

SHORT COMMUNICATION

Performance Evaluation of the Bio-Rad D-100 System for Hemoglobin A1c Assay

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SUMMARY

Background: Recently, the Bio-Rad D-100 system (Bio-Rad Laboratories) for hemoglobin A1c (HbA1c) assay was introduced.

Methods: We evaluated the precision, linearity, and method comparison of the D-100 system. The results of HbA1c from the D-100 were compared with that of the Variant II Turbo 2.0 (Bio-Rad) and G8 variant mode (Tosoh Bioscience). An additional 17 variant hemoglobin samples were compared to the immunoassay (Integra 800) results.

Results: The within-laboratory imprecision coefficient of variation was 1.28 - 1.58% for the control materials and 1.01 - 1.03% for the patient samples. The linearity was confirmed ranging from 3.6 to 19.2% in NGSP units. The mean difference (NGSP units) was as follows: D-100 vs. G8, -0.02%; D-100 vs. Variant II Turbo 2.0, 0.07%. There were no clinically significant differences in the HbA1c results in the 17 hemoglobin variants between the D-100 and immunoassay.

Conclusions: The analytical performance of the Bio-Rad D-100 system for HbA1c assay is clinically acceptable. (Clin. Lab. 2017;63:1923-1928. DOI: 10.7754/Clin.Lab.2017.170524)

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Supplementary Table and Figures

Table S1. Hemoglobin A1c results and the corresponding flag signs of 17 variant hemoglobin samples.

Sample ID	G8 (variant mode)		Variant II Turbo 2.0		D-100		Immunoassay	Hb EP		Absolute difference (immunoassay-HPLC)		
	Flag	HbA1c (%)	Flag	HbA1c (%)	Flag	HbA1c (%)	HbA1c (%)	Results	Variant (%)	D-100	Variant II	G8
16113867811	H-V0 (variant D)	5.7	None	5.6	S-window	5.7	5.6	Hb S trait	5.6	0.1	0.0	-0.1
16123839013	No flag	4.8	Variant window	6.4	E-window	5.9	5.9	Hb E trait	25.1	0.0	-0.5	1.1
15382077313	H-V1 (variant S)	6.0	No flag	6.1	S-window	6.1	5.4	Hb D trait	8.8	0.7	-0.7	-0.6
15394873113	H-V1 (variant S)	5.5	Variant window	5.7	S-window	5.9	5.5	Hb D trait	17.1	0.4	-0.2	0
16119668113	H-V1 (variant S)	5.7	Variant window	5.8	S-window	5.7	5.6	Hb D trait	17.3	0.1	-0.2	-0.1
16106553111	H-V1 (variant S)	5.9	Variant window	6.3	S-window	6.1	6.0	Hb D trait	17.4	0.1	-0.3	0.1
16095584311	H-V1 (variant S)	8.1	Variant window	8.4	S-window	8.3	8.4	Hb D trait	17.6	-0.1	0.0	0.3
15373920113	H-V1 (variant S)	5.1	Variant window	5.3	S-window	5.5	5.0	Hb D trait	17.6	0.5	-0.3	-0.1
15346837613	H-V1 (variant S)	7.3	No flag	7.9	S-window	7.6	7.3	Hb D trait	17.7	0.3	-0.6	0.0
16132563613	H-V1 (variant S)	6.0	Variant window	6.1	S-window	6.2	6.0	Hb D trait	18.1	0.2	-0.1	0.0
16122957211	H-V1 (variant S)	8.1	Variant window	8.6	S-window	8.6	8.7	Hb D trait	22.6	-0.1	0.1	0.6
15366445613	No flag	4.6	Variant window	6.7	E-window	6.5	6.6	Hb D trait	28.5	-0.1	-0.1	2.0
16107494313	7 (peak not good)	4.1	Variant window	5.7	E-window	5.5	5.5	Hb D trait	40.4	0.0	-0.2	1.4
16106053711	H-V2 (variant C)	7.5	Variant window	7.8	Minor peak	7.5	8.1	Hb D trait	40.8	-0.6	0.3	0.6
16039380613	7 (peak not good)	3.9	Variant window	5.6	E-window	5.8	5.3	Hb D trait	41.4	0.5	-0.3	1.4
15382208413	7 (peak not good)	3.7	Variant window	5.3	E-window	5.0	5.1	Hb D trait	41.8	-0.1	-0.2	1.4
15358218713	7 (peak not good)	3.8	Variant window	5.4	E-window	5.2	5.2	Hb D trait	42.8	0.0	-0.2	1.4

Performance of D-100 HbA1c Analyzer

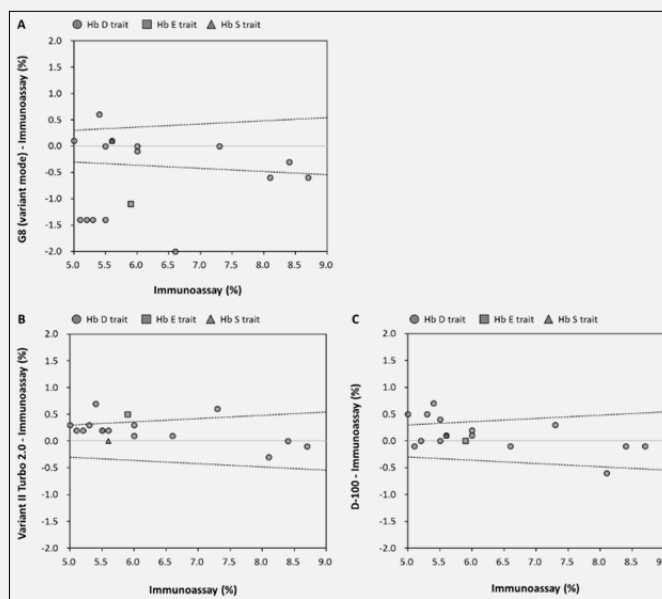


Figure S1. Differences between immunoassay and each HPLC method for hemoglobin A1c assay in variant hemoglobin samples.

The dotted line represents the allowable difference of $\pm 6.0\%$. Circle, hemoglobin D (Hb D) trait; square, hemoglobin E (Hb E) trait; triangle, hemoglobin S (Hb S) trait.

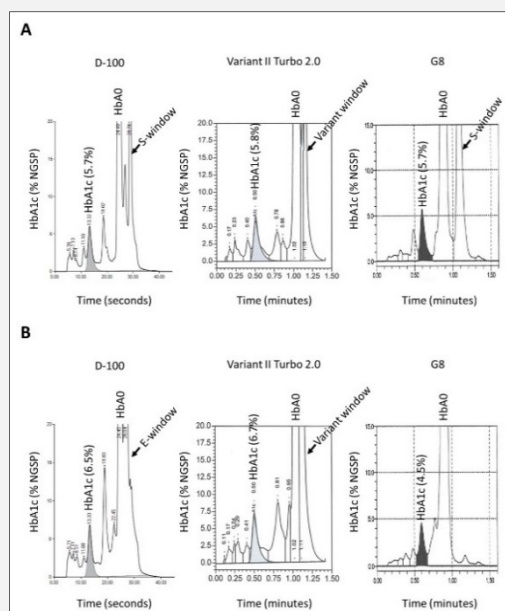


Figure S2. Sample chromatograms for the variant hemoglobin on the three HPLC methods.

(A) This sample shows a variant peak on the chromatogram in all three methods. HbA1c values were: D-100, 5.7%; Variant II Turbo 2.0, 5.8%; G8, 5.7%; and immunoassay, 5.6%. (B) This sample shows a variant peak in D-100 and Variant II Turbo 2.0, but not G8. HbA1c values were: D-100, 6.5%; Variant II Turbo 2.0, 6.7%; G8, 4.5%; and immunoassay, 6.6%.