

TEST DISC :

- Keep the test kit refrigerated 2-8°C until expiry date.
- When performing a test, allow disc to reach room temperature.
- Only take the disc out of the pouch after reading the barcode.
- Once the pouch has been opened, the disc must be loaded and inserted into the spinit[®] instrument within 10 minutes.
- Using capillary blood, the sample should be introduced within one minute into the disc after collection.



SAMPLE COLLECTION:

- Use capillary blood directly from finger, fresh venous whole-blood (EDTA) or capillary whole-blood of human origin.
- spinit[®] HbA1c disc is ready-to-use and does not require any reagent preparation step.
- spinit[®] strips:
 - The vial must be stored at room temperature;
 - Always close the vial immediately after removing a spinit[®] strip.



spinit[®] HbA1c CONTROLS:

- Store the controls refrigerated (2-8°C). Opened controls are stable for 50 days.
- Allow the control material to reach room temperature before use.
- Mix the control material thoroughly by shaking the vial for 30 seconds.
- Use Quality Control mode for control testing.
- The measured value should be within the acceptable range stated in the spinit[®] HbA1c Controls IFU.



spinit[®] INSTRUMENT:

- Switch the spinit[®] instrument on by pressing the ON button.
- Wait until spinit[®] stabilises;
- Information codes for the spinit[®] HbA1c assay:

INFO CODE	CAUSE	SOLUTION
114	Not enough sample volume to be measured.	Collect a new sample and repeat the test using a new disc.
210	Not enough reagent volume or previously used disc.	

Training materials:



Consult spinit[®] instrument instructions:

- spinit[®] user manual
- spinit[®] HbA1c controls IFU
- spinit[®] HbA1c IFU

Necessary materials to perform the test:

Supplied with the kit:

- spinit[®] HbA1c discs
- spinit[®] strips

Not supplied:

- Gloves
- Disinfectant towel
- Lancet
- Tissue paper



- Remove disc from refrigerator and wait to reach room temperature unopened;
- Press **Start** button and follow on-screen instructions;



- Scan the barcode from the disc pouch;
- Take the disc out of the pouch;



- Place the disc on a plain surface with label facing up;
- Press the reagent blister using your thumb;



- Prepare the sampling area by cleaning the finger using a disinfectant and allow it to dry;
- Remove a spinit® strip out of the vial and close the vial immediately after;
- Prick the patients finger using a lancet and wipe away the first drop of blood;



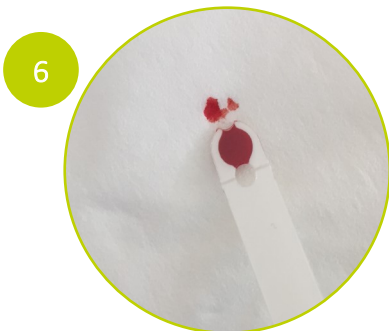
- Collect the second drop of blood by holding the tip of the strip to the surface of the blood drop;
- Observe the sample area is fully loaded. If not, it is possible to refill;
- The sample should be introduced within **one minute** into the disc after collection;



Enough sample and correctly filled;



NOT correctly filled;



- Clean the strip by gently wiping each side;
- Observe again if the sample area is fully loaded; make sure it is perfectly filled;
- If not, discard the strip and use another one.



- Insert the strip by sliding the strip tip into the disc sample well;
- Fold back to break the strip and leave the sample inside the disc;



- Once you have the disc ready, click **Next** on the screen;
- Place the disc into the instrument and follow on screen instructions;
- Wait for test result;
- Press Eject and remove disc.



For expected values, refer to spinit® HbA1c test instructions for use.
Discard lancet, strip and disc according to the country laws.
Do not re-use the disc.