HbA1c point-of-care devices: analytical performance and features

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This document or register is intended to help those working in general practice to select a fit-for-purpose device for Point-of-Care Testing (POCT) for glycated haemoglobin or HbA1c.

There are several devices available in Australia with varying analytical performance. To qualify for reimbursement, the MBS Item Number for POCT HbA1c includes a statement that GPs should use a method and instrument certified by the National Glycohemoglobin Standardization Program (NGSP) and the instrument has a total coefficient of variation (CV) less than 3.0% at 48 mmol/mol (6.5%), a critical clinical decision point.

The data in the register has been obtained from fully independent evaluations of the devices, either published in peer-reviewed publications listed in databases such as PubMed or by organisations associated with the independent evaluations of HbA1C devices or providing External Quality Assurance (EQA) programs. Preference will always be given to data from Australian based organisations.

The register provides information about multiple aspects of device performance but the most important are listed under (1) and (2) in the Table.

Only 4 of the 5 devices listed have full evaluation data available.

In (1) are listed various measures of device precision. The criteria of precision as stated in the MBS Item Number is a CV of < 3% which most devices have in, either a single evaluation or from multiple evaluations, where an average CV has been calculated from all the evaluations.

The most stringent criterion for precision is that obtained by an External Quality Assessment scheme (EQA) which assesses precision across multiple devices in many different locations. It should be noted that for the data shown, only one of the POCT devices has a CV <3.0% using this very demanding criteria. It should be noted that several laboratory based devices also do not have a CV <3.0%, a reflection of how demanding is this particular criteria.

If devices with a CV% >3.0% are used, it means that when reviewing two sequential results on the same patient, a larger difference between the two results will need to occur in order to be deemed clinically significant, as compared to using devices with a CV<3.0%.

Under (2) are listed measures of device accuracy. This shows the devices are using certified reference standards from the IFCC and NGSP. This is an important step towards making them accurate and ensuring that a patient will get the same result no matter where they are tested. Secondly it shows how well these devices perform when measuring samples containing accurately defined amounts of HbA1c in blood. The Table shows that three of the four devices fully meet the accuracy criteria.

Other measures of performance are also shown and notes appended at the bottom provide further explanations of these additional criteria, together with the sources of all the information shown in the Table.

The register will be updated with new information as it appears including other devices if they become available for sale in Australia.

Device, model[a]	Afinion™ Analyzer (Abbott)		cobas b 101 (Roche)		DCA Vantage (Siemens)		HbA1c 501 (Hemocue)		QuikReadgo HbA1c (Aidian)	
Analytical performance										
1. Precision[b]	HbA1c mmol/mol	CV %	HbA1c mmol/mol	CV %	HbA1c mmol/mol	CV %	HbA1c mmol/mol	CV %	HbA1c mmol/mol	CV %
• Mean performance from multiple evaluations (no. of studies) (1)	42 (6 studies)	2.5			42 (17 studies)	2.5				
• Performance in a single evaluation			46 (2)	2.8			46 (3)	3.4		
• Performance in RCPA EQA scheme		2.2 (5)				4.9 (5)				
• Performance in other EQA schemes (6)	41.6 & 57.4	3.4			42.2 & 57.9	3.6				
2. Accuracy[c]										
Type of certification: • NGSP certified • IFCC Certified Grade of certificate	Yes Yes Silver		Yes Yes		Yes Yes		Yes Yes		Yes Yes	
Passes or fails NGSP certification when device compared to lab based methods or reference materials	Pass (3)		Pass (4)		Pass (6)		Pass against 3 of 4 lab. Instruments (3)			
3. Interferences[d]										
• HbC	< ± 10%		< ± 10%		< ± 10%		< ± 10%			
• HbS	< ± 10%		< ± 10%		< ± 10%		< ± 10%			
• HbE	< ± 10%		+17.1 (6)		< ± 10%		< ± 10%			
• HbD	< ± 10%		< ± 10%		< ± 10%		< ± 10%			
• HbF	< ± 10% at <10.4% HbF (8)		> 10% at 9.5% HbF (4)		-12.3% (6)		Not measured (3)			

Device, model	Afinion™ Analyzer (Abbott)	cobas b101	DCA Vantage	HbA1c 501	QuikReadgo HbA1c
4. Linearity (across measuring range)[(e)]	Linear (9)	Non-linear (4)		Linear (4)	
5. Measures of user friendliness [(f)] i. System usability score (SUS) ii. SKUP assessment	Highest rating in evaluation of user-friendliness (10)	95 (4)			

Explanatory Notes:

(a) Manufacturers periodically change the models and names of their devices sometimes with changes in performance and/or features. The models indicated here are those on which the most data is available according to the previously stated criteria. Check with the device supplier on whether their current device is the same as in that listed in the Table or, if different, whether it is likely to have a similar performance.

(b) The precision or CV% of the HbA1C test should ideally be <3.0% which allows a valid comparison of a patient's HbA1c results over time as part of patient monitoring. Measures of precision may be shown under: Multiple evaluations: Single evaluations; RCPA External Quality Assurance (EQA) Program Data and other EQA program data.

(c) The accuracy of an HbA1c test is important when using set cut-off values to make a diagnosis of diabetes. The accuracy of all HbA1c tests has been much improved through manufacturers using either NGSP or IFCC standardisation or a combination of the two.
To pass NGSP standardisation instruments must show minimal differences to the stated value of samples with NGSP defined concentrations. The colour of certificates indicate the performance of the device with gold the best but silver and bronze also acceptable.

(d) Interferences or false values can occur due to the presence of a number of haemoglobin variants; a clinically significant interference is defined as a difference of ±10% from the HbA1c values of a method not subject to interferences.

(e) Linearity is assessed through the CLSI-EP-6 protocol and if any results are more than 3 mmol/mol from the regression line, the method is termed non-linear.

(f) Two assessments of design & user-friendliness are shown. The SUS score is graded as follows: >81 excellent. 71-81 good, 52-70 OK and <51 poor.

References

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