

Summary & Interpretation

Article: Challenges in Hb A1c Point-of-Care Testing: Only 5 of 19 Hb A1c Point-of-Care Devices Meet IFCC and NGSP Certification Criteria on Independent Evaluation



Article Link



Summary Link

- ❖ Origin: <https://www.finddx.org/publications-and-statements/scientific-article/challenges-in-hb-a1c-point-of-care-testing-only-6-of-19-hb-a1c-point-of-care-devices-meet-ifcc-and-ngsp-certification-criteria-on-independent-evaluation/>
- ❖ Research Funding: This study was funded by **FIND** (Foundation for Innovative New Diagnostics), who works closely with WHO under a formal collaborative agreement, through a grant from the Canadian Department of Foreign Affairs, Trade and Development and the Swiss Agency for Development and Cooperation (SDC). i-SENS provided the device and reagents free of charge.
- ❖ The link for the On Call MultiPro FIND report being archived and cited by authoritative academic institutions.
 - **Clinical Chemistry of Oxford Academic, UK:**
<https://academic.oup.com/clinchem/article/71/7/775/8148925>
 - **PubMed of NIH (National Institutes of Health), USA:**
<https://pubmed.ncbi.nlm.nih.gov/40415568/>
 - **Apollo of the University of Cambridge, UK:**
<https://www.repository.cam.ac.uk/items/31ec0e85-ab99-4ba5-9363-f670db988712>

1 Study Purpose

- 1.1 To evaluate the analytical performance of 19 HbA1c POC devices whether they meet the IFCC and NGSP certification criteria
- 1.2 To evaluate whether the 19 HbA1c POC devices suffer from interference from Hb variants.

2 HbA1c POCT devices included in the study

Model	Manufacturer	Method principle
A1CNow+	PTS Diagnostics	Immunoassay
A1C EZ 2.0	Wuxi BioHermes	Boronate affinity
A1Care	i-SENS	Enzymatic
Afinion 2	Abbott	Boronate affinity

Cobas b101	Roche Diagnostics	Immunoassay
GPP-100	Goldsite Diagnostics	Nephelometry
Hb A1c Test	LumiraDx	Immunoassay
PixoTest	iXensor	Immunoassay
Quo-Lab	EKF Diagnostics	Boronate fluorescence (quenching)
Quo-Test	EKF Diagnostics	Boronate fluorescence (quenching)
Hb A1c 501	HemoCue	Boronate affinity
Spinit	Biosurfit	Immunoassay
Greencare A1c	Greencross	Boronate affinity
Atellica DCA	Siemens	Immunoassay
On Call MultiPro	Acon Lab	Immunoassay
Lyofia	Vacure	Immunoassay
CareBuddy	Care4You	Boronate affinity
TD-4611	Taidoc	Immunoassay
Hb A1c Test	LumiraDx	Immunoassay

3 Reference adopted

3.1 Precision & Trueness: mean of the following 4 IFCC & NGSP Secondary Reference Measurement Procedures (SRMPs)

- ◊ Roche Tina-quant Gen.3 Hb A1c on Cobas c513, immunoassay (Roche Diagnostics)
- ◊ Premier Hb9210, affinity chromatography HPLC (Trinity Biotech)
- ◊ Tosoh G11, cation-exchange HPLC (Tosoh Bioscience)
- ◊ Abbott Enzymatic method on Alinity (Abbott Diagnostics)

3.2 Interference from Hb Variants: HbS, HbC, HbD, HbE, HbF

- ◊ HbS, HbC, HbD, HbE: Reference by Arkray HA8190V (HPLC) & Sebia Capillarys 3 Octa (Electrophoresis), assigned value by Premier Hb9210 (HPLC)
- ◊ HbF: Sebia Capillarys 3 Octa (Electrophoresis), assigned value by Arkray HA8190V (HPLC)

4 Performance Criteria

4.1 Precision & Trueness:

4.1.1 IFCC criteria:

- ◊ Sigma value $>2\sigma$ (for routine method)
- ◊ Sigma value $>4\sigma$ (for clinical trial)
 - Sigma value = $(TAE - \text{bias})/CV$
 - TAE (Total Allowable Error): 6.9% at HbA1c 6.7% level
 - Bias: Calculated at HbA1c 6.5% level (CLSI: EP-9-A3)
 - CV: Calculated at HbA1c 6.5% level (CLSI: EP-15-A3)
 - $CV = \frac{\sigma}{\bar{x}}$

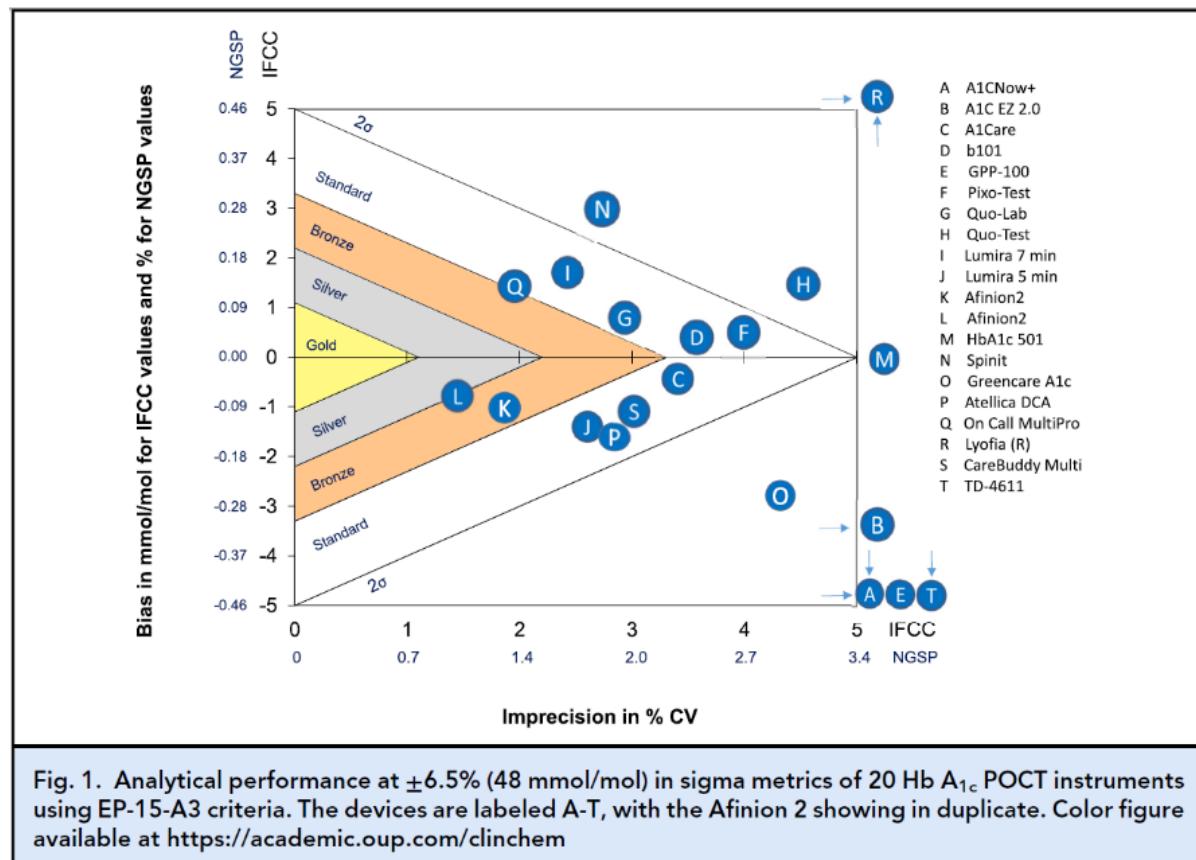
4.1.2 NGSP criteria

36 out of 40 results (of a panel of comparison specimens) must be within $\pm 5\%$ relative difference of the value obtained using an individual SRMP

4.2 Interference of Hb Variants & HbF

A mean ($n = 10$ per Hb vari-ant) relative difference exceeding $\pm 6.9\%$ in NGSP units ($\pm 10\%$ in SI units) compared to the assigned value was defined as clinically significant.

5 Results



5.1 IFCC criteria

- ❖ Gold, Silver, and Bronze zones represent a $<6.9\%$ (10.0% in SI units) TAE standard: only **Afinion 2 L, K** and **MultiPro Q** fall into the Bronze area
- ❖ Sigma value $>2\sigma$ (for routine method): A1CNow+, A1C EZ 2.0, GPP-100, Quo-Test, Hb A1c 501, Spinit, Greencare A1c, Lyofia, and TD-4611 failed. (**On Call MultiPro: 3.4 σ**)
- ❖ Sigma value $>4\sigma$ (for clinical trial): **only Afinion 2 meets the criteria**

5.2 NGSP criteria

5.2.1 Only 5 (Afinion 2 twice) have passed when compared to at least one SRMP

Device	Result using NGSP criteria			
	Premier Hb9210	Roche Cobas c513	Tosoh G11	Abbott Alinity
Afinion 2	Pass ▲	Pass ▲	Pass ▲	Pass ▲
	Pass ▲	Pass ▲	fail	Pass ▲
Quo-Lab	Pass ▲	Pass ▲	Pass ▲	Pass ▲
On Call MultiPro	fail	Pass ▲	Pass ▲	fail
Cobas b101	fail	Pass ▲	Pass ▲	fail
Atellica DCA	fail	fail	fail	Pass ▲
The other 14 devices	fail	fail	fail	fail

36/40 results must be within 5% relative difference of SRMP to pass NGSP manufacturer certification

5.3 Interference from Hb Variants

Device	HbS, HbC, HbE, HbD	HbF	Device	HbS, HbC, HbE, HbD		HbF
On Call MultiPro,	No Interference	>6.8%	A1CNow+	HbS, HbC	No conclusion due to poor performance	
A1Care	No Interference	>11%	Cobas b101	HbE		>5.1%
Quo-Lab	No Interference	>11%	Hb A1c 501	HbS, HbC, HbE		>19%
Quo-Test	No Interference	>11%	A1c EZ 2.0	Have interference but not confirmed which variant		>5.1%
Spinit	No Interference	>6.9%	GPP-100	Have interference but not confirmed which variant		
Greencare A1c	No Interference	>6.9%	PixoTest	Have interference but not confirmed which variant		
Atellica DCA	No Interference	>5.1%	CareBuddy	Have interference but not confirmed which variant		>6.9%
LumiraDx,	No conclusion due to frozen specimen unvalidated		Lyofia	No conclusion due to poor performance		
Affinion 2	Not tested due to frozen specimen inapplicable		TD-4611	No conclusion due to poor performance		

6 Conclusion for On Call MultiPro

6.1 Out of the 19 devices tested, On Call MultiPro is one of the only 5 that have passed both the IFCC criteria and the NGSP criteria when compared to at least one SRMP;

6.1.1 IFCC criteria: Out of the 20 devices tested, only **Afinion 2 L, K** and **MultiPro Q** fall into the bronze area representing <6.9% TAE (Total Allowable Error) (10.0% in SI units) when results of ep-15-A3 (precision) and EP-9-A3 (bias) at 6.5%(48 mmol/mol) were used for a graphical representation.

6.1.2 NGSP criteria: Out of the 19 devices tested, only 5 can pass when compared with at least one SRMP

6.2 On Call MultiPro has no interference to HbS, HbC, HbE, and HbD variants, the interference level of HbF of On Call MultiPro is >6.8%

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