# Comparison of Point of Care Hba1c Analytical Systems Against Laboratory Analysis Among Type 2 Diabetes Patients in Primary Health Centers in Riyadh

Ali Darraj[1], [2,] Ghulam Mustafa[1], Nuha Alhumaid[2], Emad Masuadi[3], Mohammad Tabish[4], Mazen Ferwana[3], [5]

[1]Department of Medicine, College of Medicine, Shaqra University, Shaqra 11961, Saudi Arabia

[2]College of Public Health and Health Informatics, King Saud bin Abdulaziz University for Health Sciences, Riyadh 14611, Saudi Arabia

[3]College of Medicine, King Saud bin Abdulaziz University for Health Sciences, Riyadh, Saudi Arabia

[4]Department of pharmacology, College of Medicine, Shaqra University, Shaqra 11961, Saudi Arabia

[5]Department of Family Medicine and PHC, Ministry of national Guard-Health Affairs, Riyadh, Saudi Arabia.

## ABSTRACT

Measurement of HbA1C, is widely used for routine monitoring of long-term glycemic status in patients with diabetes mellitus. The point-of-care (POC) HbA1c testing have been developed in the last years which allows rapid HbA1c determinations from capillary blood instead of conventional venous puncture, furthermore, the use of POCT for HbA1c in physician's office leads to faster patient treatment and improved outcomes, including enhanced physician and patient satisfaction. Objectives: The aim of this study was to evaluate the accuracy of two point-of-care testing (POCT) analyzers to be used on the regular HbA1c monitoring testing for type 2 diabetic patients at Primary Health Care Centers, by comparing their HbA1c results with the standardized laboratory testing. Method: A cross-sectional diagnostic study was conducted to compare the accuracy of two HbA1c point of care machines (DCA Vantage from Siemens and Afinion from Axis-Shield) with the Laboratory HbA1c reference standard. Consecutive, eligible, consented type 2 diabetic patients who were available at the laboratory for venous blood sample for standard HbA1c testing, one capillary puncture at the same visit was performed for analysis by the two HbA1c point of care testing instruments. Sample size for the five HbA1c levels strata (<7; 7-<8; 8-<9; 9-<10 & >10), was calculated in order to assess accuracy for each level. Results: A total of 246 Type 2 diabetic patients were recruited, and all had performed the 3 tests; the HbA1c reference standard, DCA Vantage HbA1c and Afinion HbA1c tests. The performance of POC devices, DCA and Afinion were compared to central laboratory HPLC method. Both POC devices showed strong positive correlations to Lab A1c with $r = 0.98$ ($p < 0.01$). The means difference for DCA was 0.002 SD 0.47 and P value 0.96, while it was 0.18 SD 0.41 and P value $p < 0.001$) for Afinion device. Sensitivity, Specificity, Positive Predictive Value (PPV) and Negative Predictive Value (NPV) for DCA A1c compared with Lab A1c results at all levels were >93% except for NPV (85.7%). While, Sensitivity, specificity, Positive Predictive Value (PPV) and Negative Predictive Value (NPV) for Afinion A1c compared with Lab A1c results at all levels were >=80%. Area Under the Curve (AUC) for DCA and Afinion was > 0.90 Conclusion: Both DCA vantage & Afinion devices have strong positive correlation with central A1c testing, however DCA is superior in terms of accuracy.

Keywords: Diabetes Mellitus, Glycemic control, Glycated hemoglobin, HbA1c, Point of care, POC.

## 1. Introduction & Literature Review

Diabetes mellitus is a worldwide health crisis with an estimated 174 million people undiagnosed. More than 80% of these unrecognized cases occur in low- and middle-income countries (LMICs) (1).

The prevalence of diabetes mellitus among the Saudi population increased over time from 12.4% in 1987 (1) to 27.7% in 2011, without significant differences in the prevalence of Type 2 Diabetes Mellitus (T2DM) between genders (2). A recent study showed that, the prevalence of diabetes in Saudi was 25.4%, and unfortunately 40.3% being unaware of having diabetes, while impaired fasting glucose (IFG) affected 25.5% of the total study samples (3).

Saudi Arabia has an uppermost prevalence (32.8%)

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of type 2 diabetes mellitus and the prediction that the rate of type 2 diabetes will increase from 32.8% in 2015 to 45.36% in 2030 (4).

Glycated hemoglobin (HbA1C) is a valued marker of glycemic treatment effectiveness and should be performed at least every 3 months when glycemic targets are not being met and when antihyperglycemic therapy is being adjusted. In some situations, such as when substantial changes are made to treatment or during gestation, it is appropriate to check A1C more often. A1C is a measurement of average blood glucose control for the last 2 to 3 months. Almost half of it comes from the last 1 month (5).

Landmark clinical trials namely Diabetes Control and Complication Trial Research and UK Prospective Diabetes Study (6) found that HbA1c levels associated with the risk of emerging diabetes complications both micro- and macrovascular diseases.

Every laboratory should use only HbA1C assay methods that are certified by the National Glycohemoglobin Standardization Program (NGSP), which certifies and approves methods annually at the manufacturer level, and the desirable specifications for HbA1C measurement are an intra-laboratory coefficient of variation (CV) less than 2% and an inter-laboratory CV less than 3.5% (7).

The point-of-care (POC) HbA1c tests allow rapid HbA1c determinations from capillary blood instead of conventional venous puncture and is found to be linked with a substantial decrease in A1C in both type 1 & type 2 DM, through boosted diabetes care by more diabetic education and warranting suitable modification of therapy while the patient is available at the office. (8, 9, 10) Furthermore, it helps improve outcomes, including greater patient and physician satisfaction and reduced cost (11).

Many studies have shown good performance for various types of those devices at ambulatory care (12)(10)(13)(14)(15)(16)(17). However, others showed that only the Afinion and the DCA Vantage met the acceptance criteria of having a total CV <3% in the clinically relevant range (18)(19).

A MetroNet study, in 2010 recommended that, before implementing a POC method, practitioners are advised to evaluate its practicability in the clinical setting, and to do periodic comparison with the laboratory readings (16). To our knowledge, no study was conducted to compared the accuracy of these two devices on different HbA1c levels.

The aim of this study was to compare the accuracy of DCA and Afinion point-of-care testing (POCT) analyzers with the standardized laboratory testing at five HbA1c levels on the regular HbA1c monitoring testing for type 2 diabetic patients at Primary Health Care Centers.

### 1.2 Research Question(s)

This study was conducted to answer the following question: "Among type 2 diabetic patients, are point-of-care testing (POCT) analyzers accurate for regular HbA1c monitoring, comparing with standardized laboratory testing?".

The previous literature review studies assume variation among POCT accuracy. However, if the POCT analyzers with high accuracy that will affect diabetic patients' management positively. The null hypothesis (H0) and alternative (H1) can be formulated as follow:

H0: the POCT analyzers accuracy is varies comparing with standardized laboratory testing (low accuracy)

H1: the POCT analyzers accuracy is high as much as standardized laboratory testing.
(high accuracy)

### 1.3 Objectives

This study is conducted to evaluate the accuracy of two point-of-care testing (POCT) analyzers to be used on the regular HbA1c monitoring testing for type 2 diabetic patients at Primary Health Care Centers by comparing their HbA1c results with the standardized laboratory testing among different levels. In addition to that, the secondary objective includes assessment of performance of POCT in uncontrolled type 2 DM (extreme HbA1c values).

## 2. Methods

The study was conducted in the laboratory of Al-Yarmouk polyclinic, National Guard Health Affairs (NGHA), under King Abdul-Aziz medical city (KAMC) in Riyadh, Saudi Arabia, during time between June and Nov 2021.

We conducted a cross-sectional accuracy study. Consecutive, consented, of 18 years and above type 2 diabetic patients who were referred to the laboratory for HbA1c testing by primary care Physicians for regular follow up were enrolled in the study. Type 1 diabetic patients, Gestational diabetes & pregnant women, types of diabetes other than type 2 diabetes, patients with mental illnesses or psychological problems, patients with known case of hemoglobinopathies, those with extreme hemoglobin level (<7 or >24 g/dL), and highly lipemic specimens stored for long periods of time or frozen were excluded from the study.

One capillary puncture and one venous extraction for each participant were performed at the same visit. The capillary samples were used for HbA1c assessment by the two index (POCT) devices, while the venous sample was used for HbA1c assessment by the central laboratory reference standard method. The index tests were the two HbA1c point of care test, DCA Vantage from Siemens and Afinion from Axis-Shield, while the reference standard was the laboratory HbA1c test.

Data collection in each sitting include medical record number, age, gender, and HbA1c results for each of the 5 HbA1c levels (strata <7; 7-<8; 8-<9; 9-<10 & >10).

Sample size was calculated by using 81.8% sensitivity of POC device and 91% specificity of the reference lab method for each of the 5 HbA1c levels (<7; 7-<8;

8-<9; 9-<10 & >10), 5% type I error and 80% power of the study, and assuming inter laboratory coefficient variation of 3.5%, the confident interval will be 95%, and the marginal error will be 5%.(23)

## 2.1. Statistical Analysis

Statistical analysis was performed using statistical package for the social sciences version 22 (SPSS,22) software. Mean and Standard deviation were used to summarize the HA1c values in different level. T-test was used for comparing mean values between the lab tests and the POC devices.

Accuracy of both POC HA1c tests were assessed using: sensitivity, specificity, negative and positive predictive value, likelihood ratios for positive and negative tests, and Receiver Operating characteristics, Area Under the Curve (AUC).

And finally, Pearson Correlation between the laboratory HbA1c, DCA HbA1c and Afinion HbA1c results were displayed, and Correlation coefficient & P value were calculated.

# 3. Results

The study included 246 Type 2 diabetic patients, with a mean age of 51.6 ±SD13.3, 63.9% between 41-60 years, and female constitutes 51.2% (table 1)

Sensitivity, specificity, Positive Predictive Value (PPV) and Negative Predictive Value (NPV) for DCA A1c compared with Lab A1c results at all levels are >93% except for NPV (85.7%). Likelihood ratio for positive and negative tests at all levels are strong and very useful in discriminating between disease and non-disease except for negative test for A1c level <7 vs. >= 7 which is poor.

However, Sensitivity, specificity, Positive Predictive Value (PPV) and Negative Predictive Value (NPV) for Afinion A1c compared with Lab A1c results at all levels are >=80%. Likelihood ratio for positive and negative tests at all levels are strong and very useful in discriminating between disease and non-disease except for negative test for A1c level < 9 vs >=9 and < 10 vs >=10 which is moderate (table 2).

False Negatives (FN) for DCA A1c ranges from (2.6% to 6.1%) for different A1c levels which is lower than Afinion A1c (5.3%-20%), and DCA NPV readings were better than Afinion.

At HbA1c cutoff level 7, Area Under the Curve (AUC) for DCA and Afinion is 0.987 and 0.974 respectively, for cutoff level 8 AUC is 0.960 and 0.949 respectively, for cutoff level 9 AUC is 0.914 and 0.982 and for cutoff level 10 AUC is 0.962 and 0.938 respectively (fig 1)

Mean difference between lab A1c and DCA A1c (0.002) is generally lower than between lab A1c and Afinion A1c (0.182), with non-statistically significant P value (0.96) for the first, while significant for the second (<0.001), and the highest difference is at HbA1c level between 8-8.99 with P value of 0.001 for both. The mean difference, between DCA A1c & Afinion A1c is statistically significant P value <0.001 and the highest difference at >10 A1c level.

Kappa agreements between lab A1c and DCA A1c, between lab A1c and Afinion A1c and between DCA A1c and Afinion A1c are 0.82, 0.74 and 0.76 respectively. (table 3)

Both POC devices showed strong positive correlations to Lab A1c with $r = 0.98$ ($p < 0.01$). (Fig 2)

**Table (1): Baseline characteristics of the study sample**

| | | N | % |
|---|---|---|---|
| Age (years) | < =40 | 42 | 17.1 |
| | 41 - 50 | 85 | 34.6 |
| | 51 - 60 | 72 | 29.3 |
| | >60 | 47 | 19.1 |
| Gender | Male | 120 | 48.8 |
| | Female | 126 | 51.2 |
| Group ( different levels of HbA1c) | < 7 | 53 | 21.5 |
| | 7 - 7.99 | 49 | 19.9 |
| | 8 - 8.99 | 41 | 16.7 |
| | 9 - 9.99 | 40 | 16.3 |
| | 10+ | 63 | 25.6 |

**Table (2): HbA1c test accuracy results for DCA and Afinion POC instruments**

| | Sensitivity | Specificity | Positive Likelihood Ratio | Negative Likelihood Ratio | Positive Predictive Value | Negative Predictive Value |
|---|---|---|---|---|---|---|
| Lab A1c vs DCA A1c | | | | | | |
| < 7 vs >=7 | 97.4% | 100.0% | infinity | 3.0% | 100.0% | 91.4% |
| < 8 vs >=8 | 95.1% | 97.1% | 32.35 | 0.05 | 97.9% | 93.4% |
| < 9 vs >=9 | 93.2% | 99.3% | 133.28 | 0.07 | 99.0% | 95.3% |
| < 10 vs >=10 | 93.1% | 95.2% | 19.45 | 0.07 | 85.7% | 97.8% |
| Lab A1c vs AfinionA1c | | | | | | |
| < 7 vs >=7 | 94.7% | 100.0% | infinity | 0.05 | 100.0% | 84.1% |
| < 8 vs >=8 | 90.8% | 99.0% | 92.60 | 0.09 | 99.2% | 88.6% |
| < 9 vs >=9 | 85.7% | 97.8% | 39.21 | 0.15 | 93.1% | 95.2% |
| < 10 vs >=10 | 80.0% | 98.4% | 48.80 | 0.20 | 94.1% | 93.8% |
| DCA A1c vs AfinionA1c | | | | | | |
| < 7 vs >=7 | 95.7% | 94.8% | 18.50 | 0.05 | 98.3% | 87.3% |
| < 8 vs >=8 | 92.0% | 97.2% | 32.50 | 0.08 | 97.7% | 90.4% |
| < 9 vs >=9 | 93.6% | 98.0% | 46.50 | 0.07 | 96.7% | 96.1% |
| < 10 vs >=10 | 83.6% | 97.3% | 31.45 | 0.17 | 90.2% | 95.3% |

| Table (3): Mean and Mean difference of HbA1c levels for laboratory, DCA and Afinion tests | | | | | |
|---|---|---|---|---|---|
| | Group | Mean (SD) | Mean (SD) | Mean (SD) | P-value |
| Lab A1c - DCA A1c | | **Lab A1c** | **DCA A1c** | Differences | |
| | < 7 | 5.92 (0.57) | 5.89 (0.56) | 0.03 (0.15) | 0.159 |
| | 7 - 7.99 | 7.37 (0.27) | 7.31 (0.35) | 0.06 (0.28) | 0.152 |
| | 8 - 8.99 | 8.5 (0.27) | 8.29 (0.36) | 0.22 (0.33) | <0.001 |
| | 9 - 9.99 | 9.4 (0.25) | 9.38 (0.49) | 0.03 (0.4) | 0.696 |
| | 10+ | 11.26 (1.11) | 11.5 (1.43) | -0.23 (0.73) | 0.013 |
| | **Overall** | **8.574(2.05)** | **8.576(2.20)** | **-0.002(0.47)** | **0.96** |
| Lab A1c - Afinion A1c | | **Lab A1c** | **Afinion A1c** | | |
| | < 7 | 5.92 (0.57) | 5.82 (0.48) | 0.1 (0.2) | 0.001 |
| | 7 - 7.99 | 7.37 (0.27) | 7.22 (0.31) | 0.16 (0.26) | <0.001 |
| | 8 - 8.99 | 8.5 (0.27) | 8.22 (0.41) | 0.28 (0.31) | <0.001 |
| | 9 - 9.99 | 9.4 (0.25) | 9.21 (0.45) | 0.19 (0.37) | 0.003 |
| | 10+ | 11.26 (1.11) | 11.06 (1.37) | 0.2 (0.64) | 0.014 |
| | **Overall** | **8.574(2.05)** | **8.392(2.06)** | **0.182(0.41)** | **<0.001** |
| DCA A1c - Afinion A1c | | **DCA A1c** | **Afinion A1c** | | |
| | < 7 | 5.89 (0.56) | 5.82 (0.48) | 0.07 (0.21) | 0.02 |
| | 7 - 7.99 | 7.31 (0.35) | 7.22 (0.31) | 0.1 (0.24) | 0.008 |
| | 8 - 8.99 | 8.29 (0.36) | 8.22 (0.41) | 0.07 (0.37) | 0.257 |
| | 9 - 9.99 | 9.38 (0.49) | 9.21 (0.45) | 0.17 (0.32) | 0.002 |
| | 10+ | 11.5 (1.43) | 11.06 (1.37) | 0.44 (0.69) | <0.001 |
| | **Overall** | **8.576(2.20)** | **8.392(2.06)** | **0.184(0.45)** | **<0.001** |

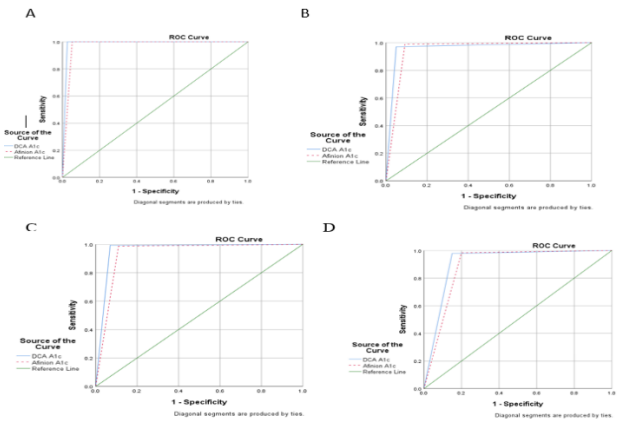


*Figure (1): Receiver Operating Characteristics (ROC) for HbA1c levels for DCA compared with Afinion POC instruments.*

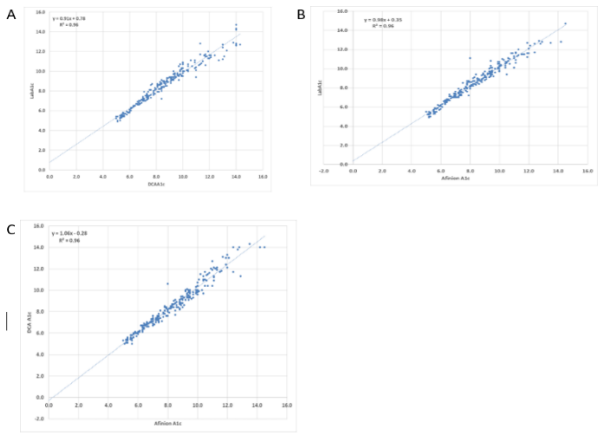


*Figure (2): Correlations between the laboratory HbA1c, DCA HbA1c and Afinion HbA1c*

## 4. Discussion

Glycemic control rates declined over the last decade from 44.5% to 35.8%, which may subsidize to augmented rates of macrovascular and microvascular diabetic complications, which may impact health care costs (20).

With advanced laboratory manufactures especially reduction of processes, point of care (POC) Hba1c testing has become a crucial method to aid decision making, HbA1c is a time-efficient tool for proper monitoring, screening and diagnosis of diabetes mellitus, and many point of care instruments were developed and available in the market, However; there is still controversy about their accuracy (21).

The results of our study depict that the correlations between both DCA and Afinion A1c and the lab results were strong, positive, and significant. Furthermore, the accuracy measures and AUC for both instruments were comparable to reference central laboratory results.

The benefits of POC testing are many, which include, patient satisfaction, more ease testing, instant response to patients while at the clinic, omitting recurrent visits, and development of patient's encouragement (22).

Many studies have supported our findings, (18)(21)(23)(24) however; other studies did not (25)(26)(27)(28).

A long-term randomized control trial (RCT) was conducted in both type 1 and type 2 diabetic patients and found that HbA1c levels decreased significantly at 6 and 12 months in the POC group compared to the control group and those changes were similar for both type 1 and type 2 diabetic patients (10), mostly that indicate to the benefits of POC testing which listed above.

False Negatives (FN) for DCA A1c for different A1c levels were lower than Afinion A1c and both devices were worked better in lower A1c levels, and in connection to that, Negative Predictive Values (NPV) results were better for DCA than Afinion, which makes DCA device superior to Afinion in screening sittings, however; Specificity and PPV for both were high at all A1c levels. The accuracy rates for our

results were better than those reported by Schwarchs KL (2009) (16).

The correlation (r) for both devices in our study was close to +1, which indicates a strong positive correlation between DCA, Afinion and the laboratory a1c results. These results were much better than the results found by Laurance Kennedy (2005) where (r) value was 0.72 for POC and laboratory A1C results and by Schwarchs KL (2009) where (r) value was 0.884 (29)(16)

In addition, the mean A1c produced by both devices were almost equivalent to that of central laboratory a1c with high kappa test, a result that is similar to Schwarchs KL (2009) (16).

The cost impact study by A Chadee (2014), at Ontario province 2013 and 2014, showed that replacing all laboratory HbA1c tests with point-of-care HbA1c testing would save almost $4.7 million over the next year. (30)

### Limitations

The study was a single center, comparing 2 POC A1c devices for a short duration, which limits the generalizability of its findings.

### 4.1. Conclusions

POC a1c testing devices are time-efficient tools for monitoring of long-term glycemic control, Both DCA vantage & Afinion devices have strong positive correlation, however DCA is superior in terms of accuracy. Using those devices is expected to improve diabetic care, improve patients & diabetic team satisfaction and reduce cost. Long term, metacentric researches are recommended.

## 5. Declarations

This study was conducted in laboratory of AL Yarmouk polyclinic, king Abdul-Aziz housing city, National Guard Health Affairs (NGHA), in Riyadh. The laboratory staff involved in data collection were:

The scientific and ethical approval was from king Abdullah International Medical Research Center (Research protocol: RC15/050)

### 5.2 Scientific and Ethics approval

The scientific and ethical approval was performed at King Abdullah International Medical Research Center (Research protocol: RC15/050). The research committee review the IRB on the ethical aspect of proposal.

### 5.3 Acknowledgement

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