



3-Minute HbA1c Test CLIA-Waived

SIMPLE
FAST
RELIABLE

Afinion™ HbA1c is an *in vitro* diagnostic test for quantitative determination of glycated hemoglobin (% hemoglobin A1c, HbA1c) in human whole blood.



3-Minute HbA1c Test

The American Diabetes Association Guidelines state:

“Use of point-of-care testing for HbA1c allows for timely decisions on therapy changes, when needed.”

SIMPLE

- CLIA Waived
- Factory Calibrated
- Ready-To-Use Controls
- Operator-Free System Check
- Sampling Volume 1.5 µL

FAST

- 3-Minute Test Time
- No Sample Preparation

RELIABLE

- National Glycohemoglobin Standardization Program (NGSP) Certified
- No Interference From Hb Variants

PRODUCT SPECIFICATIONS

Method	Boronate affinity
Sample Type	Capillary whole blood, venous whole blood with anticoagulants (EDTA, heparin or citrate)
Calibration	Factory calibrated – no customer calibration required
Controls	2 levels of liquid controls
Precision	<3% CV
Standardization	Traceable to the International Federation of Clinical Chemistry (IFCC) Reference Method for measurement of HbA1c. HbA1c values are reported according to the NGSP recommendations.
Measuring Range	4% – 15% HbA1c

ADA TESTING RECOMMENDATIONS

- Perform the HbA1c test at least two times a year in patients who are meeting treatment goals and who have stable glycemic control.
- Perform the HbA1c test quarterly in patients whose therapy has changed or who are not meeting glycemic goals.

EXPECTED VALUES

% HbA1c	Interpretation of Results
4-6	Non-Diabetic Range
7	ADA Target
8-12	Above Target

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