LumiraDx™

HbA1c Test Specifications

For *in vitro* diagnostic use.

Intended use

The LumiraDx HbA1c test is an *in vitro* diagnostic test for the quantitative determination of hemoglobin A1c (IFCC mmol/mol and NGSP %) in human capillary and venous whole blood samples (EDTA). The LumiraDx HbA1c Test Strips are intended for use with the LumiraDx Instrument. It is an automated *in vitro* diagnostic test for near-patient testing. HbA1c is used for the monitoring of long-term glycaemic control in individuals with diabetes mellitus, and as an aid in screening and identifying patients who may be at risk for developing diabetes.

The LumiraDx HbA1c test is for Professional Use Only. For patients ≥2 years of age.

Test description

The LumiraDx HbA1c test is a single use fluorescence immunoassay device designed to measure HbA1c in human whole blood. The test procedure involves the lysis of capillary or venous whole blood followed by addition of the hemolysate to the Sample Application Area of the Test Strip inserted in the Instrument. The Instrument is programmed to perform the analysis when the sample has reacted with the reagents within the Test Strip. The analysis is based on the amount of fluorescence the Instrument detects within the measurement area of the Test Strip. The concentration of the analyte in the sample is proportional to the fluorescence detected. The results are displayed on the Instrument touch-screen <7 minutes from the addition of sample.

The LumiraDx HbA1c test is traceable to the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) primary reference method for the measurement of HbA1c.

Built-in quality controls

The LumiraDx Platform is integrated with several built-in quality control checks to ensure that the Instrument and Test Strips are functioning correctly for every test run. These checks include:

- Electrical component operation, heater operation, battery charge state, mechanical actuators, sensors and optical system performance
- Test Strip positioning
- Test Strip expiry
- Monitoring of Test Strip performance and microfluidics controls during test runtime
- The HbA1c test contains an Onboard Quality Control (OBC) assay
- Sufficient sample volume
- Hemoglobin correction

HbA1c quality controls

To complete a quality control assessment of the LumiraDx Instrument and HbA1c Test Strips, you must use the LumiraDx HbA1c quality controls. The LumiraDx HbA1c quality controls come in two levels. The frequency of testing should be determined by local guidelines. Refer to the LumiraDx HbA1c quality controls pack insert for information on testing procedure for the LumiraDx HbA1c quality controls.

Method comparison

The LumiraDx HbA1c Test was evaluated at the European Reference Laboratory for Glycohaemoglobin (ERL) by Dr. Erna Lenters-Westra (Clinical Chemistry Department, Isala, Zwolle, The Netherlands). The aim of the evaluation was to assess the performance of fresh EDTA whole blood samples compared to values assigned using four IFCC and NGSP certified Secondary Reference Measurement Procedures (SRMPs)*. The method comparison results between the mean of the 4 SRMPs and the mean of the 2 LumiraDx Instruments can be found below.

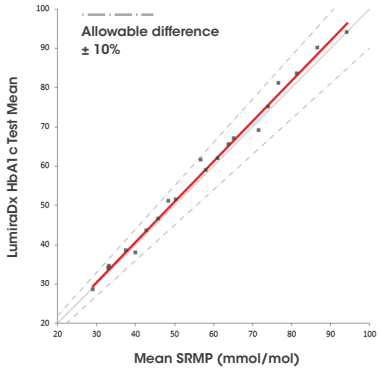

Figure 1: Method comparison results between the mean of the 4 SRMPs and the mean of the 2 LumiraDx Instruments in mmol/mol

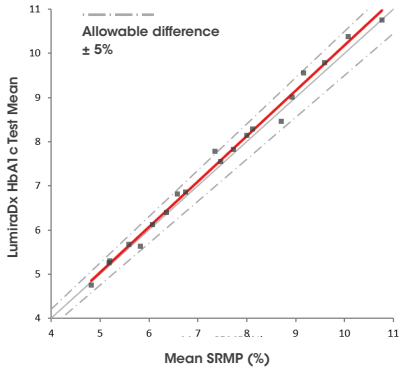

Figure 2: Method comparison results between the mean of the 4 SRMPs and the mean of the 2 LumiraDx Instruments in % HbA1c

*The 4 IFCC and NGSP SRMPs used in this evaluation were:

1. Roche Tina-quant Gen.3 HbA1c on Cobas c513, immunoassay, IFCC and NGSP certified SRMP (Roche Diagnostics)
2. Premier Hb9210, boronate affinity chromatography HPLC, IFCC and NGSP certified SRMP (Trinity Biotech)
3. Tosoh G11, cation-exchange HPLC, IFCC certified SRMP (Tosoh Bioscience)
4. Abbott Enzymatic method on Alinity, IFCC and NGSP certified SRMP (Abbott Diagnostics).

Precision

A precision study was carried out in venous whole blood (EDTA) on a protocol based on CLSI EP5-A3. The study was carried out at 2 concentrations of HbA1c, each was tested in 1 run of 5 replicates per day, for 5 days across 3 sites. The results of the precision study are summarised below:

HbA1c Concentration (%)	Within Day Precision (%CV)	Between Day Precision (%CV)	Between Site Precision (%CV)	Total Precision (%CV)	n
Level 1- 6.5 – 7.5% (48 – 58 mmol/mol)	2.9%	2.0%	1.9%	4.0%	70
Level 2 - 8.5 – 9.5% (69 – 80 mmol/mol)	2.3%	1.7%	1.6%	3.4%	75

HbA1c test specifications

Certification	IFCC, NGSP
Displayed results	Haemoglobin A1c (IFCC mmol/mol and NGSP %)
Storage temperature	2–30°C (36–86°F)
Operating temperature	15–30°C (59–86°F)
Measuring range	20-130 mmol/mol (4.0-14.0%)
Sample size	15 µl
Sample type	Capillary fingerstick or venous whole blood (EDTA) via lysis device
Time to result	< 7 minutes
Hb variant interference	No significant interference from HbS, HbC, HbE or HbD*
Reference range[1]**	Non-diabetic: <39 mmol/mol (5.7% HbA1c) Pre-diabetic: 39 - 47 mmol/mol (5.7 - 6.4% HbA1c) Diabetic: ≥ 48 mmol/mol (≥6.5% HbA1c)

* See LumiraDx HbA1c Test Product Insert for additional details
**Each laboratory should determine a reference range that is representative of the patient population to be evaluated.

References:
1. American Diabetes Association. Standards of Care in Diabetes - 2023.

For more information visit lumiradx.com or contact the LumiraDx Customer Services by email: customerservices@lumiradx.com or Phone: 0080058647239

Product is not available in all countries and regions. Please check with your local LumiraDx sales representative or distributor for availability in specific markets.

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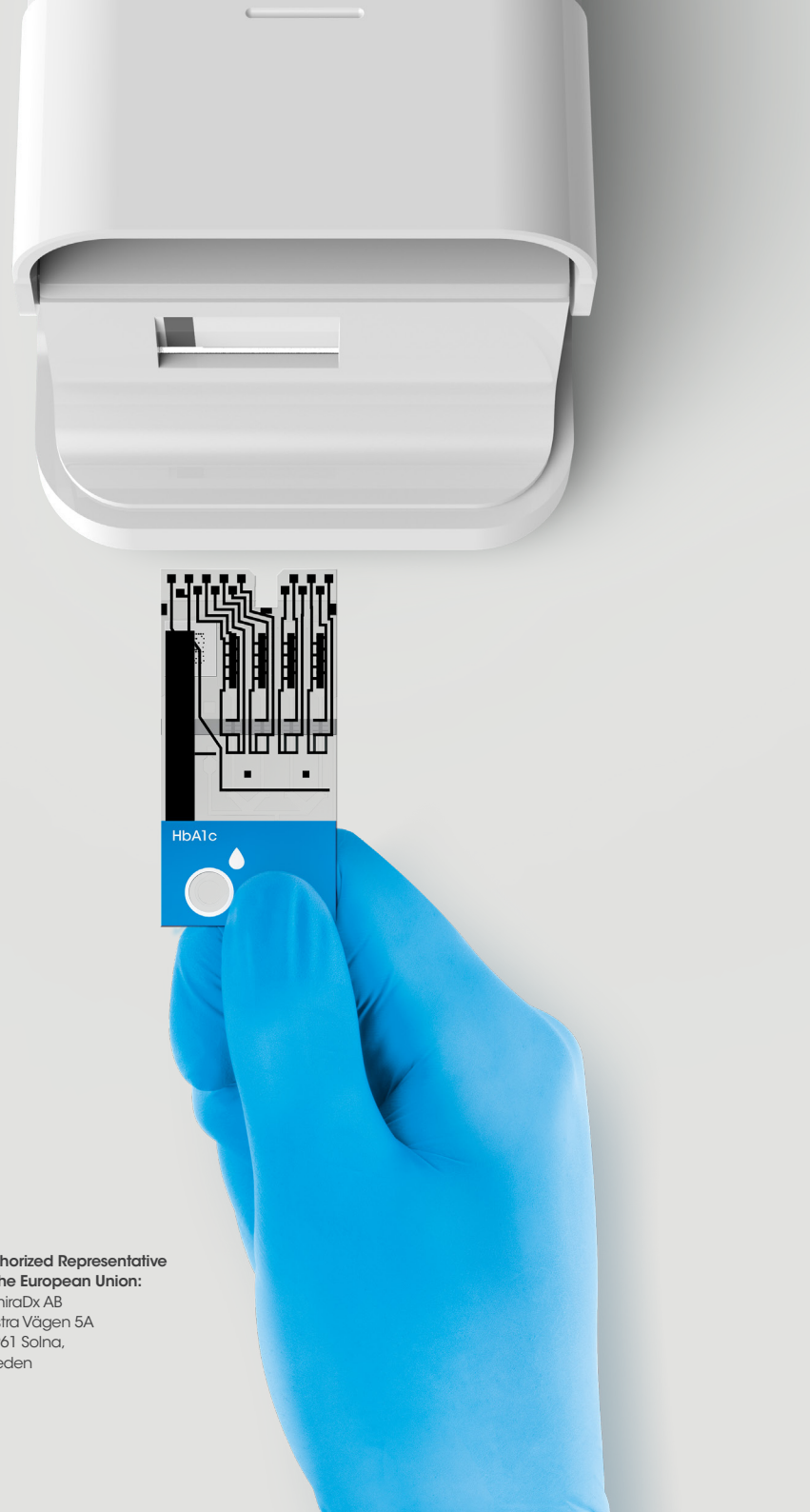

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