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Results from 15years of quality surveillance for a National Indigenous Point-of-Care Testing Program for diabetes

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Results from 15 Years of Quality Surveillance for a National Indigenous Point-of-Care Testing Program for Diabetes

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Abstract

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Introduction:

Diabetes is a major health problem for Australia's Aboriginal and Torres Strait Islander peoples. Point-of-care testing for haemoglobin A1c (HbA1c) has been the cornerstone of a long-standing program (QAAMS) to manage glycaemic control in Indigenous people with diabetes and recently, to diagnose diabetes.

Methods:

The QAAMS quality management framework includes monthly testing of quality control (QC) and external quality assurance (EQA) samples. Key performance indicators of quality include imprecision (coefficient of variation [CV%]) and percentage acceptable results. This paper reports on the past 15 years of quality testing in QAAMS and examines the performance of HbA1c POC testing at the 6.5% cut-off recommended for diagnosis.

Results:

The total number of HbA1c EQA results submitted from 2002 to 2016 was 29,093. The median imprecision for EQA testing by QAAMS device operators averaged 2.81% (SD 0.50; range 2.2 to 3.9%) from 2002 to 2016 and 2.44% (SD 0.22; range 2.2 to 2.9%) from 2009 to 2016. No significant difference was observed between the median imprecision achieved in QAAMS and by Australasian laboratories from 2002 to 2016 ($p=0.05$; two-tailed paired t-test) and from 2009 to 2016 ($p=0.17$; two-tailed paired t-test). For QC testing from 2009 to 2016, imprecision averaged 2.5% and 3.0% for the two levels of QC tested. Percentage acceptable results averaged 90% for QA testing from 2002 to 2016 and 96% for QC testing from 2009-2016. The DCA Vantage was able to measure a patient and an EQA sample with an HbA1c value close to 6.5% both accurately and precisely.

Conclusion:

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HbA1c POC testing in QAAMS has remained analytically sound, matched the quality achieved by Australasian laboratories and met profession-derived analytical goals for 15 years.

Key Words

HbA1c
Point-of-care testing
Diabetes
Indigenous health
Analytical quality

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1. Introduction

The prevalence of diabetes in Australia's Aboriginal and Torres Strait Islander population is 3-4 times higher than in the non-Indigenous Australian population and the onset of diabetes occurs at an earlier age and at much higher rates in Aboriginal and Torres Strait Islander people than in the non-Indigenous population [1]. Aboriginal and Torres Strait Islander people also experience four-times more deaths due to diabetes than non-Indigenous Australians [1].

The early detection and management of diabetes through good glycaemic control is crucial in preventing long-term micro- and macro-vascular complications of diabetes including end-stage renal disease, retinopathy, neuropathy and cardiovascular disease.

Point-of-care (POC) pathology testing allows pathology tests to be conveniently conducted during a patient consultation with results rapidly available for timely clinical action. POC testing for haemoglobin A1c (HbA1c) and urine albumin:creatinine ratio (ACR) on the DCA 2000/Vantage device (Siemens HealthCare Pty Ltd) has been the cornerstone of the QAAMS (Quality Assurance for Aboriginal and Torres Strait Islander Medical Services) POC Testing Program for diabetes management in Australia for the past 18 years. The QAAMS Program commenced as a small pilot in 1999. Through continuing funding from the Australian Government, the program has grown to include just over 200 DCA devices at Indigenous health services across Australia, the majority of which (greater than 75%) are in rural and remote locations. The program empowers Aboriginal Health Workers (Aboriginal people who are qualified in the practice of primary healthcare and who live and work in the community) to conduct POC testing on their Indigenous patients with diabetes when the patients visit the health service, with the patients receiving immediate clinical follow-up on their POC results during that same visit. POC testing has been shown to be culturally safe and clinically effective in supporting diabetes care for Australia's Indigenous population [2-6]. The program is managed by the Flinders University International Centre for

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Point-of-Care Testing, on behalf of the Australian Government, with the Royal College of Pathologists of Australasia (RCPA) Quality Assurance Programs Pty Ltd providing the proficiency testing component of the program.

The fundamental elements that have been responsible for the longevity and sustainability of QAAMS are comprehensive training and competency assessment programs, continuous surveillance of analytical quality through quality control (QC) and external proficiency (QA) testing, and intensive scientific and technical support services for participating services [7-9].

Haemoglobin A1c (HbA1c) has been a well-established pathology marker for monitoring long term diabetes control for more than 30 years. In Australia, since 2014, the HbA1c test has been approved to diagnose diabetes in accredited laboratories. This paper reviews the quality management framework employed by QAAMS, reports on the analytical performance of the HbA1c test on DCA devices enrolled in the program over the last 15 years (2002-2016) and examines the performance of the DCA Vantage POC testing device at the 6.5% (48 mmol/mol) cut-off value used in Australia for HbA1c for the diagnosis of diabetes [10].

2. Methods

The quality management framework for QAAMS comprises training for device operators, competency certification, continuous testing of quality control (QC) and external quality assurance (QA) samples and support for participating services.

2.1. Point-of-Care Testing Device

Over the lifetime of QAAMS, two models of the Siemens DCA point-of-care testing device have been used in the program. From 1999 to mid-2009, HbA1c testing was conducted on the DCA 2000 model and thereafter the original DCA 2000 device was systematically replaced with a

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newer model of the device, the DCA Vantage. Analytically, the two models are identical, with both measuring HbA1c by a light-scattering, latex inhibition agglutination immunoassay [11]. The DCA Vantage provides a larger results display screen, greater functionality for data entry and has capacity for electronic transfer of results.

2.2. Training of device operators

Device operators in QAAMS have access to a wide range of training resources, including a hard copy training manual, colour posters providing simple step-by-step guides showing how to conduct patient, QC and QA tests; a training power-point presentation; web-streamed videos of training available 24 hours a day/7 days a week on the QAAMS website (www.qaams.org.au); and a DVD containing all the above resources in electronic form. Training for participants is available in flexible formats including face-to-face (on-site visits, regional or annual workshops) or e-learning options (teleconference, videoconference or on-line videos). At the completion of training, all operators undergo a written and practical assessment to obtain a competency certificate (with 2-year expiry) as a qualified POCT device operator in the program.

2.3. Proficiency Testing

QAAMS participants are sent their proficiency testing (external quality assurance testing [EQA]) kits at the start of each calendar year. Each kit contains 24 lyophilised samples with reconstitution fluid; the samples comprise 6 paired and linearly related levels of HbA1c covering a range from approximately 5 to 12%. Each sample has an assigned target value and limits for acceptable performance which currently, for HbA1c, are +0.4 up to 6.7% and 6% at concentrations greater than 6.7% [12]. Two samples are made up and tested each month and there are two 6-monthly testing cycles per year (January to June and July to December).

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The material provided is the same as that used in the RCPA QAP's Glycohaemoglobin Program for Australasian laboratories, which enables direct comparison of analytical performance across the two programs.

At the start of each month, each service receives a monthly summary report detailing performance for QAP testing during the previous month. The report format has undergone modification and refinement over the years, with a focus to improve user-friendliness and cultural safety while providing relevant, readily interpretable tabular and graphical information on analytical performance. The report includes: a list of results submitted for each sample tested (colour coded green, orange or red, depending on their quality), the 'target values' for those samples (the median value of all results received) and a histogram showing the (de-identified) results returned for each sample by all participants, with an arrowhead pointing to the results reported by the individual service concerned. This report enables a simple and immediate visual assessment of performance.

At the completion of each 6-monthly cycle, key performance indicators of quality are calculated including:

- Percentage acceptable results (the percentage of results within the pre-set allowable limits of performance set by the RCPA QAP, as reported above); this indicator provides a measure of the accuracy of EQA testing, and,
- The median within-site imprecision (CV%); this indicator used as a standard measure of imprecision across all laboratory proficiency testing programs run by the RCPA QAP, as well as QAAMS.

2.4. Quality Control Testing

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In QAAMS, device operators at all participating services are required to test samples with two levels of HbA1c, reflective of a patient with optimal [approximately 5.5%] and poorly controlled diabetes [around 11.0%], from the Siemens Normal and Abnormal HbA1c QC kit each month.

From 1999 to 2015, device operators recorded their monthly QC results manually on a colour-coded QC result sheet and faxed them to the QAAMS Quality Manager from the International Centre for Point-of-Care Testing. The QC results sheets were designed to provide operators with a guide to immediately interpret the quality of their QC result and the action to be taken. The colour codes mimicked a 'traffic light' system. A QC result which fell within the 'green' zone meant the result was of sound quality and patient testing could proceed at the service; a result which fell within the 'orange zone' meant that patient testing could still proceed but the quality of testing would be monitored closely over subsequent months by the QAAMS Quality Manager. A 'red' result meant that the QC test result should be rejected and patient testing should cease until the reason for unacceptable performance had been addressed and resolved by the QAAMS Quality Manager.

Since 2016, QC testing results from each service can be entered electronically in a newly-developed 'QC Results' section on the QAAMS website, with entered results displayed using the same colour-coded system as described above and results being available for immediate review by the QAAMS Quality Manager.

The acceptable limits for QC testing are: within ±7.5% from the target value (set by the manufacturer for each lot number of QC kit) for the 'green zone', between ±7.5% and 10% from the target value for the 'orange zone' and >10% for the 'red zone'. QC limits were designed to provide a crude guide to overall analytical performance at the health service level and allowed for potential discrepancies between the manufacturer-assigned target values and the mean of

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participant results. The QC limits equate to between-site goals for total allowable error; that is, they encompassed allowable error due to both inaccuracy and imprecision. At six-monthly intervals (corresponding to the EQA testing cycles), the within-service imprecision (CV%) for QC testing is calculated for each individual service, following the receipt of a minimum of four QC results for each level tested. The median within-site imprecision is then calculated and, like EQA testing, can be compared with the analytical goals set by the program.

2.5. Support Services

As part of its quality management package, QAAMS provides a telephone support hotline, manned by a QAAMS scientist during normal business hours from Monday to Friday.

2.6. Performance of DCA Vantage at Diagnosis Cut-Off (HbA1c 6.5%)

The analytical performance of the DCA Vantage specifically at an HbA1c of 6.5% (the cut-off value used for the diagnosis of diabetes in Australia) was examined in two ways.

Firstly, within-day (n=10) and between-day (n=10) imprecision studies were performed by a Centre staff member with limited training, on three different DCA Vantage devices, using a de-identified patient whole blood sample with an HbA1c value of 6.5%, as measured by an HPLC method (BioRad Variant II) in the local accredited pathology laboratory.

Secondly, one of the six (paired) samples supplied by the RCPA Quality Assurance Programs Pty Ltd by QAAMS has a target value for HbA1c of 6.8% (close to the cut-off value of 6.5%). The median within-site imprecision achieved by QAAMS participants for this specific EQA sample was calculated from all results returned for each QA testing cycle for the past 5 years (cycles 26-35, 2011 to 2016).

3. Results

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Throughout the results section the data has been analysed from (i) 2002 to 2016, incorporating data from both the superseded DCA 2000 and the DCA Vantage and (ii) from 2009 to 2016 when the DCA Vantage was introduced into the program.

3.1. Number of POCT Devices and Quality Assurance Tests for HbA1c

Across the lifetime of the QAAMS Program, the number of POCT devices (DCA 2000 and/or DCA Vantages) at participating services has risen steadily from 45 in 1999 to 200 in 2016 (Fig. 1). The total number of external quality assurance samples for HbA1c tested in the 30 testing cycles from 2002 to 2016 was 29,093.

3.2. Percentage Acceptable Results

The percentage of HbA1c results for QA testing that were within the allowable limits of performance set by the program organisers (see above) averaged 89.5% (SD 5.5; range 77-96%) from 2002-2016 and 94.0% (SD 1.3; range 92-96%) from 2009 to 2016 when the DCA Vantage became available in the program.

For QC testing, the percentage of acceptable HbA1c results for QC testing averaged 95.6% (SD 2.61; range 88-98%) over the 16 testing cycles from 2009 to 2016.

3.3 Imprecision

Fig. 2 displays the median within-site imprecision (CV%) for HbA1c QA testing achieved by participating services in the program over the past 15 years from 2002 to 2016. The median imprecision achieved nationally by QAAMS device operators has averaged 2.81% (SD 0.50; range 2.2 to 3.9%) from 2002 to 2016 and 2.44% (SD 0.22; range 2.2 to 2.9%) from 2009 to 2016 since the DCA Vantage has been in use.

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It is possible to directly compare the performance of QAAMS services with Australian laboratories because the QAAMS and laboratory-based RCPA Glycohaemoglobin QAP use the same material for HbA1c testing. The median imprecision achieved by Australasian laboratories was 2.69% (SD 0.42; range 2.1 to 3.6%) from 2002 to 2016 and 2.34% (SD 0.16; range 2.1 to 2.6%) from 2009-2016. There was no statistically significant difference the median imprecision achieved by QAAMS and by Australasian laboratories from 2002 to 2016 (p=0.05; two-tailed paired t-test) and from 2009 to 2016 (p=0.17; two-tailed paired t-test).

From 2002 to 2008, the Australian Government recommended that HbA1c POC testing in QAAMS should achieve a minimum imprecision (CV%) goal of 4% or less. Since 2009, the Government, consistent with international recommendations, have recommended that the desirable analytical goal for imprecision for HbA1c testing in QAAMS should be ≤3% [13-16]. Results from more than 29,000 QA samples tested in QAAMS has shown that HbA1c POC testing has consistently been equivalent to laboratory testing for HbA1c and met these analytical goals over the past decade and a half.

Table 1 summarises the median within-site imprecision for HbA1c QC testing from 2009-2016 when the DCA Vantage replaced the DCA 2000. For the 'Normal' QC level, the imprecision has averaged 2.5% (SD 0.46; range 1.8% to 4.0%). For the 'Abnormal' QC level, imprecision has averaged 3.0% (SD 0.43; range 2.3% to 3.8%) across this time period.

3.4 Performance of DCA Vantage at Diagnosis Cut-Off (HbA1c 6.5%)

The imprecision observed for HbA1c POC testing when a patient sample with a laboratory-assigned value of 6.5% was measured using three different DCA Vantage devices is summarised in Table 2. For the within-day study, the mean HbA1c value for the sample across the three

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devices was 6.58%, with inter-device CV%s ranging from 1.4 to 1.8%. For the between-day study, the mean HbA1c value across the three devices was 6.54%, with CV%s ranging from 1.7 to 2.2%. For the EQA sample that had a target value of 6.8%, the program-wide imprecision achieved by the DCA Vantage devices in QAAMS for this level of HbA1c over the past 5 years (and 10 testing cycles) is summarised in Table 3. Imprecision averaged 2.75% (range 2.5% to 2.9%) at this HbA1c level.

4. Discussion

Haemoglobin A1c (HbA1c) has been a well-established pathology marker for long-term diabetes control for more than 30 years, with HbA1c providing a weighted estimate of a patient's glycaemic control over the preceding three- to four-month window. HbA1c is measured serially on patients with diabetes to track their glycaemic control across time and, importantly, the test needs to distinguish clinically significant changes in a patient's glycaemic control over time; for these reasons, it is critical that the test method for HbA1c is precise. As mentioned previously, within Australia, there is general consensus that a CV% of ≤2% is the optimal analytical goal for HbA1c, with ≤3% being the desired goal and ≤4% being the minimum goal for HbA1c devices (no matter whether the device is used in the laboratory or at the point of care)[16]. In the QAAMS Program, results from EQA testing in particular show the imprecision for HbA1c POC testing has continued to improve across the past 15 years and has met the profession-based analytical goals. In addition, there has been no statistically significant difference between the imprecision achieved by QAAMS and Australian laboratories over this period.

In recent times, there has been considerable debate in the international literature about the potential to use HbA1c for the diagnosis of diabetes [17-23], with the 6.5% cut-off representing the level at which the prevalence of moderate retinopathy begins to increase exponentially [24]. In Australia, the Commonwealth Government approved the use of HbA1c for diagnosis in

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accredited pathology laboratories in late 2014 (along with a Medicare rebate item number). The decision followed published recommendations on analytical performance criteria required for the use of HbA1c as a diagnostic tool [25]; these recommendations stated that a test method using HbA1c for diagnosis 'could be relied on, in the context of using HbA1c as a diagnostic tool, if the routine coefficient of variation [imprecision of the test] is ≤3% … and external quality assurance results are consistently within … allowable limits of performance'.

For POC testing devices used outside the laboratory, the use of the HbA1c test for diagnosis has been even more contentious. There are a large number (more than 15) of POC HbA1c testing devices that are available on the global market and each has different analytical performance characteristics [10]. This led the American Diabetes Association (ADA) to hold the view from 2009 to 2011 that: 'The ADA cautions that point-of-care devices for measuring HbA1c should not be used for diagnosis' [26] and 'Point-of-care instruments have not yet been shown to be sufficiently accurate or precise for diagnosing diabetes' [17]. The 2017 ADA recommendations state that: 'Although point-of-care A1C assays may be NGSP certified, proficiency testing is not mandated for performing the test, so use of point-of-care testing assays for diagnostic purposes is not recommended but may be considered in the future, if proficiency testing is performed and documented' [27]. There is strong evidence from international studies that there are POCT devices available that perform to analytically acceptable standards in terms of accuracy and precision at the diagnosis cut-off point (and indeed across all levels of HbA1c seen in patients with diabetes) [28-30]. We argue that these POCT devices are suitable for the diagnosis of diabetes and the performance of each individual POC device should be assessed independently when considering its suitability for use to diagnose diabetes. Sneenan et al [31] also support the view that POCT devices should be considered for the diagnosis of diabetes.

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In December 2015, the Australian Government approved the use of the HbA1c test for diagnosis in Indigenous primary care services enrolled exclusively in the QAAMS POC Testing Program, along with a separate Medicare item number. This landmark decision was based largely on the consistently high analytical quality of POC testing for HbA1c in QAAMS, as evidenced by the results of continuing EQA and QC testing over the past 15 years.

In summary, the QAAMS Program sets an international benchmark for POC testing models for diabetes management. The program has demonstrated longevity and been shown to be clinically, culturally and operationally effective. Underpinning its sustainability is the commitment to continuing surveillance of the analytical quality of POC testing.

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Fig.1. General location of Indigenous medical services participating in the QAAMS Program.

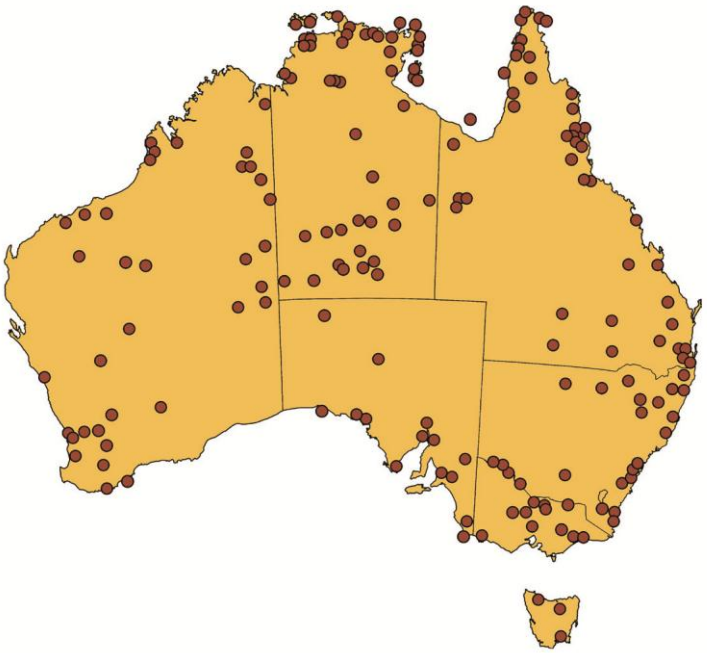

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Fig.2. Median within-site imprecision (CV%) achieved by participating QAAMS services for HbA1c QA testing over the past 15 years from 2002 to 2016.

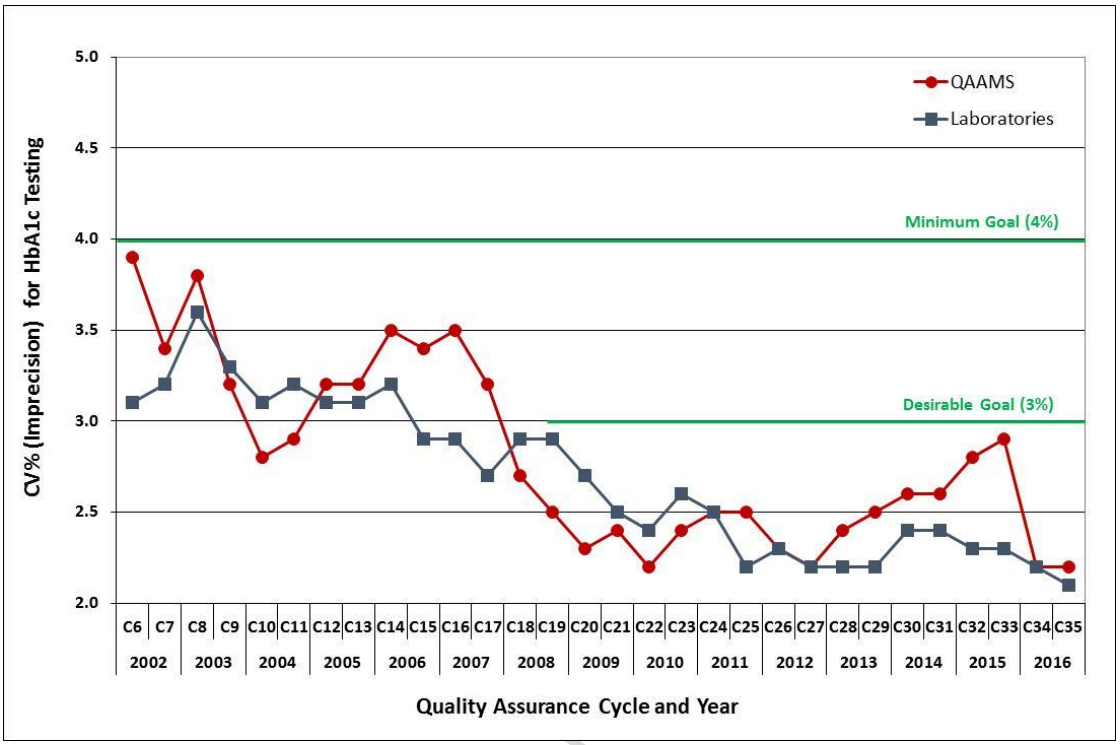

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Table 1
Median within-site imprecision (CV%) achieved for HbA1c QC testing from 2009-2016.

Year	2009		2010		2011		2012		2013		2014		2015		2016	
Cycle	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35
QC Normal	2.2	1.8	2.5	2.6	4.0	2.3	2.9	2.8	2.4	2.6	2.1	2.8	2.3	2.4	2.4	2.5
QC Abnormal	2.6	2.6	2.9	3.0	3.5	2.3	2.7	3.0	2.3	3.3	3.0	3.8	3.4	3.6	3.0	3.3

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Table 2
Within- and between-day imprecision for HbA1c using a patient sample with a laboratory reference value of 6.5%.

	DCA Vantage 1	DCA Vantage 2	DCA Vantage 3
Within-day imprecision			
Mean HbA1c (%)	6.61	6.60	6.52%
SD	0.09	0.12	0.11
CV%	1.36%	1.82%	1.69%
Number of repeats	10	10	10
Between-day imprecision			
Mean HbA1c (%)	6.60	6.51	6.52
SD	0.12	0.11	0.14
CV%	1.82%	1.69%	2.15%
Number of repeats	10	10	10

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Table 3

Program-wide imprecision achieved by the DCA Vantages in QAAMS for the external quality assurance sample with an HbA1c value of approximately 6.8% over the 5 year period from 2012 to 2016.

Year	2012	2013	2014	2015	2016
Cycles	26,27	28,29	30,31	32,33	34,35
QAAMS					
Mean HbA1c (%)	6.92	7.01	6.76	7.04	6.82
SD	0.19	0.20	0.19	0.20	0.17
CV%	2.75%	2.85%	2.81%	2.84%	2.49%
Number	284	332	460	489	482
Laboratory					
Mean HbA1c (%)	6.86	6.90	6.67	6.98	6.73

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Highlights

- From 2002 – 2016 29,093 HbA1c external quality assurance samples submitted by QAAMS
- Matched the quality achieved by Australasian laboratories and met analytical goals
- Quality performance goals met when HbA1c POC testing for diagnosis introduced
- QAAMS HbA1c point-of-care testing has been analytically sound for the last 15 years

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