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Original article

Full title:

# Diagnostic accuracy and feasibility of point-of-care glycosylated hemoglobin estimation in field conditions in India

Running title:

HbA1c point-of-care test at temperate climate

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# Diagnostic accuracy and feasibility of point-of-care glycosylated hemoglobin estimation in field conditions in India


## Abstract:

*Background:* Measurement of glycosylated hemoglobin (HbA1c) levels is standard of care in assessment of glycemic control among diabetes mellitus patients. Traditional high performance liquid chromatography (HPLC) based tests are expensive, need specialized equipment, and have a longer turn-around-time. Point-of-care tests to estimate HbA1c levels are now commercially available but with only limited studies from developed nations. We performed this study to understand diagnostic accuracy of two commercially available HbA1c point-of-care test.

*Methods:* The study was conducted in an urban and a rural outpatient clinic in central India. We compared HbA1c estimated from two index tests (Hemocue Hb501, Sweden; SD Biosensor, South Korea) from capillary blood samples and compared it with HPLC, as a reference standard in an independent and a blinded manner. We estimated diagnostic accuracy of the index tests as compared to the reference standard.

*Results*: The area under Reciever Operating Curve (ROC) for SDBiosensor device was 0.935 (95% CI=0.886-0.983), and for HemocueHb501 device was 0.938 (95% CI=0.893-0.984). A SDBiosensor device HbA1c value of above 7.0%=53 mmol/mol (positive test) correctly predicted poor glycemic control 92% times (vs. 81.58% for HemocueHb501divice). A HemocueHb501device HbA1c value of less than 7.0%=53 mmol/mol (negative test) correctly predicted optimal glycemic control 91% times (vs. 85% by SDBiosensor device). There were 4, and 11 device failures, and 14 and 12 test failures with SDBiosensor device and HemocueHb501 device respectively. Ambient air temperatures were no different for the test failure rates as compared to the test success events.

*Conclusion:* Commercially available point-of-care tests evaluated in this study are comparable and an acceptable alternative to HPLC based measurements for assessment of glycemic control. Tests and device failure rates of both the index tests were similar.

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## Introduction

The number of people living with diabetes in India is estimated to be about 60 million, a number which is expected to increase to 130 million by the year 2030 (1). Achieving optimal glycemic control is central to management of Diabetes Mellitus. Glycosylated Hemoglobin level (HbA1c) is a well established measure of glycemic control, central to the care of people living with diabetes mellitus. With rising prevalence of diabetes, it is necessary to make HbA1c test available as a point-of-care test at all levels of care.

The circulating glucose attaches with the hemoglobin fraction of red blood cells and form glycosylated hemoglobin. Long term glycemic control up to 3 months (representing the life span of red blood cells) is best determined by HbA1c level. The use of HbA1c in the management of diabetes has been well established since the DCCT and UKPDS trials (2–4). For the 1st time, American Diabetic Association (ADA) in 2009 updated their guideline of diagnosis of diabetes, taking HbA1c into account (5). Since then HbA1c has been used as a convenient marker for both diagnosis and follow up of diabetes patients using the cutoffs of 6.5% (48 mmol/mol) and 7% (53 mmol/mol) respectively (6). HbA1c based targets are more meaningful as they provide an assessment of glycemic control over the previous 2-3 months, unlike blood glucose measurements obtained at a single point of time that are influenced by diet, exercise, and drug adherence in the previous few hours (7). The HbA1c value is the gold standard measurement of micro vascular complications of diabetes and has become the cornerstone in diabetes care (7).

More than 30 different methods have been described to estimate HbA1c (8). Various methods available for HbA1c level measurement, separate HbA1c from other types of hemoglobin using charge difference (e.g. ion-exchange high performance liquid chromatography-HPLC, electrophoresis or iso electric focusing), or structural difference (e.g. affinity chromatography or immunoassay) or chemical analysis (e.g. photometry and spectrophotometry) (9–14). Due to the inconsistency in the technique used and reporting format, ADA recommends IFCC units (mmol/mol) and derived NGSP units (%) using the IFCC-NGSP master equation (7,15). The methods certified by National Glyco-hemoglobin Standardization Program (NGSP) a US-based organization relates individual techniques to HbA1c values as obtained in the landmark DCCT trial. The most commonly used techniques are ion-exchange high performance liquid chromatography (HPLC), capillary chromatography, borate affinity assay, and immunoassay, HPLC being considered as the gold standard (15). However it has greater technical needs, including equipment, expenditure, and longer turnaround times. In past few years the concept of point-of-care (POC) HbA1c testing has emerged. Commonly used POC, HbA1c assays use the principles of borate affinity or immunoassay. In borate affinity assays glycated-hemoglobin binds to borate resins, with a potential to overestimate HbA1c, as the technique is not HbA1c specific (16). In contrast immunoassay uses Anti-HbA1c antibodies against glycated N-terminal of beta-hemoglobin chain. While this technique is attractive, interference with other hemoglobin chains remains a concern (16).

Previous HbA1c diagnostic accuracy studies were conducted in high-income countries that have more controlled environmental and logistic conditions for storage of test kits and operation of the equipments. Field conditions in India are entirely different. Rural India faces issues like frequent interruption of power supply, higher ambient temperature and relative humid conditions. Our study is the first study from a tropical middle-income country, conducted in actual operational field environment at an urban and rural health care system.

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We aimed to compare two commercially available point-of-care devices to compare their performance with respect to accuracy and feasibility. The current study was designed to answer two research questions: 1) Among individuals with diabetes mellitus do point-of-care HbA1c measurement devices (based on immunoassay or borate affinity principle), as compared to HPLC as a reference standard, are accurate to make an assessment of optimal glycemic control (HbA1c ≤ 7%= 53 mmol/mol), 2) In a community based setting in a rural area, is use of POC device to estimate HbA1c level feasible?

## Methods

**Design:** A cross-sectional diagnostic accuracy and feasibility study

**Setting:** The study was carried at two locations, medical out-patient department at All India Institute of Medical Sciences Bhopal, Madhya Pradesh (Urban), and Primary Health Center at Chiklod, Madhya Pradesh (Rural). Individuals with diabetes mellitus seeking care at both these facilities were evaluated for glycemic control.

**Participants:** The study sought to include all individuals with diabetes mellitus who presented to the health care facility for assessment of glycemic control. It was necessary for the individuals to have been previously diagnosed with diabetes (based on ADA criteria: fasting plasma glucose of 126mg/dL or above or post prandial plasma glucose of 200mg/dL or above or HbA1c level of 6.5%= 48mmol/mol or above for at least three months prior to date of inclusion in the study. We obtained a written informed consent from all eligible participants. We excluded participants who denied a written informed consent. No other exclusions were used. Due to logistic reasons, the participants were sampled from these facilities once every week for the study duration.

**Study procedures:** All eligible and consenting participants were administered a questionnaire to collect information about demographics, duration of diagnosis of diabetes mellitus, their current therapies, and any past history of a hemoglobinopathy. Subsequently samples for index tests (SDBiosensor and HemocueHb501) and the reference standard i.e. HPLC were collected within a 10 minute interval of each other. We first collected a 2mL venous sample in an EDTA tube, that was immediately stored between 4 and 8 degree Celsius in an ice-pack-containing vaccine carrier. These samples were transported to the laboratory in the same day in a temperature controlled environment for HPLC based HbA1c estimation (Reference Standard). The test was performed in a National Accreditation Board for Testing and Calibration Laboratories (NABL) accredited laboratory. Then we collected capillary blood samples by finger-prick. We collected one drop of capillary blood (about 5µL) for each of the index tests. The characteristics of the two index tests are detailed in Table 1. The point-of-care tests were performed in front of the patient, by using standard techniques as per manufacture's guidelines. Briefly, in the borate affinity meter (Hemocue A1c 510) blood sample collected by a reagent pack (which draws appropriate volume into the reagent pack), and the reagent pack was inserted in the cartridge. Cartridge was then inserted into the machine, and the results were displayed on the meter in three minutes (17). In the immunoassay meter (SD A1c care) a drop of blood (about 5µL) was collected in a reagent tube, and allowed to mix for a minute. A test strip was inserted into the meter, and 5µL of blood-reagent mixture was applied to the sample port on the strip. The strip was inserted into the meter and results were obtained in three minutes (18). Other differences between both the index tests are provided in supplementary Table-1. Both the index tests were and interpreted, blinded to the results of the reference standard. The HPLC results were available by the next day.

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For all the tests we will collected the following variables to know the feasibility of the point-of-care HbA1c assays: 1) Device failure events: the device did not get powered on, or was unable to perform the measurement. 2) Test failure events: the device gave an error message or the testing cartridge was prematurely ejected and no meaningful output was received. Test failure events are expected to result in wastage of the testing strips or cartridges and hence escalation of costs. We also measured ambient room-temperature of the facility where the tests were carried out, using a temperature logger device (Lascar Electronics).

**Ethics issues:** This study protocol was approved by Institutional Human Ethics Committee of AIIMS Bhopal (Project No IHEC-LOP/2015/IM0056 dated 15 May 2015). Study procedure was explained to all participants and written informed consent was obtained.

**Statistical analysis**

We determined diagnostic accuracy of the index tests by non-parametric measures (Bland-Altmann analysis and estimating AUC by ROC analysis). We compared distribution of HbA1c values obtained by both index tests and the reference standard. Using a cut-off of 7% i.e. 53 mmol/mol HbA1c, we estimated traditional measures of diagnostic accuracy (sensitivity, specificity, positive & negative predictive values and likelihood ratios). We measured precision of our estimates by calculating 95% confidence intervals. All Statistical analysis was performed using statistical software SPSS 2015 verson.

**Results**

The study was conducted between April to September 2016 considering the most hot and humid months. A total of 114 patients were included in the study. Most patients were middle aged (Mean age 53.4 years (SD 11.5), with an age range of 18 to 80 years. A total of 45 (39.5%) participants were women. About 40% of the patients were female. Hypertension and peripheral neuropathy were the most commonly associated co-morbidities (20% each). Metformin was the most frequent prescribed drug in about 60% of patients and 14% of the patients were on Insulin. A valid reference standard HbA1c by HPLC method was obtained in all 114 participants. The mean HbA1c level by reference standard of HPLC was 8.03%=64 mmol/ml (SD 2.02%). A valid HbA1c estimate by index Hemocue A1c501 and SDA1c Biosensor was obtained in 103 and 110 participants respectively. As compared to HPLC, the median HbA1c values were similar in SDA1c device, and Hemocue A1c501 device. The distribution of the HbA1c values is depicted in Figure 1. The Bland-Altmann plots (plot of difference between index test and reference standard vs. the mean HbA1c value by both techniques) show majority of the mean values between the acceptable range of 2SD on either side. There is no difference in the distribution of values for lower (<7% or 53 mmol/mol), intermediate (7-10% or 53-86 mmol/mol) and high (>10% or 86 mmol/mol) as shown in Figure 2.

Hemocue A1c501 assay for detection of poor glycemic control (HbA1c value >7% or 53 mmol/mol) was 95.38% sensitive (95% CI =87.29-98.42), but only 68.89% specific (95%CI= 54.33-80.47). In contrast the sensitivity of SDA1c device was 90.63% (95%CI 81.02-95.63) and specificity was 87.18% (95%CI 73.29-94.2). An SDA1c device HbA1c value of above 7.0% or 53 mmol/mol (positive test) correctly predicted poor glycemic control 92% times (vs. 81.58% for

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Hemocue A1c501 device). Hemocue A1c501 device HbA1c value of less than 7.0 or 53 mmol/mol (negative test) correctly predicted optimal glycemic control 91% times (vs. 85% by SDA1c device) as in Table 1. The overall test performance by receiver operating curve (ROC) derived analysis area under the curve (AUC) analysis was similar. The AUC for SDA1c device was 0.935 (95%CI=0.886-0.983), and for Hemocue A1c501 device was 0.938 (95%CI=0.893-0.984) as in Figure 3.

The device failure rate was 4 and 11 respectively with SD A1c device and Hemocue A1c501 device. We encountered 14 test failures with SD A1c device as compared to 12 test failures with Hemocue A1c501 device. We could perform the test after using a new test strip in all these 26 situations. The test failures for the SDA1c device occurred at median ambient room temperature of 35 degrees celcius (Range 28-35 degrees), and with Hemocue A1c501 device at median temperature of 36 degree celcius (Range 35 to 37 degrees). However the test non-failure events (or test success events) occurred at the median temperature of $37^0$ C (25-42) for SD A1c and median $36^0$ C (25-42) for Hemocue A1c501 device. The mean number of test strips used to perform single test was 1.20 with SDA1c device and 1.19 with Hemocue A1c501 device.

**Discussion**

Scope of point-of-care HbA1c tests in clinical practice have been demonstrated by various authors in last decade.The recent Meta analysis by Hirst et al. 2017 emphasized the reservations of these point-of-care devices showing either negative or positive biases(19). The current study was undertaken to find out the accuracy of the available point-of-care HbA1c tests and feasibility of the tests in field conditions of India.

In the current study we demonstrated that both the techniques for point-of-care estimation of HbA1c levels were comparable to the reference standard. The current study is one of the largest and only such works from developing world. We encountered more device failures with the Hemocue A1c501 device and comparable test failures with both the index devices. This provides us with important insights about performance of point-of-care tests in actual field conditions of temperate climates like India.

Our diagnostic study included those participants who would have received the tests in actual clinical practice. Most participants in our study were middle-aged men with uncontrolled type 1 or 2 diabetes. These demographics are comparable to previous studies in terms of age (20–24), (17,21,22) but had a lower representation of women as compared to Martin et al. 2005 and karami et al. 2014 (20,25). The mean HbA1c level by HPLC reference standard in our study was 8% = 64mmol/mol (SD 2.02%), higher than in previous studies of Peterson et al. 2010 and martin et al. 2010 (26,27). These differences are a reflection of poor glycemic control in a developing country setting. Since there was a greater variation in the HbA1c values in our study, it has a potential to bias diagnostic accuracy estimates towards the null, as compared to the studies that included participants with lower mean HbA1c values. Despite this, only 2.3% and 4.8% values were outside the two-standard deviation in the Bland-Altmann plot for SDA1c and Hemocue A1c501 device respectively. This variation is comparable to previously reported studies (22,28). Previous HbA1c point-of-care test studies are listed in Table 2.

There was a slight difference in diagnostic accuracy estimated in the two assays evaluated in our study. While Hemocue A1c501 device assay had a higher sensitivity and lower specificity,

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SDA1c device assay had a lower sensitivity but a higher specificity. These differences were observed as diagnostic accuracy was evaluated at a clinically meaningful cut-off of 7%= 53 mmol/mol HbA1c, a level used to classify patients with optimal glycemic control. While there is a more recent guideline that suggests different target levels for different individuals with diabetes mellitus, yet 7%= 53 mmol/mol is a benchmark we usually strive for. These differences in the diagnostic accuracy estimates are due to small variations around the cut-off in both assay methods (SDA1c assay with a mean 0.34 lower, and Hemocue A1c501 device with a mean 0.43 higher values) as compared to reference HPLC based measurements. For a clinician who is assessing poor glycemic control, a Hemocue A1c501 measurement of 7%= 53 mmol/mol or higher, is 81% predictive of similar result by HPLC in contrast to 92% predictiveness by SDa1c assay (positive predictive value). In contrast if aim is to assess optimal glycemic control Hemocue A1c501 assay is 91% predictive in contrast to 85% by SDA1c assay (negative predictive value). Overall both assays are similar as their AUCs in ROC analysis are similar. The overall test performances of both index tests in current study are also comparable to a study by Marley et.al (2015) from Australia (22).

There was higher device failure with Hemocue A1c501 device in our study. Device failure is a condition when either the device does not switch on, or is unable to receive a test strip or cartridge. The Key reason for high device failure with Hemocue A1c501 device (11/114) was power failure, as this equipment operates only on running electricity and does not have a battery back-up. The principal reason for SDA1c device to fail was battery run-off. Availability of running electricity is a constraint, and longer battery life is an asset for any point-of-care device in a developing country setting. We encountered 14 test failures with SDA1c device and 12 test failures with Hemocue A1c501 device. Test failure is a condition where the device gives an error message after insertion of the test strip. We could re perform the test after using a new test strip in all these 26 situations. The test failures were random and could not be explained by temperature and more parameters have to be taken into account in future studies. The test failure rate, and test-strip/cartridge wastage was similar for both devices. While both the manufacturers suggest performing the test below a room temperature of 28 degree Celsius, the ambient room temperatures were higher than this benchmark on most occasions. This is also typical of a tropical developing country scenario where point-of-care tests are performed in non temperature controlled environment. The room temperatures are above 28 degrees Celsius in most months of the year in our locality.

The current study was conducted in the same population that would have received the test in actual practice. The performance of the index tests and interpretation of its results was blinded and independent of the reference standard. Both the index tests and reference standard were performed using blood samples that were collected at minimal dealy. We used clinically useful cut-offs for interpretation for our results. The study was conducted in two different facilities, where the ambient temperature ranged from 25-42 degrees. The range of HbA1c tested was also wide ranging from 4.5 to 15.3%.

Our study had certain limitations. We did not study the variant hemoglobins and absolute hemoglobin level of the patients, however this is unlikely to affect results of our study as prevalence of hemoglobinopathies is likely to be low. Our sample size was modest, yet this is one of the large studies conducted. Our testing environment was at variance with what would

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have been prescribed by the manufacturers, but this limitation is inherent, as actual temperature and humidity levels in developing country facilities are likely to be less than ideal.

## Conclusion

Both the commercially available point-of-care HbA1c tests evaluated in this study (i.e. borate affinity or immunoassay) has similar results in comparison to the reference HPLC method. The sensitivity of both the point-of-care HbA1c tests are fairly good meaning that they can serve as acceptable alternate to time consuming HPLC method as a rapid screening tool. The higher positive predictive value imply we can fairly rely on the result of HbA1c > 7% =53 mmol/mol, for early titration of the drugs. The comparatively lower specificity and negative predictive values at HbA1c > 7% may make the clinicians watchful before changing the drugs. Both of these point-of-care tests correlate well with the standard reference test with a wide range of temperature (25-42 degree Celsius). Temperature had no significant effect on device and test failures.

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Figure Legends:

Figure 1:

The median (inter-quartile range) HbA1c by SDA1c device was 7.85 (6.9-8.9); Hemocue device was 7.2 (6.3-8.3) and by HPLC was 7.8 (6.5-8.9),

SD= SD Biosensor A1c Care, HC= Hemocue A1c501, HPLC= High Performance Liquid Chromatography

Figure 2:

Bland Altman Plot is used for visualizing the concordance between HbA1C levels estimated by two methods. Difference in HbA1C by two methods is plotted on y-axis and mean of HbA1C by two methods is plotted on x-axis. If both methods are concordant then it is expected that most of the observations would line around line of 0 differences (black, bold horizontal line at 0.00). In case of discordance most values would lie beneath 2 standard deviations of mean differences on either side (blue and horizontal line).

**A)** The mean difference between SDA1c and HPLC is -0.34. It can be seen that there were no outliers in the group of mean (HPLC & SD) < 7. There was 1 outlier in the group of Mean HbA1c (HPLC & SD) 7-10. There were 2 outliers in the group of mean HbA1c (HPLC & SD) >10. It means both the tests are concordant.

**B)** The mean difference between Hemocue and HPLC is +0.47. It can be seen that there were 2 outliers in the group of mean (HPLC & HC) < 7. There were 2 outliers in the group of Mean HbA1c (HPLC & HC) 7-10. There was 1 outlier in the group of mean HbA1c (HPLC & HC) >10. It means both the tests were concordant.

SD= SD Biosensor A1c Care, HC= Hemocue A1c501, HPLC= High Performance Liquid Chromatography

Figure 3:

The Area under the curve (AUC) for SDA1c device is 0.935 (95%CI 0.886-0.983), and for Hemocue A1c501device is 0.938 (95%CI 0.893-0.984).

SD= SD Biosensor A1c Care, HC= Hemocue A1c501

**Table 1:** Diagnostic accuracy of point-of-care HbA1c measurement

| Comparison | TP | FP | FN | TN | Sensitivity | Specificity | PPV | NPV | LR+ | LR- |
|---|---|---|---|---|---|---|---|---|---|---|
| Hemocue A1c501 vs HPLC (n=103) | 58 | 5 | 6 | 34 | 95.38 (87.29,98.42) | 68.89 (54.33,80.47) | 81.58 (71.42,88.7) | 91.18 (77.04,96.95) | 3.066 (2.6 -3.5) | 0.067 (0.034 - 0.13) |
| SDA1c vs HPLC (n=110) | 62 | 14 | 3 | 31 | 90.63 (81.02,95.63) | 87.18 (73.29, 94.4) | 92.06 (82.73, 96.56) | 85 (70.93-92.94) | 7.069 (4.76-10.5) | 0.107 (0.076 - 0.15) |

HbA1c of 7% (53 mmol/mol) or greater is considered as a positive test indicating poor glycemic control

(TP= true positive, FP= false positive, FN= false negative, TN= true negative, PPV= positive predictive value, NPV= negative predictive value, LR+ = positive likelihood ratio, LR- = negative likelihood ratio).



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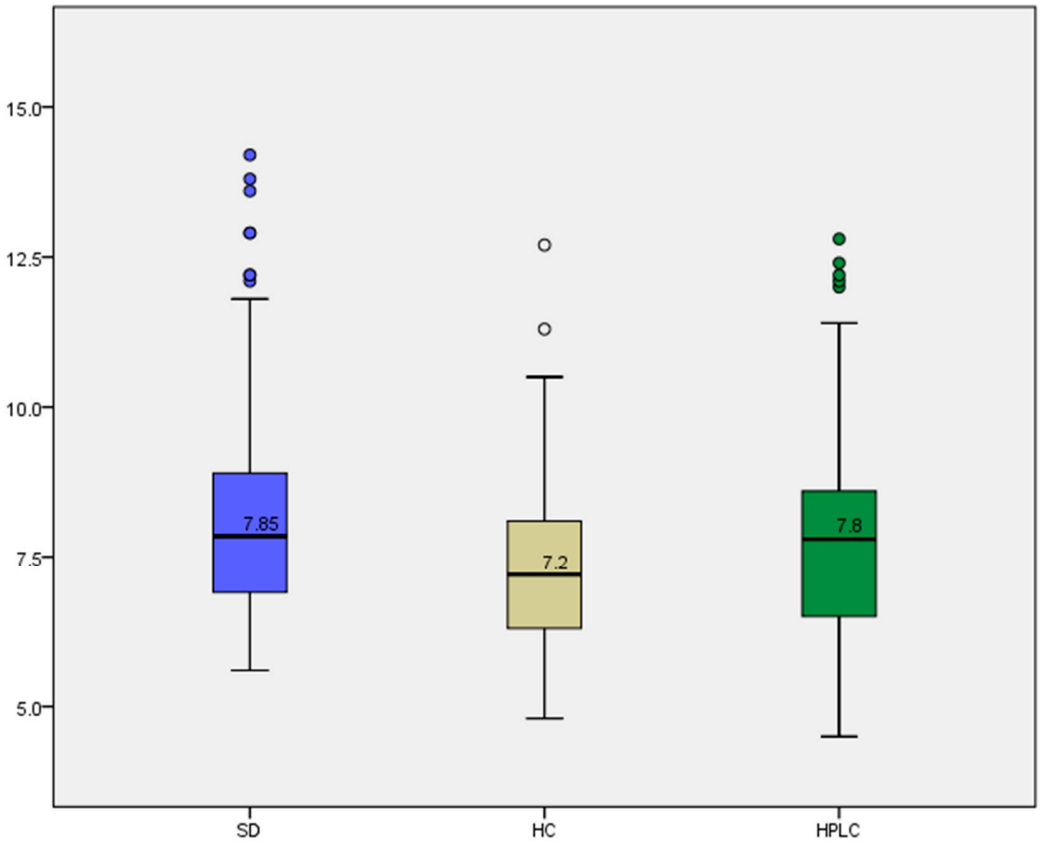
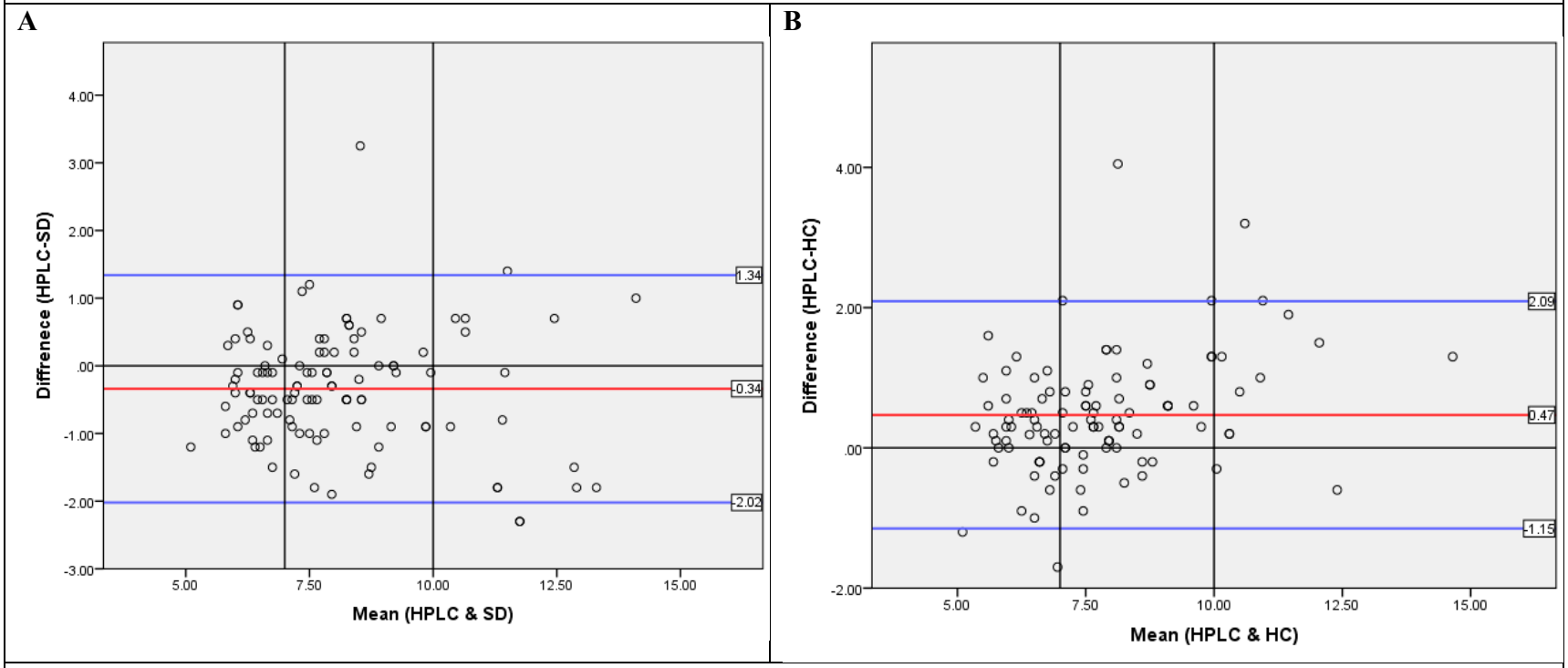
**Figure 1:** Box plot of the point-of-care HbA1c tests and reference standard.




The median (inter-quartile range) HbA1c by SDA1c device was 7.85 (6.9-8.9); Hemocue device was 7.2 (6.3-8.3) and by HPLC was 7.8 (6.5-8.9),

SD= SD Biosensor A1c Care, HC= Hemocue A1c501, HPLC= High Performance Liquid Chromatography

**Figure 2:** Bland Altman plot A) SD vs HPLC, B) Hemocue vs HPLC




Bland Altman Plot is used for visualizing the concordance between HbA1C levels estimated by two methods. Difference in HbA1C by two methods is plotted on y-axis and mean of HbA1C by two methods is plotted on x-axis. If both methods are concordant then it is expected that most of the observations would line around line of 0 differences (black, bold horizontal line at 0.00). In case of discordance most values would lie beneath 2 standard deviations of mean differences on either side (blue and horizontal line).

**A)** The mean difference between SDA1c and HPLC is -0.34. It can be seen that there were no outliers in the group of mean (HPLC & SD) < 7. There was 1 outlier in the group of Mean HbA1c (HPLC & SD) 7-10. There were 2 outliers in the group of mean HbA1c (HPLC & SD) >10. It means both the tests are concordant.

**B)** The mean difference between Hemocue and HPLC is +0.47. It can be seen that there were 2 outliers in the group of mean (HPLC & HC) < 7. There were 2 outliers in the group of Mean HbA1c (HPLC & HC) 7-10. There was 1 outlier in the group of mean HbA1c (HPLC & HC) >10. It means both the tests were concordant.

SD= SD Biosensor A1c Care, HC= Hemocue A1c501, HPLC= High Performance Liquid Chromatography



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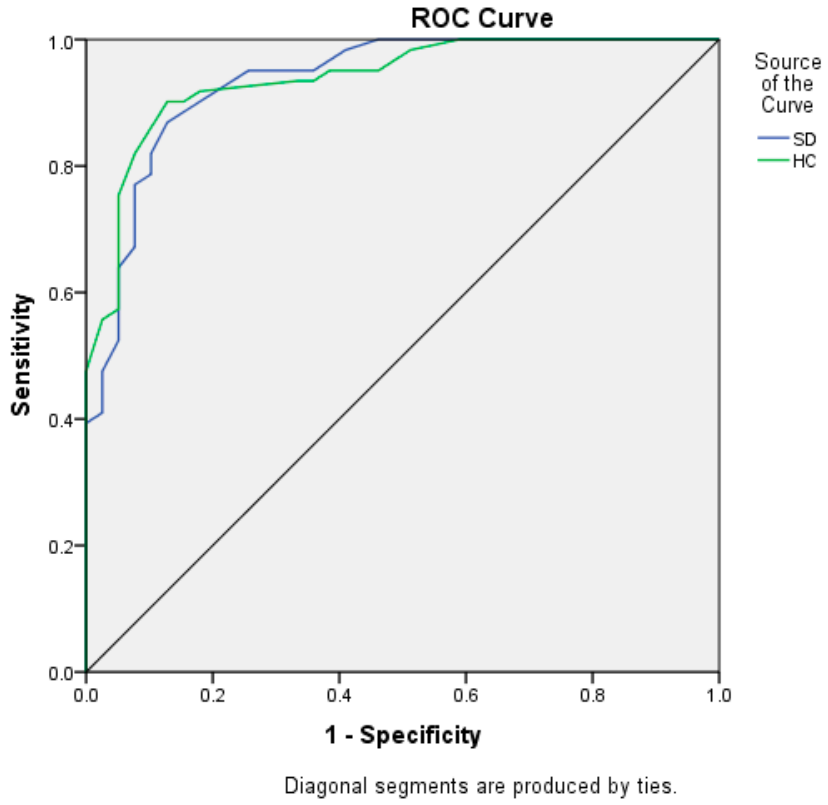
**Figure 3:** Area under the curve for SDA1c and Hemocue A1c devices for reference standard HbA1c cut-off of 7%




The Area under the curve (AUC) for SDA1c device is 0.935 (95%CI 0.886-0.983), and for Hemocue A1c501device is 0.938 (95%CI 0.893-0.984).

SD= SD Biosensor A1c Care, HC= Hemocue A1c501

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**Supplementary Table 1: Characteristics of the two index tests**

| **Characteristics** | **HemoCue® HbA1c 501 System (Sweden)** (17) | **SD Biosensor A1c Care (South Korea)** (18) |
|---|---|---|
| Principle | Boronate affinity assay for determination of HbA1c percentage in whole blood | Immuno assay |
| Calibration | Factory calibrated and traceable to IFCC and NGSP/DCCT | Easy Calibration by cartridges |
| Sample Material | Capillary or venous whole blood | Capillary or venous whole blood |
| Measurement Range | 20 – 130 mmol/mol (IFCC)<br>4.0 – 14.0 % (NGSP) | 20 - 140 mmol/mol (IFCC)<br>4.0 - 15.0 % (NGSP) |
| Coefficient of Variation | CV < 3% | CV < 3% |
| Output Results | In 5 minutes | In 3 minutes |
| Sample Volume | 4 µL | 5 µl |
| Dimensions | 198 mm (H) × 217 mm (W) × 136 mm (D) | 163 mm (H) x 96 mm (W) x 56 mm (D) |
| Weight | 1.600 kg | 0.450 kg |
| Storage Temperature | Analyzer: 10 – 35 °C (50 – 95 °F) Test Cartridge: unopened 2-32 °C (36-90 °F) | 0 °C– 32 °C |
| Operating Temperature | 17 – 32 °C (63 – 90 °F) | 15 to 32 °C (59 to 90 °F) |
| Power | 9 V DC / 1.5 A | 12 V DC/ 1.5 A |
| Battery Backup | Absent | 4 AA Battery is used to run analyzer |
| Interface | Printer, PC and Barcode Scanner | Thermal Printer, Barcode Scanner, HbA1c Management Software |
| Quality Control | Built-in self test Check Cartridge, system can be verified using liquid controls | Built-in self test Check Cartridge |
| Cost of Analyzer | INR 200,000 (About 3500 USD) | INR 50,000/- (About 850 USD) |
| Cost per test | INR 300/- (About 5 USD) | INR 200/- (About 3.5 USD) |