

## Position Statement

Subject: **Use of 'Point of Care' Testing for the Measurement of Haemoglobin A1c (HbA1c)**  
Approval Date: March 2018  
Review Date: March 2021  
Review By: Board of Professional Practice and Quality  
Number: 2/2018

---

### Introduction

Several point-of-care (POCT) instruments are capable of generating HbA1c results from whole blood samples. This Position Statement is intended to provide guidance for appropriate use of these devices for the management of diabetes. At this stage, POCT testing for HbA1c does not appear to be sufficiently robust for diagnostic purposes. The report highlights potentially vulnerable areas such as the need for whole blood Quality Assurance material. Use of the appropriate external quality assurance (EQA) programs are essential.

### Background

The earliest reports indicate that the performance of different devices for the POCT measurement of HbA1C varied considerably<sup>1-4</sup>. Haemoglobin variants were identified as a source of error from an early stage<sup>5</sup>. Randomised controlled studies did not reveal any outcome or cost benefit associated with POCT measurement of HbA1C in a primary care setting<sup>6</sup>, nor was it associated with increased patient or health professional satisfaction<sup>7</sup>. Nevertheless, the potential for improved management in specific settings, including rural and remote Australia, was recognised<sup>8</sup>. POCT was found to be non-inferior to pathology laboratory testing for measuring glycated haemoglobin (HbA1c)), in an Australian primary care trial of its impact on therapeutic control<sup>9</sup>.

By 2009, evidence suggested that analytical performance was subject not only to the type of device, but also to the between batch variability in consumables<sup>10</sup>. Accordingly, participation in external quality assurance programs was recommended<sup>10</sup>. The technology was adapted to enable HbA1C kits to be sold over the counter for direct to consumer usage<sup>11</sup>. New devices were developed, but only a minority (25%) met analytical requirements<sup>12</sup>. Device-specific reference ranges were recommended, but this was in the era before standardization of HbA1C<sup>13</sup>. Additional outcomes trials permitted meta-analysis, but this continued to fail to demonstrate clinical benefit<sup>14</sup>.

### Appropriate Use

It was recognised that longitudinal monitoring of patients was less of a problem than the determination of HbA1C in relation to diagnostic thresholds<sup>15</sup>. Participation in external quality assurance programs was associated with progressive improvement. Reports of validation of individual devices have become the predominant form of publication, but the importance of widespread problems with bias is widely reported. This has led to calls for periodic re-calibration<sup>16</sup>. Some studies have claimed that POCT devices in primary care can perform well enough to enable their use for diagnostic purposes, but the potential impact on population-wide diabetes prevalence may not have been considered<sup>17</sup>. Improved outcomes in Australian rural and remote settings, particularly aboriginal health services, persist as one of the most favourable applications of POCT HbA1C<sup>18</sup>.

## Quality of results

Initiatives including the International Federation of Clinical Chemistry (IFCC) traceability suggest that POCT devices tended to be less precise, but differences in precision can be partially ameliorated by calibration procedures. It remains to be determined whether or not re-calibration can compensate for between-batch variability in reagents. The impact of imprecision on disease prevalence demands careful scrutiny of inaccuracy, no matter how trivial. Surveillance of both the instruments and their reagents<sup>19,20</sup> via external quality assurance programs will remain an essential feature. At present, whole blood quality assurance materials are mandatory. It would be helpful if more stable EQA reagents could be developed to allow longitudinal monitoring.

## Evaluation

Local evaluation by NSW Health Pathology has concluded that 2 of 6 devices were fit for purpose (a second device was re-evaluated following the presentation of new data). This occurs against a background in which several devices fluctuate between satisfactory and unsatisfactory<sup>21</sup>. A small minority appear to meet requirements on a predictable basis.

## Useful links:

<https://www.rcpa.edu.au/getattachment/be70bab5-49f5-4e23-a671-5495c2f14b4a/Point-of-Care-Testing.aspx>

## References

1. Porter KH, Myers GL. Implications of point-of-care testing for hemoglobin A1c. *Diabetes Technology & Therapeutics* 2000;2:527-8.
2. Hawkins RC. Comparison of four point-of-care HbA1c analytical systems against central laboratory analysis. *Singapore Medical Journal* 2003;44:8-11.
3. Sicard DA, Taylor JR. Comparison of point-of-care HbA1c test versus standardized laboratory testing. *Annals of Pharmacotherapy* 2005;39:1024-8.
4. Bjuhr M, Berne C, Larsson A. External quality assessment of HbA(1c) for point of care testing. *Uppsala Journal of Medical Sciences* 2006;111:201-7.
5. Haliassos A, Drakopoulos I, Katriasis D, Chiotinis N, Korovesis S, Makris K. Measurement of glycosylated hemoglobin (HbA1c) with an automated POCT instrument in comparison with HPLC and automated immunochemistry method: evaluation of the influence of hemoglobin variants. *Clinical Chemistry & Laboratory Medicine* 2006;44:223-7.
6. Khunti K, Stone MA, Burden AC, et al. Randomised controlled trial of near-patient testing for glycosylated haemoglobin in people with type 2 diabetes mellitus. *British Journal of General Practice* 2006;56:511-7.
7. Stone MA, Burden AC, Burden M, Baker R, Khunti K. Near patient testing for glycosylated haemoglobin in people with Type 2 diabetes mellitus managed in primary care: acceptability and satisfaction. *Diabetic Medicine* 2007;24:792-5.
8. Marley JV, Davis S, Coleman K, et al. Point-of-care testing of capillary glucose in the exclusion and diagnosis of diabetes in remote Australia. *Medical Journal of Australia* 2007;186:500-3.
9. Bubner TK, Laurence CO, Gialamas A, et al. Effectiveness of point-of-care testing for therapeutic control of chronic conditions: results from the PoCT in General Practice Trial. *Medical Journal of Australia* 2009;190:624-6.
10. Linters-Westra E, Slingerland RJ. Hemoglobin A1c point-of-care assays; a new world with a lot of consequences! *Journal of Diabetes Science & Technology* 2009;3:418-23.
11. Chang A, Frank J, Knaebel J, Fullam J, Pardo S, Simmons DA. Evaluation of an over-the-counter glycosylated hemoglobin (A1C) test kit. *Journal of Diabetes Science & Technology* 2010;4:1495-503.

12. Lenters-Westra E, Slingerland RJ. Six of eight hemoglobin A1c point-of-care instruments do not meet the general accepted analytical performance criteria. *Clinical Chemistry* 2010;56:44-52.
13. Petersen JR, Omoruyi FO, Mohammad AA, Shea TJ, Okorodudu AO, Ju H. Hemoglobin A1c: assessment of three POC analyzers relative to a central laboratory method. *Clinica Chimica Acta* 2010;411:2062-6.
14. Al-Ansary L, Farmer A, Hirst J, et al. Point-of-care testing for Hb A1c in the management of diabetes: a systematic review and metaanalysis. *Clinical Chemistry* 2011;57:568-76.
15. Alleyn CR, Laffel LM, Volkening LK, et al. Comparison of longitudinal point-of-care and high-performance liquid chromatography HbA1c measurements in a multi-centre trial. *Diabetic Medicine* 2011;28:1525-9.
16. Malkani S, Korpi-Steiner N, Rao LV. Reducing analytical variation between point-of-care and laboratory HbA1c testing. *Journal Of Diabetes* 2013;5:192-6.
17. Solvik UO, Roraas T, Christensen NG, Sandberg S. Diagnosing diabetes mellitus: performance of hemoglobin A1c point-of-care instruments in general practice offices. *Clinical Chemistry* 2013;59:1790-801.
18. Spaeth BA, Shephard MD, Schatz S. Point-of-care testing for haemoglobin A1c in remote Australian Indigenous communities improves timeliness of diabetes care. *Rural & Remote Health* 2014;14:2849.
19. Zhou R, Tong Q, Zuo C, et al. Point-of-care testing of HbA1C is traceable to IFCC reference method by external calibration. *Clinica Chimica Acta* 2014;433:249-53.
20. Manley SE, Hikin LJ, Round RA, et al. Comparison of IFCC-calibrated HbA(1c) from laboratory and point of care testing systems. *Diabetes Research & Clinical Practice* 2014;105:364-72.
21. Lenters-Westra E, Slingerland RJ. Three of 7 hemoglobin A1c point-of-care instruments do not meet generally accepted analytical performance criteria. *Clinical Chemistry* 2014;60:1062-72.