

STANDARD F HbA1c



» Background

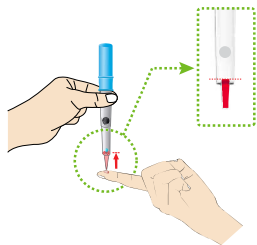
STANDARD F HbA1c is for quantitative measurement of glycated hemoglobin (HbA1c) in human capillary or venous whole blood. This test is to monitor glyceic control in people with diabetes.

» Product Specification

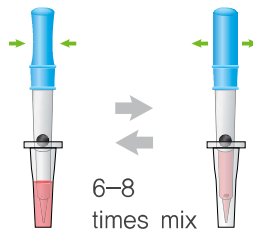


STANDARD F HbA1c	
Intended use	Quantitative measurement of glycated hemoglobin (HbA1c)
Specimen type	Whole blood
Specimen volume	5 µl
Measurement range	4 – 15 % [NGSP], 20 – 140 mm/mol [IFCC]
Reference range	≤ 5.6% (Normal) 5.7 – 6.4% (Prediabetes) ≥ 6.5% (Diabetes) 7% (ADA target for diabetes patients)
Testing time	3 mins
No Interference	Common Hb variants (HbS, HbE, HbC, HbD, HbF)
Storage condition	2 – 30°C / 36 – 86°F

» Test Procedure



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

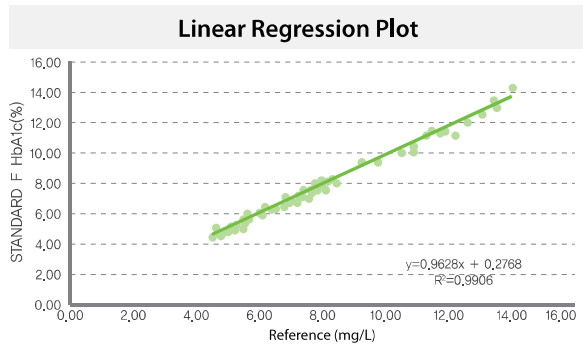


Mix the sample with the extraction buffer and collect all the mixture with the Spot™ (Blue).



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

» Method Comparison



Reference method vs STANDARD F HbA1c

Correlation with HPLC	$y=0,9628x - 0,2768$; $R^2=0,9906$, $n=80$
CV%	< 3%
Differ(%)	within 6% (NGSP criteria)

» Ordering Information

Category	Product	Pack Size	CAT No.
Chronic disease	STANDARD F HbA1c	20 Tests	10A1C10B
	SDB HbA1c Control	Lv1 x 10 / Lv2 x 10	03ACS10