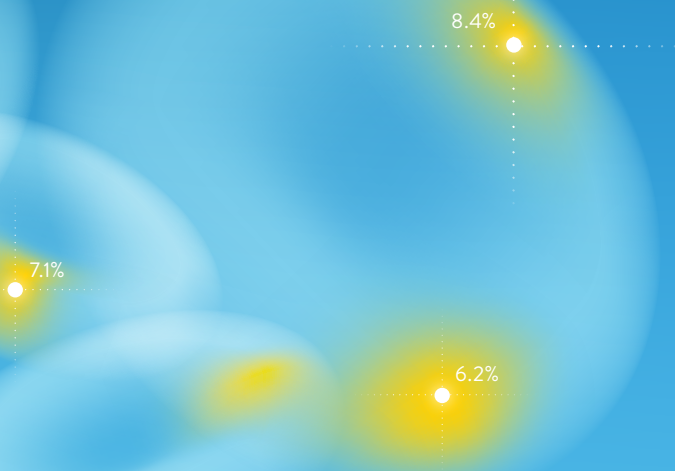
Abbott

ACCURACY AND PRECISION OF THE AFINION™ HbA1c



While point of care (POC) has the potential to save time, money and effort for patients, healthcare practitioners and healthcare facilities, it is important to ensure the accuracy and precision of these tests. The market for POC glycated hemoglobin (HbA1c) tests has grown quickly over the last few years, and there are more and more point-of-care testing (POCT) options available to physicians, making it increasingly difficult to determine which devices are truly reliable. It is essential to choose a device that is evidence-backed and laboratory-equivalent.[1]

AFINION™ HbA1c

- The performance has been investigated in a large number of studies over the years (see the following summary tables).
- Recent studies comparing the Afinion™ HbA1c assay to routine and reference laboratory methods have consistently shown a bias close to zero and a coefficient of variation (CV) below 2% (NGSP units).[2-6]
- The test has recently been judged to be excellent.[5]
- Clinical assessments performed in healthcare settings show the reliable performance in the hands of non-laboratory staff using fingerprick capillary blood.[2,7]
- External quality assurance data from the College of American Pathologists proficiency testing survey and the EurA1c trial demonstrate the good performance is in the hands of end users and that the Afinion™ HbA1c matches or even outperforms routine laboratory methods.[8,9]
- The Afinion™ HbA1c has been certified by the IFCC and the NGSP for more than a decade, which demonstrates the traceability of the results to the IFCC reference measurement procedure and to the Diabetes Control and Complications Trial reference method.[8,10]

"Point-of-care testing for HbA1c offers a wealth of opportunities to provide a rapid, accurate and easy to access tool for healthcare professionals, with performance of some devices matching or even outperforming routine laboratory instruments."[11]

COMPARISON OF THE AFINION™ HbA1c TEST WITH LABORATORY METHODS

PUBLICATION	COMPARATOR	ACCURACY AFINION™	PRECISION AFINION™	FURTHER CRITERIA	CONCLUSION
Nathan DM, et al. *J Diabetes Sci Technol.* 2019.[2]	**Reference method:** Premier Afinity™ HbA1c assay on the Premier Hb9210™ HbA1c Analyzer	**Mean difference, technician (venous):** Absolute: -0.01% HbA1c Relative: -2.1% **Mean difference, non-technician (fingerstick):** Absolute: -0.2% HbA1c Relative: -3.41% **Absolute bias:** -0.2% HbA1c	**CV, technician performed (venous):** 0.78–1.18% **CV, non-technician performed (fingerstick):** 1.39–1.54%	**Technician performed (venous):** r^2 = .977, P < .001 **Non-technician performed (fingerstick):** r^2 = .978, P < .001	The POCT performed acceptably compared to the laboratory assay under realistic clinical conditions.
Arnold WD, Kupfer K, Little RR, et al. *J Diabetes Sci Technol.* 2019.[3]	**Reference method:** Tosoh glycohemoglobin test on the Tosoh HLC®-723G8 Analyzer at a NGSP SRL	**Relative bias (venous):** -0.25–-0.60% **Relative bias (fingerstick):** -0.33–-0.80%	**Total CV (venous):** 1.31–1.64% **Total CV (fingerstick):** 1.30–2.03%	**Total error (venous):** 2.93–3.80% **Total error (fingerstick):** 2.87–4.75%	The POCT evaluated is precise across its measuring range using both fingerstick and venous whole blood. The total error is well under the accepted quality requirement of ≤ 6%.
Arnold WD, Kupfer K, Swensen MH, et al. *J Diabetes Sci Technol.* 2019.[4]	**Reference method:** Tosoh glycohemoglobin test on the Tosoh HLC®-723G8 Analyzer at a NGSP SRL	**Bias (venous):** Differential: -0.005% Relative: -0.058% **Bias (fingerstick):** Differential: -0.021% Relative: -0.311%	**Total CV (venous):** 1.11–1.69% **Total CV (fingerstick):** 0.62–1.93%	**Correlation (venous and fingerstick):** r = 0.99 97% of results fell within ± 6% of the NGSP reference method results regardless of sample type	The results indicate that the POCT evaluated here is accurate and precise using both fingerstick and venous whole blood.

PUBLICATION	COMPARATOR	ACCURACY AFINION™	PRECISION AFINION™	FURTHER CRITERIA	CONCLUSION
Lenters-Westra E, English E. *J Diabetes Sci Technol*. 2018.[5]	**Reference method:** Four certified SRMs: Premier Hb9210™ HbA1c Analyzer Roche Tina-quant® HbA1c Gen. 3 Tosoh HLC®-723G8 Analyzer Abbott HbA1c (enzymatic) on ARCHITECT™ c4000	**Mean absolute bias (venous):** 0.01/-0.01% HbA1c 0.03/0.04% HbA1c 0.03/0.04% HbA1c 0.01/0.01% HbA1c	**CV (venous):** 1.2% at 6.5% HbA1c 0.9% at 9% HbA1c 1.7% at 48 mmol/mol* HbA1c 1.1% at 75 mmol/mol* HbA1c	**Sigma:** 5.8	The analytical performance was excellent for the Afinion™ 2 Analyzer and the Quo-Lab® HbA1c Analyzer, acceptable for the HemoCue® HbA1c 501, and unacceptable for the A1Care™ HbA1c Analyzer according to different criteria used.
Sobolesky PM, et al. *Clinical Biochemistry*. 2018.[6]	**Reference method:** Tosoh HLC®-723G8 Analyzer at a NGSP SRL	**Total bias (venous):** Relative: -0.6% at 6.5% HbA1c Absolute: -0.04% at 6.5% HbA1c	**Total CV (venous):** 0.85–1.46%	**Correlation:** r = 0.994 97.1% of the POC results fell within the target value of ± 6% of the NGSP reference method results	The accuracy and precision of the Afinion™ HbA1c method was comparable to the laboratory HbA1c methods supporting the FDA's recent approval of the Afinion™ HbA1c Dx device for use in the diagnosis of diabetes.
Torregrosa ME, et al. *Endocrinol Nutr*. 2015.[12]	**Reference method:** Adams™ A1c HA-8160	**Mean absolute bias (venous):** -0.04% at 6.6% HbA1c	**CV (venous):** 1.8% at 7% HbA1c	**Correlation (venous):** r = 0.98	Only the Afinion™ AS100 Analyzer met all the NGSP performance criteria.

Note: All numbers presented in NGSP units except those marked with "*".

SRL = secondary reference laboratory

SRM = secondary reference measurement

COMPARISON OF POC METHODS

PUBLICATION	COMPARATOR	ACCURACY	PRECISION	FURTHER CRITERIA	CONCLUSION
Lenters-Westra E, English E. *J Diabetes Sci Technol*. 2018.[5]	**Reference method:** (Four certified SRMs)	**Mean absolute bias:**	**CV:** at 6.5%/9% HbA1c (at 48/75 mmol/mol HbA1c)*	**Sigma:**	The analytical performance was excellent for the Afinion™ 2 Analyzer and the Quo-Lab® HbA1c Analyzer, acceptable for the HemoCue® HbA1c 501, and unacceptable for the A1Care™ HbA1c Analyzer according to different criteria used.
	Afinion™ 2	-0.06–0.04% HbA1c	1.2/0.9% (1.7/1.1%)*	5.8	
	Quo-Lab®	-0.08–0.04% HbA1c	1.6/1.8% (2.4/2.4%)*	4.0	
	HemoCue®	-0.18–-0.08% HbA1c	2.1/1.7% (3.4/2.7%)*	2.1	
	A1Care™	-0.13–-0.02% HbA1c	4.1/2.9% (6.2/4.1%)*	1.4	
Torregrosa ME, et al. *Endocrinol Nutr*. 2015.[12]	**Reference method:** Adams™ A1c HA-8160	**Mean absolute bias:** at 4.6–9.9% HbA1c	**CV:** at 7% HbA1c (53 mmol/mol)	**Correlation:**	Our study showed that the Afinion™ AS100 Analyzer is superior to the other two POC analyzers for monitoring blood glucose control in patients with diabetes mellitus at the office.
	Afinion™	-0.04% HbA1c	1.8%	r = 0.98	
	DCA Vantage®	-0.28% HbA1c	3.74%	r = 0.98	
	In2it™	0.06% HbA1c	7.14%	r = 0.83	

PUBLICATION	COMPARATOR	ACCURACY	PRECISION	FURTHER CRITERIA	CONCLUSION
Lenters-Westra E, Slingerland RJ. *Clin Chem*. 2014.[13]	**Reference method:** (Three certified SRMs)	**Mean absolute bias:**	**CV:** at 6.2–6.4%/8.0–8.9% (at 44–47/61–74 mmol/mol HbA1c)*		Afinion™, DCA Vantage®, Cobas® b 101 and B-Analyst® instruments met the generally accepted performance criteria for HbA1c. Quo-Test® HbA1c Analyzer, Quo-Lab® HbA1c Analyzer and InnovaStar® met the criteria for precision, but not for bias.
	Afinion™	-0.08–0.05%	1.3/1.4% (2.1/1.9%)*		
	B-Analyst®	0.11–0.19%	1.2% at 8.0–8.9% (1.6%)*		
	Cobas® b 101	-0.05–0.09%	1.8/1.2% (2.8/1.5%)*		
	DCA Vantage®	-0.15–0.06%	1.9/3.2% (3.1/4.2%)*		
	InnovaStar®	0.13–0.18%	1.2/0.9% (1.9/1.3%)*		
	Quo-Lab®	0.16–0.20%	1.9/1.6% (2.7/2.0%)*		
	Quo-Test®	0.19–0.22%	2.1/1.7% (3.1/2.2%)*		
Hirst JA, et al. *Clin Chem Lab Med*. 2017.[14]	**Meta-analysis:** Afinion™ B-Analyst® Cobas® b 101 DCA Vantage® InnovaStar® Quo-Lab® Quo-Test® A1c Gear® A1cCare A1CNow® NycoCard™ CLOVER A1c®		**Total CV:** 1.9% 1.5% 1.5% 2.5% 2.3% 1.9% 3.4% 1.4% 2.7% 2.9% 3.8% 3.8%		There were sufficient data to carry out meta-analysis on the diagnostic accuracy for five devices (Afinion™, DCA Vantage® Analyzer, A1CNow®, Quo-Test® HbA1c Analyzer and NycoCard™ READER II). Sensitivity across all the devices was similar. The Afinion™ and DCA Vantage® Analyzer had the highest specificity at a cutoff of 6.5% HbA1c.

Note: All numbers presented in NGSP units except those marked with "*".

SRL = secondary reference laboratory

SRM = secondary reference measurement

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