Pre-evaluation of the LumiraDx HbA1c Test

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Background

The LumiraDx HbA1c test is a next-generation point of care test 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.

Run on the smart, connected, highly portable LumiraDx Platform, the LumiraDx HbA1c test utilises a novel active microfluidic immunoassay technology. The Platform was designed to improve global accessibility to diabetes testing, and to increase ease of use in community-based healthcare settings.

The LumiraDx HbA1c test is certified and traceable to the International Federation of Clinical Chemistry (IFCC) Primary Reference Measurement Procedure (PRMP) and is National Glycohemoglobin Standardization Program (NGSP) certified.

Methods

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 this initial 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).

Materials

Across one day, twenty (20) fresh EDTA whole blood samples were analysed in duplicate across two LumiraDx Platforms.

The HbA1c samples were value-assigned using four IFCC and NGSP certified SRMPs:

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

The bias was calculated using the mean of the four SRMP at 30, 48 and 75 mmol/mol, the results were calculated using Analyse-it®.

Results

Table 1 shows the actual measured values of both LumiraDx Instruments and the mean of the 4 SRMPs. Figures 1 and 2 show the results of the Deming regression line between the mean of the 4 SRMPs and the mean of the 2 LumiraDx Instruments in mmol/mol and % HbA1c.

Mean SRMP		LumiraDx Instrument 1		LumiraDx Instrument 2		LumiraDx Instrument Mean	
mmol/mol	%	mmol/mol	%	mmol/mol	%	mmol/mol	%
29.1	4.81	28	4.7	29	4.8	28.5	4.75
33.3	5.20	34	5.3	35	5.4	34.5	5.35
33.1	5.18	33	5.2	35	5.4	34.0	5.3
37.5	5.58	38	5.6	39	5.7	38.5	5.6
40.1	5.82	36	5.4	40	5.8	38.0	5.6
42.9	6.08	43	6.1	44	6.2	43.5	6.15
45.9	6.35	46	6.4	47	6.4	46.5	6.4
48.4	6.58	50	6.7	52	6.9	51.0	6.8
50.3	6.75	52	6.9	51	6.8	51.5	6.85
56.8	7.35	60	7.6	63	7.9	61.5	7.75
58.1	7.47	58	7.5	60	7.6	59.0	7.55
61.0	7.73	62	7.8	62	7.8	62.0	7.8
63.9	8.00	64	8.0	67	8.3	65.5	8.15
65.2	8.12	67	8.3	67	8.3	67.0	8.3
71.7	8.71	69	8.5	69	8.5	69.0	8.5
74.1	8.93	77	9.2	73	8.8	75.0	9.0
76.7	9.17	80	9.5	82	9.6	81.0	9.55
81.3	9.59	82	9.6	85	9.9	83.5	9.75
86.6	10.07	94	10.8	86	10.0	90.0	10.4
94.2	10.77	97	11.0	91	10.5	94.0	10.75

Table 1: Method comparison results between the mean of the 4 SRMPs and the 2 LumiraDx Instruments in mmol/mol and % HbA1c

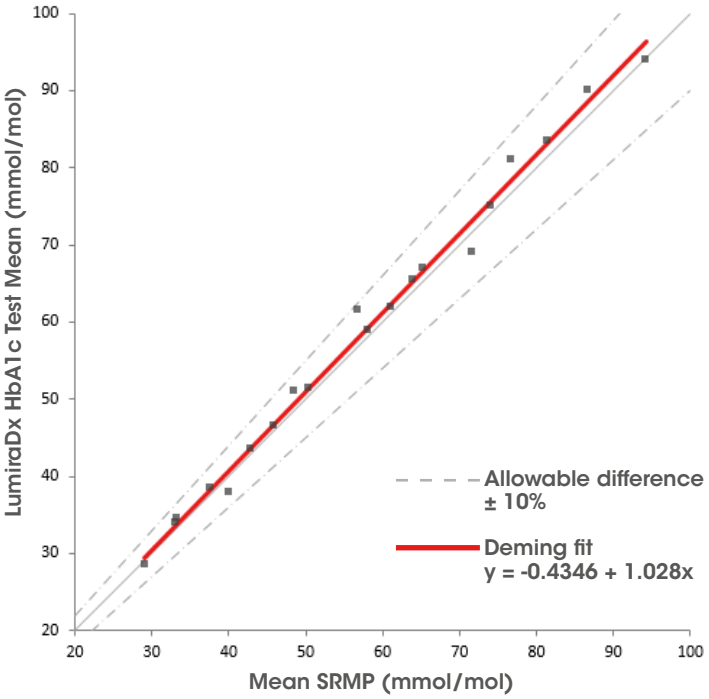

Figure 1: Method comparison results between the mean of the 4 SRMPs and the mean of the 2 LumiraDx Instruments in mmol/mol

Comparability

	X	Predicted Y	95% CI
1	30.0	30.4	29.15 to 31.65
2	48.0	48.9	48.11 to 49.69
3	53.0	54.0	53.24 to 54.84
4	64.0	65.3	64.29 to 66.40
5	75.0	76.7	75.17 to 78.13
6	86.0	88.0	86.00 to 89.92

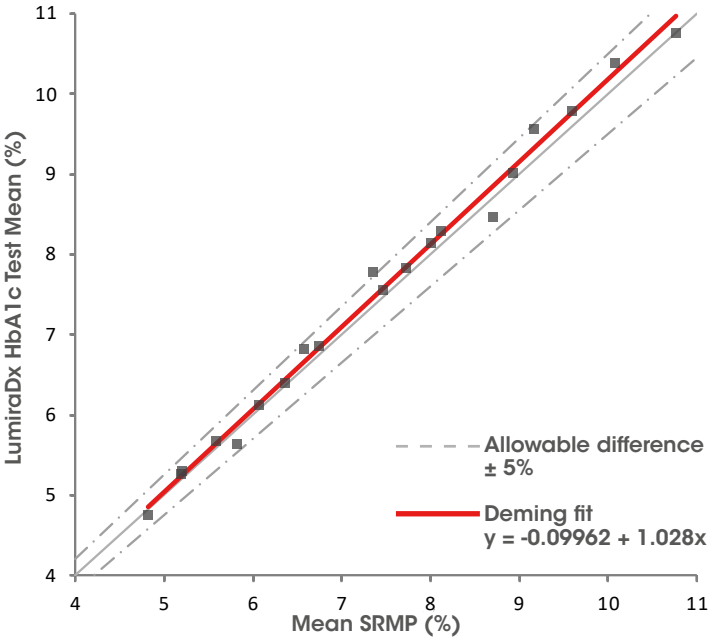

Figure 2: Method comparison results between the mean of the 4 SRMPs and the mean of the 2 LumiraDx Instruments in % HbA1c

Comparability

	X	Predicted Y	95% CI
1	5.00	5.04	4.929 to 5.150
2	6.50	6.58	6.509 to 6.654
3	7.00	7.10	7.022 to 7.168
4	8.00	8.12	8.026 to 8.219
5	9.00	9.15	9.016 to 9.285
6	10.00	10.18	10.000 to 10.357

The bias at 30 mmol/mol (5.0%) was 0.4 mmol/mol (0.04%), at 48 mmol/mol 0.9 mmol/mol (0.08%) and at 75 mmol/mol was 1.7 mmol/mol (0.15%).

Conclusion

The LumiraDx Instrument is a very modern POCT instrument with many positive features which may be of advantage in community-based healthcare settings. For example:

- the Instrument is very small and portable
- the Test Strips can be transported and stored at room temperature
- the Instrument can run on battery power
- the software is easy to use

The results from the pre-evaluation study showed acceptable/good analytical performance. However, we still need to perform a full evaluation to further assess broader analytical performance. Feedback was also provided to LumiraDx that a shorter assay time and overall simplicity of the pre-analytical steps should be considered for future configurations of the product.

The pre-evaluation will be followed-up by a full evaluation which is due to commence in 2023.