

ABSTRACT

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*ACCURACY OF HbA1c EXAMINATION USING TURBIDIMETRIC INHIBITION IMMUNOASSAY (TINIA) METHOD COMPARED TO HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) METHOD
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Diabetes mellitus (DM) is a chronic metabolic disease characterized by elevated blood glucose levels and a continuously increasing prevalence worldwide. Glycated hemoglobin (HbA1c) serves as a primary parameter for the diagnosis and monitoring of diabetes because it reflects the average blood glucose level over the previous two to three months. High-Performance Liquid Chromatography (HPLC) is recognized as the gold standard method for HbA1c measurement, whereas the Turbidimetric Inhibition Immunoassay (TINIA) method is widely used in clinical laboratories due to its practicality and efficiency. This study aimed to evaluate the accuracy of the TINIA method for HbA1c measurement using the HPLC method as the reference standard.

This study employed an analytical observational design with a cross-sectional approach involving 30 EDTA blood samples obtained from patients enrolled in the Prolanis program. Accuracy was assessed based on the percentage of inaccuracy (% bias) and percentage recovery (% recovery). Data normality was evaluated using the Shapiro–Wilk test, followed by the Wilcoxon signed-rank test.

The results showed an average HbA1c level of 7.197% for the HPLC method and 6.687% for the TINIA method, with a bias of 11.361% and a recovery rate of 111.361%, exceeding the National Glycohemoglobin Standardization Program (NGSP) limits of $\leq \pm 5\%$ and the ideal recovery range of 95%–105%. The Wilcoxon test revealed a significant difference between the two methods ($p = 0.002$). It was concluded that the TINIA method does not yet meet NGSP accuracy standards and cannot be used interchangeably with the HPLC method.

Keywords: Accuracy, HbA1c, HPLC, TINIA

References: 15 Books (2016–2026)