

STANDARD F

HbA1c



SD BIOSENSOR

STANDARD F HbA1c is a test for quantitative measurement for glycated hemoglobin (HbA1c) in human capillary venous whole blood. The test is to monitor glycemic control in people with diabetes.

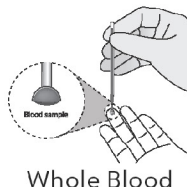
- Optimized performance
- No interference with Hb S, Hb F, Carbamylated Hemoglobin
- Reagents can be stored at room temperature: 2-30°C / 36-86°F
- IFCC / NGSP certified



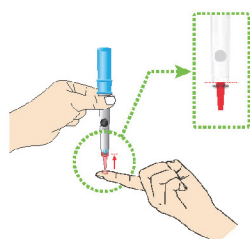
Specification

Specimen Type	Whole Blood
Specimen Volume	5 µl
Measurement Range	4 - 15 % [NGSP], 20 - 140 mm/mol [IFCC]
Reference Range	≤ 5.6% (Normal) 5.7 - 6.4% (Prediabetes) ≥ 6.5% (Diabetes) 7% (ADA target for diabetes patients)
Testing Time	3 mins.
No interference	Common Hb variants (HbS, HbE, HbC, HbD, HbF)
Storage Condition	2 - 30°C / 36 - 86°F

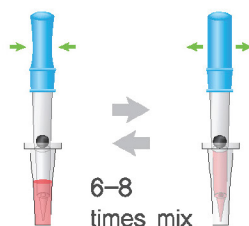
METHODS OF SAMPLE COLLECTION



TEST PROCEDURE



Collect 5µl of blood sample with the Spotit™ (Blue).



Mix the sample with the extraction buffer and collect all the mixture with the Spotit™ (Blue).



Apply the sample mixture into the sample well of the test device.

METHOD COMPARISON

Reference Method vs STANDARD F HbA1c

Correlation with HPLC	$y=0.9765x + 0.1254, R^2=0.9973, n=80$
CV%	<3%
Differ (%)	Within 6% (NGSP Criteria)

ORDERING INFORMATION

Category	Product	Pack Size
Chronic Disease	STANDARD F HbA1c	20 Test
	SDB HbA1c Control	Lv1 x 10 / Lv2 x 10