BLOOD SPOT TEST SPECIFICATIONS

Hemoglobin A1c

Clinical Information

Hemoglobin A1c (HbA1c) is a glycated form of hemoglobin that results from the binding of hemoglobin in red blood cells to glucose in the bloodstream. Once the hemoglobin has bound to glucose, it remains glycated. Circulating red blood cells have a lifespan of 120 days, therefore the amount of HbA1c at any time point reflects the average exposure of red blood cells to glucose over the previous 3 months. It can therefore indicate impaired glucose tolerance even when occasional fasting plasma glucose measurements are normal.

The American Diabetes Association's current guidelines (www.diabetes.org/diabetes-basics/diagnosis/) state that a normal level of HbA1c is <5.7%; a level of 5.7%-6.4% is indicative of prediabetes; and a level of 6.5% or higher is diagnostic of diabetes. The 2018 updated guideline "Standards of Medical Care in Diabetes" recommends testing every 3 months in patients with diabetes to ensure glycemic targets are being maintained, and states that levels of HbA1c above 7% in diabetics are associated with an increased risk of developing microvascular complications such as retinopathy, neuropathy, and diabetic kidney disease.

References:

American Diabetes Association. Standards of Medical Care in Diabetes—2018. Diabetes Care 2018;41(Suppl 1).

Geberhiwot T, Haddon A, Labib M. HbA1c predicts the likelihood of having impaired glucose tolerance in high-risk patients with normal fasting plasma glucose. Ann Clin Biochem. 2005;42:193-5.

Grant T, Soriano Y, Marantz PR, et al. Community-based screening for cardio-vascular disease and diabetes using HbA1c. Am J Prev Med. 2004;26:271-5.

Perry RC, Shankar RR, Fineberg N, McGill J, Baron AD; Early Diabetes Intervention Program (EDIP). HbA1c measurement improves the detection of type 2 diabetes in high-risk individuals with nondiagnostic levels of fasting plasma glucose: the Early Diabetes Intervention Program (EDIP). Diabetes Care. 2001;24:465-71.

Singer DE, Nathan DM, Anderson KM, Wilson PW, Evans JC. Association of HbA1c with prevalent cardiovascular disease in the original cohort of the Framingham Heart Study. Diabetes 1992;41:202-8.

Assay Method: Immunoturbidimetric

Intra-assay Precision

Intra-assay precision was determined by choosing three samples spanning the reference range, and analyzing them multiple times within the same run. Results are shown below:

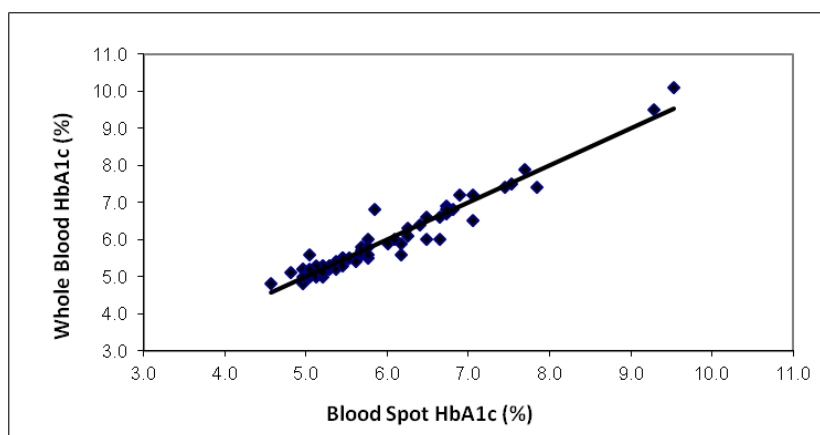| Mean HbA1c (%)	Standard Deviation	Coefficient of Variation (C.V. %)
4.8	0.41	8.5
5.0	0.34	6.8
5.4	0.30	5.4

Inter-assay Precision

Inter-assay precision was determined by choosing three samples spanning the reference range, and analyzing them multiple times throughout different runs. Results are shown below:

Mean HbA1c (%)	Standard Deviation	Coefficient of Variation (C.V. %)
5.1	0.15	2.9
5.9	0.24	4.0
6.8	0.27	4.0

Accuracy

To test the accuracy of the dried blood spot assay for HbA1c, dried blood spot samples collected at the same time as corresponding EDTA whole blood samples were analyzed by linear regression. Resulting correlation data are shown below (R = 0.97):

Analyte Stability

The dried blood spot samples are stable for more than 1 month at room temperature.

Specimen Collection

Kits for blood spot collection contain a filter paper collection card, finger lancets, an alcohol prep pad, sterile gauze, a band-aid, easy-to-follow instructions, and a mailer to return the sample for analysis.