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ORIGINAL ARTICLE

Performance Evaluation of the Newly Developed H-120 HbA1c Analyzer

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SUMMARY

Background: **The aim of this study is to evaluate the analytical performance of Mindray H-120, a newly developed and launched Hemoglobin A_{1c} (HbA_{1c}) analyzer that is based on ion-exchange high-performance liquid chromatography (HPLC).**
Methods: **In both standard and variant modes of the H-120 analyzer, precision, accuracy, linearity, and potential interference from Hb variants were assessed. In addition, the consistency of results between the H-120 analyzer and other commonly used analyzers was evaluated.**
Results: **The H-120 analyzer showed excellent precision and accuracy. The coefficients of variation (CVs) of repeatability and reproducibility were not greater than 0.5%. The H-120 analyzer provided results that were consistent with IFCC-assigned external quality control samples with a bias of ± 2.0%. The HbA_{1c} level showed a good linear relationship between 3.0% and 20.1%. The results from the standard and variant modes for the H-120 analyzer were in perfect agreement (r = 1.000), and the HbA_{1c} results showed a high level of consistency ($r \geq 0.998$) when comparing the H-120 with the other two analyzers, D100 and Capillarys 3 TERA. The H-120 analyzer can detect nine of the ten most common Hb variants, and 83.8% of the variant samples do not affect HbA_{1c} measurements.**
Conclusions: **The H-120 analyzer offers outstanding fundamental performance, robust variant detection capabilities, and user-friendly, efficient operation, making it suitable for the requirements of clinical laboratories.**
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KEYWORDS

Mindray H-120, HbA_{1c}, performance evaluation, HPLC

INTRODUCTION

Hemoglobin A_{1c} (HbA_{1c}) results from the non-enzymatic attachment of glucose to hemoglobin. The glycation occurs at the valine residue located at the N-terminus of the β-chain. The process of HbA_{1c} formation is gradual, irreversible, and characterized by low instability and minimal biological variability. Its levels indicate the average blood glucose concentration in the body over the previous two to three months, providing a more objective measure of chronic hyperglycemia. HbA_{1c} is crucial for diagnosing diabetes, assessing glucose manage-

ment in diabetic individuals, and formulating treatment strategies [1-3].

HbA_{1c} testing is typically performed using various techniques, including ion-exchange high-performance liquid chromatography (HPLC), immunoassays, affinity methods, capillary electrophoresis, and enzymatic methods. Each of these techniques has unique features and performance levels, and their results may be influenced by factors like lipid levels, anemia, medications, or Hb variants [4]. Consequently, it is essential to validate the performance of an analyzer in a clinical laboratory prior to its use to guarantee the instrument's effectiveness.

The H-120 by Mindray is a recently developed and launched automated HbA_{1c} analyzer, which employs the high-performance liquid chromatography (HPLC) method to quantify HbA_{1c}. This analyzer operates in two distinct modes: standard mode and variant mode. This study aims to assess whether the analytical and clinical performance of the H-120 analyzer aligns with the requirements of clinical laboratories.

MATERIALS AND METHODS

Samples

A total of 779 EDTA-anticoagulated residual whole blood samples were collected at Peking University Shenzhen Hospital, including 594 non-variant samples and 185 samples containing Hb variants. In addition, we purchased 66 variant samples and eight external quality samples from the IFCC reference laboratory. The eight external quality samples have been assigned target values by the reference method. The variant samples were divided into 5 parts and stored in a -80°C freezer prior to analysis. All variant samples were validated through Sanger sequencing. This study complied with the tenets of the Declaration of Helsinki and was approved and supported by the Ethics Committee of Peking University Shenzhen Hospital. This study was a retrospective study using residual samples from the clinical laboratory, and the requirement for signed informed consent from the patients was waived.

Instruments and reagents

This study utilized four HbA_{1c} analyzers: H-120 (Mindray, Shenzhen, China), D-100 (Bio-Rad, CA, USA), Capillarys 3 TERA (Sebia, Lisses, France), and Premier Hb9210 (Trinity Biotech, Bray, Ireland) and their corresponding calibrators, quality controls and reagents. The H-120 is based on the high-performance liquid chromatography (HPLC) method to quantify HbA_{1c} through the separation of different Hb components. The system is user-friendly, allowing for straightforward replacement of columns, reagents, and filters, with the column capable of sustaining up to 10,000 tests. The H120 operates in two modes: standard mode, which runs for 30 seconds, and variant mode, which runs for 60 seconds. In standard mode, if the analyzer identifies abnormal Hb variants, it will automatically switch to variant mode to retest the sample, without requiring any reagent changes.

Methods

Precision

In accordance with the CLSI EP05-A3 guidelines, samples were analyzed twice a day for 20 consecutive days on the H-120 analyzer, utilizing both standard and variant modes with two different levels of quality control samples and two levels of whole blood samples. The intra-batch precision, inter-day precision, and total precision were calculated.

Linearity

According to the CLSI EP06-A3 guidelines, a high and a low HbA_{1c} sample were mixed in different ratios to obtain six samples with different HbA_{1c} concentrations (0%, 20%, 40%, 60%, 80%, 100%). Each sample was tested three times using the H-120 in standard and variant modes, respectively. Linear regression analysis was then conducted, and the biases of the measured values from the expected values were calculated.

Accuracy

According to the CLSI EP09-A3 guidelines, accuracy was assessed using eight IFCC external quality samples that were assigned target values using the IFCC reference method. These samples were assayed using the H120 and the biases between the assay results and the target values were calculated.

Inter-mode comparison

A total of 221 residual whole blood samples were obtained for analysis. Each sample was evaluated once in both the standard mode and the variant mode. The results obtained from the different modes were analyzed using Passing-Bablok regression analysis, Bland-Altman analysis, and bias analysis at medical decision thresholds of 6.5% and 9.0%.

Interferences of Hb variants

A comprehensive analysis was conducted on 251 variant samples, comprising 185 obtained from our laboratory and 66 from the IFCC reference laboratory. This examination included the four most common Hb variants worldwide - HbS, HbC, HbD, and HbE - as well as six Hb variants that are frequently observed in southern China, namely Hb New York, Hb G-Taipei, Hb G-Coushatta, Hb J-Bangkok, Hb G-Honolulu, and Hb Q-Thailand [5]. Each sample was analyzed once using both the H-120 and Premier Hb9210 analyzers. The Premier Hb9210 served as a comparative method due to its utilization of affinity chromatography, which is believed to be unaffected by prevalent Hb variants [6]. The consistency of the HbA_{1c} results obtained from the H-120 was evaluated in comparison to those from the Premier Hb9210 analyzer. According to the most recent criteria established by the National Glycohemoglobin Standardization Program (NGSP), an acceptable bias is defined

Table 1. Precision results of HbA_{1c} measured on the H-120 analyzer.

Samples	Standard mode				Variant mode			
	HbA_{1c} (%)	intra-batch (CV, %)	inter-day (CV, %)	total precision (CV, %)	HbA_{1c} (%)	intra-batch (CV, %)	inter-day (CV, %)	total precision (CV, %)
QC1 (low)	5.74	0.4	0.3	0.5	5.75	0.2	0.1	0.3
QC2 (high)	10.48	0.2	0.2	0.4	10.51	0.2	0.1	0.2
Sample 1 (low)	5.97	0.2	0.2	0.3	5.94	0.1	0.3	0.3
Sample 2 (high)	12.38	0.1	0.2	0.3	12.39	0.1	0.1	0.2

CV coefficient of variation, QC quality control.

Table 2. Comparison of HbA_{1c} results obtained using H120 with IFCC-assigned values for 8 external samples.

IFCC quality samples	IFCC target values (%)	H-120 measured values (%)	Relative bias	Slope	Intercept	r
Sample 1	5.00	4.91	-1.80%	1.0006	-0.005	0.999
Sample 2	5.68	5.77	1.58%			
Sample 3	6.83	6.73	-1.46%			
Sample 4	7.55	7.66	1.46%			
Sample 5	8.40	8.45	0.60%			
Sample 6	9.27	9.27	0.00%			
Sample 7	10.39	10.31	-0.80%			
Sample 8	11.17	11.19	0.20%			

IFCC International Federation of Clinical Chemistry and Laboratory Medicine.

Table 3. Information of variant samples and sensitivity of variants flagged on the H-120 analyzer.

Hb variants	Number	Standard mode		Variant mode	
		flag	unacceptable results n (%)	flag	unacceptable results n (%)
Hb C	24	yes	0 (0%)	yes	0 (0%)
Hb D	19	yes	4 (21%)	yes	2 (11%)
Hb S	23	yes	1 (4%)	yes	1 (4%)
Hb E	88	yes	84 (95%)	yes	7 (8%)
Hb New York	10	yes	2 (20%)	yes	2 (20%)
Hb J-Bangkok	24	yes	24 (100%)	yes	21 (88%)
Hb Q-Thailand	19	yes	0 (0%)	yes	0 (0%)
Hb G-Taipei	18	yes	6 (33%)	yes	6 (33%)
Hb G-Coushatta	19	yes	2 (11%)	yes	2 (11%)
Hb G-Honolulu	15	yes	1 (7%)	yes	1 (7%)
Total	259	/	124 (47.9%)	/	42 (16.2%)

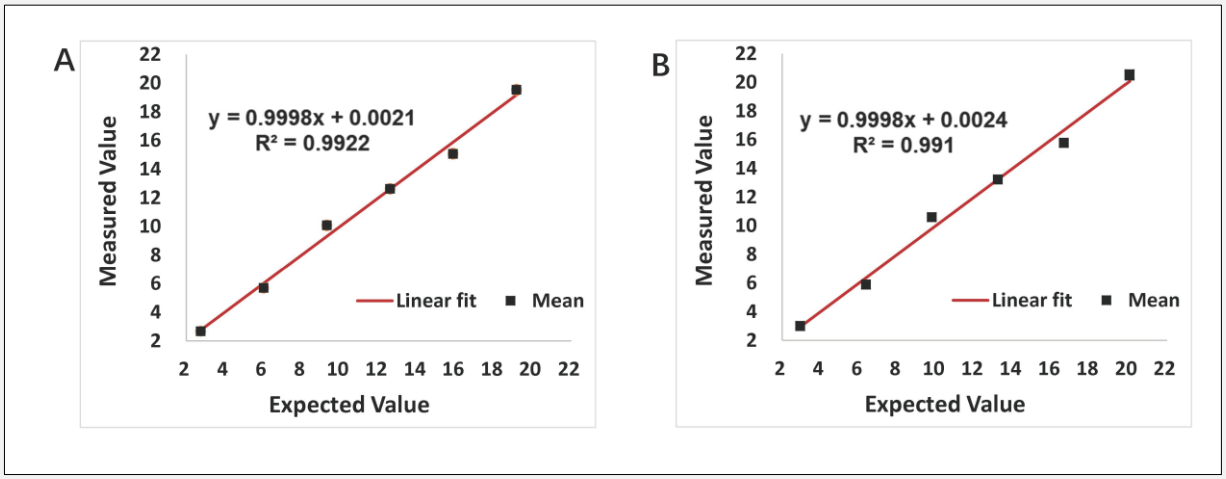

Figure 1. Linearity evaluation results of HbA_{1c} measured on the H-120 analyzer.

A) Standard mode, B) Variant mode.

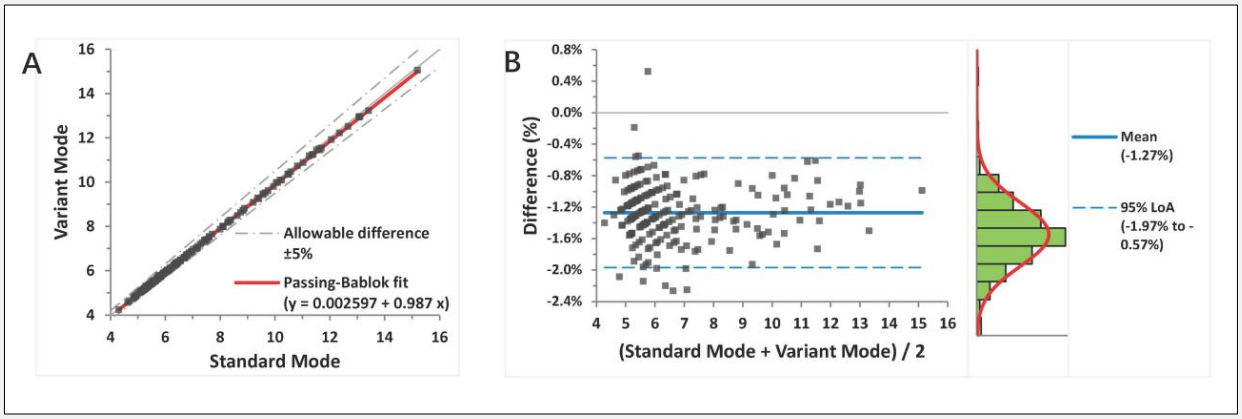

Figure 2. Comparison between standard mode and variant mode.

A) Passing-Bablok regression, B) Bland-Altman analysis.

as a relative bias within ± 5% (https://ngsp.org/critsumm.asp).

Methods comparison

A total of 199 samples were analyzed once with the H-120 and D100 analyzers, and 170 samples were analyzed once with the H-120 and Capillarys 3 analyzers. Passing-Bablok regression and Bland-Altman analysis were used to assess the agreement of the H-120 results with those of the D100 and Capillarys 3 TERA.

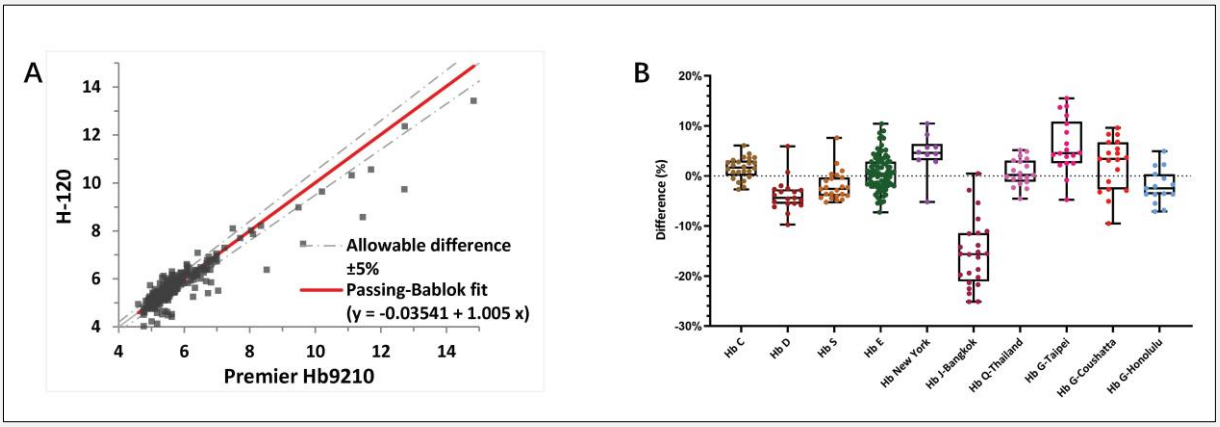

Figure 3. Interference of Hb variants. The Premier Hb9210 was used as a comparative method.

A) Passing-Bablok regression, B) Boxplot analysis.

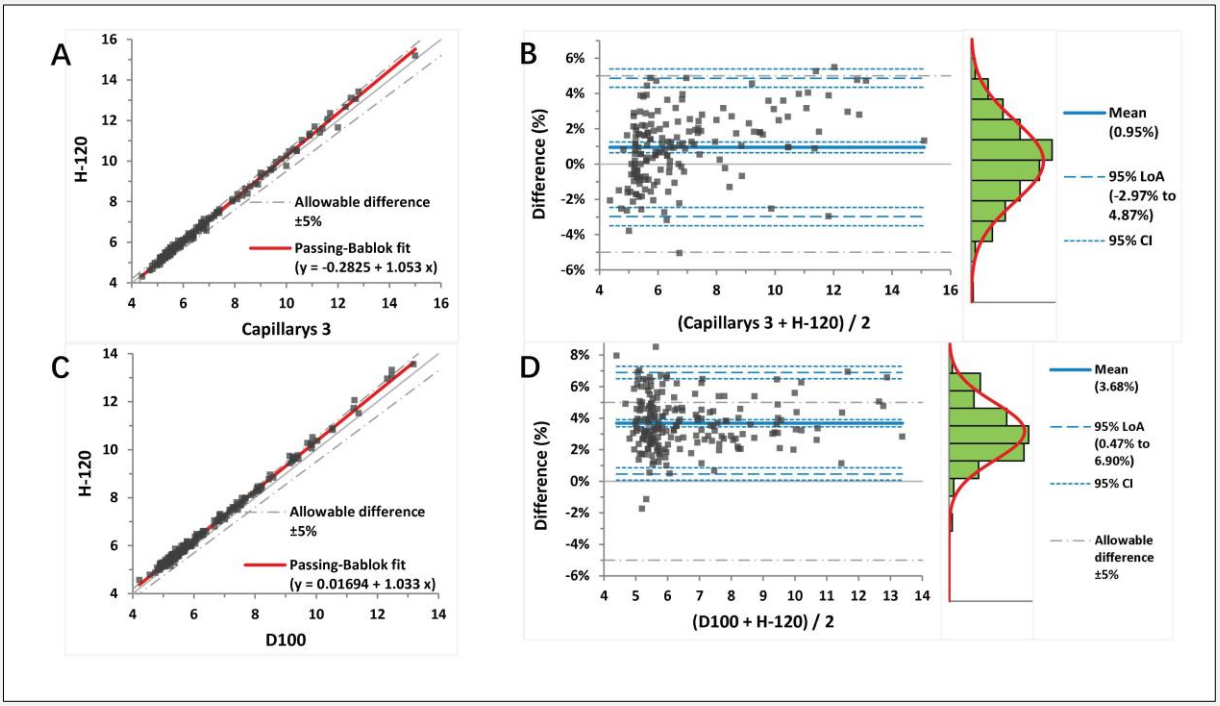

Figure 4. Comparison between H-120 and other analyzers.

Passing-Bablok regression: A) H-120 and Capillarys 3, C) H-120 and D-100. Bland-Altman analysis: B) H-120 and Capillarys 3, D) H-120 and D-100.

RESULTS

Precision

In standard mode, the total precision results for the two quality control samples were 0.4% and 0.5%, while both whole blood samples showed a precision of 0.3%. In variant mode, the total precision results for the quality control samples were 0.2% and 0.3%, and the whole blood samples also had precision values of 0.2% and 0.3%. For all quality control and whole blood samples tested in both standard and variant modes, the intra-batch precision was below 0.4%, and the inter-day precision was under 0.3% (Table 1).

Linearity

The HbA_{1c} results obtained from the two measurement modes of the H-120 analyzer showed a very good linear relationship in the range of 3.0% ~ 20.1%. In the standard mode, the regression equation between the actual test value and the expected value was Y = 0.9998*X + 0.0021 (r = 0.996) (Figure 1A), and in the variant mode, the regression equation was Y = 0.9998*X + 0.0024 (r = 0.995) (Figure 1B).

Accuracy

The bias of the measurements of the eight IFCC quality samples obtained by the H-120 analyzer from the reference values were all within ± 2%. Regression analysis was performed on the measured values and the target values, and the slope and intercept were 1.0006 and -0.005, respectively. The correlation coefficient r was 0.999, and the results were consistent (Table 2).

Inter-mode comparison

The regression equation of the results in the variant mode and the standard mode was Y = 0.987*X + 0.003 (r = 1.000) (Figure 2A), and the biases at the medical decision levels of 6.5% and 9.0% were -1.3% (-1.3% to -1.2%) and -1.3% (-1.4% to -1.2%), respectively. The inter-mode biases were within ± 2.5% (Figure 2B).

Interference of Hb variants

For samples containing Hb variants (HbS, HbC, HbD, HbE, Hb G-Taipei, Hb G-Coushatta, Hb J-Bangkok, Hb G-Honolulu, Hb Q-Thailand), the H-120 analyzer was able to identify them as “suspected variant” in both the standard and variant modes (Supplementary Figure 1, Table 3). The regression equation for the HbA_{1c} results for variant samples using the H-120 and Hb9120 analyzers was Y = 1.005*X + 0.03541 (Figure 3A). Among the Hb variants tested, the proportion of samples with a relative bias within ± 5% was 83.8% in the variant mode (Table 3). The most significant enhancement in the variant mode is the elimination of interference from HbE; nevertheless, both modes remained influenced by Hb J-Bangkok (Table 3, Figure 3B).

Methods comparison

The regression equation of the H-120 and Capillarys 3 test results was Y = 1.053*X - 0.2825, with a correlation coefficient of 0.998 (Figure 4A). The biases at the 6.5% and 9.0% medical decision levels were 1.0% (0.8% to 1.3%) and 2.2% (1.7% to 2.7%), respectively. The mean bias of the results for all the samples was 0.95% (Figure 4B). The regression equation of the H-120 and D100 detection results was Y = 1.033*X + 0.017, with a correlation coefficient of 0.998 (Figure 4C), the biases at the 6.5% and 9.0% medical decision levels were 3.6% (3.3% to 3.9%) and 3.5% (3.1% to 3.9%), respectively, and the mean deviation of the results for all the samples was 3.68% (Figure 4D).

DISCUSSION

Diabetes mellitus is one of the most common chronic diseases threatening human health due to the aging of the global population and the continuous increase in the number of diabetes patients. The importance of HbA_{1c} in the screening, diagnosis, and treatment monitoring of diabetes is continually increasing. With the increased standardization of HbA_{1c} testing globally, the differences in results between different laboratories and different monitoring methods have gradually narrowed, greatly improving the accuracy of diabetes diagnosis and providing an accurate basis for treatment [7].

The present study evaluated the performance of the newly introduced Mindray H-120 HbA_{1c} analyzer in terms of precision, linearity, accuracy, consistency of results between modes, interference of Hb variants and method comparisons. The H-120 demonstrated excellent precision, with a total precision of less than 0.5% in NGSP units in both standard and variant modes; these CVs meet current recommendations [8,9]. The linearity was found to be outstanding within the range of 3.0% to 20.1%. The evaluation of accuracy, as determined by the use of external quality control samples from IFCC, indicated that the method is traceable to the IFCC reference measurement procedure. Furthermore, the H-120 exhibited a high degree of concordance with the results obtained from the D100 and Capillarys 3.

Hb variants represent one of the most prevalent interfering factors in HbA_{1c} testing [10]. The four most common Hb variants, HbS, HbC, HbD, and HbE, account for the majority of all identified Hb variants. It is crucial for HbA_{1c} analyzers to possess the capability to detect and report these Hb variants while also mitigating their interference with HbA_{1c} results [11]. The current study assessed the performance of the H-120 analyzer in identifying common global and regional Hb variants in southern China. The findings indicated that the H-120 successfully detected the Hb variants in this study, with the exception of Hb New York. Notably, in over 80% of the variant samples analyzed, the discrepancy between the variant mode of the H-120 and the Hb9120 analyzer was within ± 5%.

In conclusion, the H120 demonstrates superior analytical capabilities that fulfill the requirements of clinical laboratories. The system can identify the majority of Hb variants and mitigate their impact on HbA_{1c} measurements. Additionally, the H120 has two detection modes. If it detects an Hb variant in standard mode, it will automatically switch to variant mode to retest the sample without requiring a change of reagents.

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Declaration of Interest:
The authors report no conflicts of interest.

References:

1. International Expert Committee. International Expert Committee report on the role of the A1C assay in the diagnosis of diabetes. Diabetes Care 2009 Jul;32(7):1327-34. (PMID: 19502545)

2. Diabetes Control and Complications Trial Research Group; Nathan DM, Genuth S, et al. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. N Engl J Med 1993 Sep 30;329(14):977-86. (PMID: 8366922)

3. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). UK Prospective Diabetes Study (UKPDS) Group. Lancet 1998 Sep 12;352(9131): 837-53. (PMID: 9742976)

4. Little RR, Roberts WL. A review of variant hemoglobins interfering with hemoglobin A1c measurement. J Diabetes Sci Technol 2009 May 1;3(3):446-51. (PMID: 20144281)

5. Xu A, Chen W, Xie W, Wang Y, Ji L. Hemoglobin variants in southern China: results obtained during the measurement of glycated hemoglobin in a large population. Clin Chem Lab Med 2020 Jul 20;59(1):227-32. (PMID: 32687481)

6. Rohlfing C, Hanson S, Estey MP, Bordeleau P, Little RR. Evaluation of interference from hemoglobin C, D, E and S traits on measurements of hemoglobin A1c by fifteen methods. Clin Chim Acta 2021 Nov;522:31-5. (PMID: 34352282)

7. Little RR, Rohlfing C, Sacks DB. The National Glycohemoglobin Standardization Program: Over 20 Years of Improving Hemoglobin A1c Measurement. Clin Chem 2019 Jul;65(7):839-48. (PMID: 30518660)

8. Little RR, Rohlfing CL, Sacks DB; National Glycohemoglobin Standardization Program (NGSP) Steering Committee. Status of hemoglobin A1c measurement and goals for improvement: from chaos to order for improving diabetes care. Clin Chem 2011 Feb;57(2):205-14. (PMID: 21148304)

9. Weykamp CW, Mosca A, Gillery P, Panteghini M. The analytical goals for hemoglobin A(1c) measurement in IFCC units and National Glycohemoglobin Standardization Program Units are different. Clin Chem 2011 Aug;57(8):1204-6. (PMID: 21571810)

10. Little RR, La'ulu SL, Hanson SE, Rohlfing CL, Schmidt RL. Effects of 49 Different Rare Hb Variants on HbA1c Measurement in Eight Methods. J Diabetes Sci Technol 2015 Jul;9(4):849-56. (PMID: 25691657)

11. Yadav N, Kumar Mandal A. Interference of hemoglobin variants in HbA1c quantification. Clin Chim Acta 2023 Jan 15;539:55-65. (PMID: 36476843)

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