



# 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.

**afinion™**



*Put science on your side.*

 **Abbott**  
A Promise for Life

# 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  $\mu$ L

## FAST

- 3-Minute Test Time
- No Sample Preparation

## RELIABLE

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

## PRODUCT SPECIFICATIONS

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

For *in vitro* diagnostic use. Refer to the Operator's manual for warnings, precautions and limitations regarding proper use of the Afinion AS100 analyzer. Manuals can be found on [www.abbottdiagnostics.com](http://www.abbottdiagnostics.com).

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1-877-4ABBOTT

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