.**
- When applying the sample, **you only need to apply 1 large drop** – or about 20µL of sample – on to the sample application area. The ideal place to squeeze the Lysis Buffer Tube is at the top of the Tube towards the crown of the Dropper Lid. Refer to the below image for further guidance.

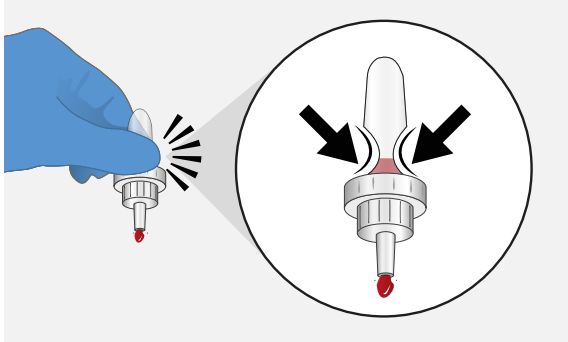


Image 4.

Ideal area on Lysis Buffer Tube to squeeze to generate a large drop of haemolysate

Note: regardless of how hard or how soft you squeeze the tube, the resultant drop should be almost exactly 20µL in volume.

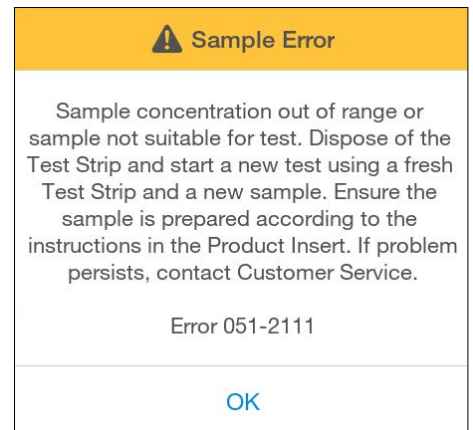
Stability of the Sample in the Lysis Buffer:

What do you do if one of the below has occurred?

- You are sampling now, but want to perform the test later
- A user error has occurred, but your sample is perfectly fine

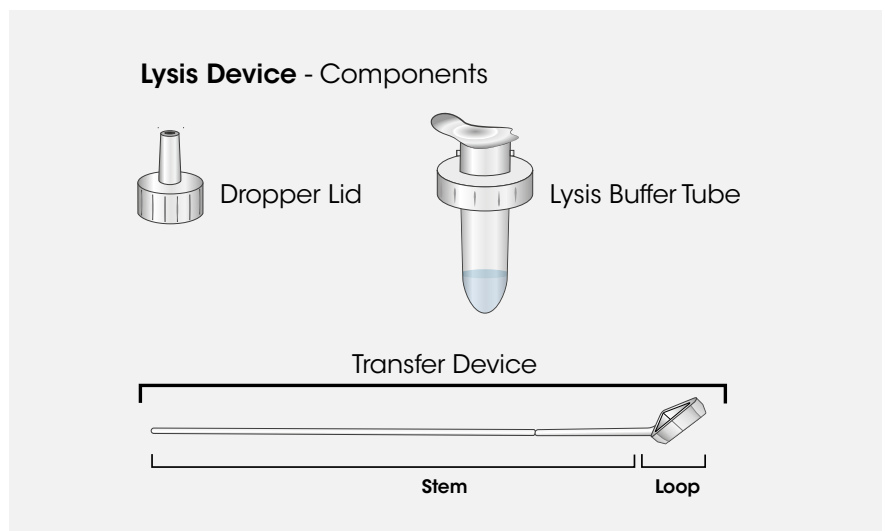
Note: if you receive an Error 051-2111, which is most often due to over-filling or under-filling the Transfer Device, please discard the prepared sample and collect/prepare a new fingerstick

The sample is stable in the buffer solution for up to 5 hours. You can place it off to the side in a tube holder and use it as soon as you are ready to run a LumiraDx HbA1c test.



Lysis Device Defined:

You'll see specific terms to refer to the different components of the Lysis Device referred to in the Product Insert. Here are all of them easily defined:



* Not all products are available in all countries and regions. Please check with your local LumiraDx sales representative or distributor for availability in specific markets.