Appendix 1

**Reliability and Validity of HbA1C Point-of-Care testing (Clover A1c)**

Tania Gayle Robert Lourdes 1, Nur Liana Ab Majid 1, Wan Shakira Rodzlan Hasani 2, Hamizatul Akmal Abd Hamid 1,Mohd Ruhaizie Riyadzi 1, Halizah Mat Rifin 1, Thamil Arasu Saminathan 1, Hasimah Ismail1, Muhammad Fadhli Mohd Yusoff 1

1 Institute for Public Health, National Institutes of Health, Ministry of Health Malaysia

2 Department of Community Medicine, School of Medical Sciences, Universiti Sains Malaysia

Corresponding author’s email: drtania@moh.gov.my

**Summary**

Point-of-care testing (POCT) is essential for on-site diagnosis and quicker turn-around time for treatment because of its portability and mobility. This study aimed to determine the reliability and validity of Clover A1c analyser in measuring blood HbA1C. Diagnostic performance was measured using sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV). Good agreement could be seen in all parameters of measurements, although the agreement between capillary versus laboratory blood results showed a slightly better agreement. The Clover A1c analyser is a POCT analyser that is accurate and dependable and may be used in both clinical and public settings.

**Keywords**

Point-of-care testing (POCT), Clover A1c analyser, reliability, validity, HbA1C

**Introduction**

Due to its mobility and transportability, point-of-care testing (POCT) is crucial for on-site diagnosis and shorter therapy turnaround times, especially when medical resources are scarce (1). HbA1c is an important measurement for diabetes management to achieve adequate glycaemic control. HbA1c can be considered superior compared to glucose monitoring as it shows an average glycaemic control over 2-3 months inclusive of both pre-prandial and post-prandial blood glucose control (2). This study was aimed to determine the reliability and validity of Clover A1c analyser in measuring blood HbA1C.

**Materials and Methods**

This was a cross sectional study using proportionate quota sampling. The sample size to determine the level of agreement between capillary blood cholesterol measured by the POCT analyser and venous blood analysed in the lab was calculated based on intraclass correlation coefficient (ICC). Diagnostic performance was measured using sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV). Respondents from a research centre under the Ministry of Health Malaysia aged 18 years and above not known to have diabetes were recruited. A total of 398 respondents had their capillary blood and venous blood taken respectively and measured by Clover A1c analyser. Venous blood was also tested by a standardized laboratory for HbA1c evaluation. Descriptive analysis and reliability analysis using ICC were employed. All data were analysed using SPSS version 22.0.

**Results and Discussion**

Agreement between capillary blood tested using Clover A1c and venous blood from the laboratory was 0.964 (95% CI 0.96, 0.97), p<0.001. Agreement between venous blood tested using Clover A1c and venous blood from the laboratory was 0.951 (95% CI 0.94, 0.96), p<0.001. Agreement between capillary and venous blood tested using Clover A1c showed 0.962 (95% CI: 0.95, 0.97), p<0.001. Sensitivity for this analyser was 82.0% and specificity was 98.8%. The Positive Predictive Value (PPV) was 92.6% and Negative Predictive Value (NPV) was 96.8%. From the results, good agreement could be seen in all parameters of measurements, although the agreement between capillary versus laboratory blood results showed a slightly better agreement comparatively. POCT devices are used worldwide to screen for a wide range of illnesses. However, periodic evaluation of these devices is required to reduce imprecision and inaccuracy (1). POCT for HbA1c unquestionably enhances patient, physician, and staff satisfaction, and improves the management among diabetics (4), (5).

Table 1: Descriptive results of HbA1c results measured using Clover A1care

|  |  |  |  |
| --- | --- | --- | --- |
| **HbA1c**  | **Capillary (n=397)** | **Venous (n=398)** | **Lab (n=402)** |
| Mean (%) ± SD | 5.76 ± 1.19 | 5.76 ± 1.24 | 5.82 ± 1.36 |
| Minimum (%) | 4.20 | 4.20 | 4.00 |
| Maximum (%) | 14.00 | 14.00 | 17.00 |
| **Sex** |  |  |  |
| Male | 148 (37.3%) | 148 (37.2%) | 149 (37.1%) |
| Female | 249 (62.7%) | 250 (62.8%) | 253 (62.9%) |
| **Age** |  |  |  |
| 18-39 years | 243 (61.2%) | 243 (61.1%) | 246 (61.2%) |
| 40-59 years | 122 (30.7%) | 122 (30.7%) | 123 (30.6%) |
| 60 years and above | 32 (8.1%) | 33 (8.3%) | 33 (8.2%) |

Table 2: Diagnostic performance of Clover A1care (HbA1c 6.3%)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Sensitivity (%)** | **Specificity (%)** | **Positive Predictive Value (PPV)** | **Negative Predictive Value (NPV)** |
| Capillary | 82.0 | 98.8 | 92.6 | 96.8 |
| Venous | 80.6 | 96.7 | 82.0 | 96.4 |

Table 3: Agreement between blood tested by Clover A1c versus capillary and venous blood

|  |  |
| --- | --- |
| **Categories of blood testing** | **Agreement** |
| Capillary versus Lab | 0.964 (0.96, 0.97), p<0.001 |
| Capillary versus Venous | 0.962 (0.95, 0.97), p<0.001 |
| Lab versus Venous | 0.951 (0.94, 0.96), p<0.001 |

**Conclusion**

Clover A1c showed good reliability as it had good agreement between both capillary and laboratory venous blood. We may draw the conclusion that it is a valid and reliable POCT analyser that can be applied in clinical and community settings where logistics may be problematic.

**References**

1. Park HD. Current status of clinical application of point-of-care testing. Archives of Pathology & Laboratory Medicine. 2021 Feb 1;145(2):168-75.
2. Schnell, O., Crocker, J. B., & Weng, J. (2017). Impact of HbA1c Testing at Point of Care on Diabetes Management. Journal of diabetes science and technology, 11(3), 611–617. https://doi.org/10.1177/1932296816678263
3. Egbunike V, Gerard S. The Impact of Point-of-Care A1C Testing on Provider Compliance and A1C Levels in a Primary Setting. The Diabetes Educator. 2013;39(1):66-73. doi:10.1177/0145721712465340
4. Patzer K-H, Ardjomand P, Göhring K, et al. Implementation of HbA1c Point of Care Testing in 3 German Medical Practices: Impact on Workflow and Physician, Staff, and Patient Satisfaction. Journal of Diabetes Science and Technology. 2018;12(3):687-694. doi:10.1177/1932296818759690
5. Spaeth, B. A., Shephard, M. D., & Schatz, S. (2014). Point-of-care testing for haemoglobin A1c in remote Australian Indigenous communities improves timeliness of diabetes care. *Rural and remote health*, *14*(4), 2849.