



– HbA1c
at its simplest

Key facts

- Based on the boronate affinity test principle
- Only 3 minutes test time using the Afinion™ AS100 Analyzer
- 1.5 µL whole blood sample volume
- 4-18% HbA1c measuring range
- Hb-range 6-20 g/dL
- No interference from Hb variants HbF, HbS, HbC and HbJ
- Traceable to the IFCC Reference Method
- Reports DCCT/UKPDS aligned values

Making HbA1c values readily accessible

Preventing late macro- and microvascular complications is today one of the main clinical challenges of diabetes mellitus. Measurements of HbA1c have proven to be an important tool in keeping track of the metabolic control^{1,2,3,4,5}.

In the busy everyday working environment, Afinion™ HbA1c provides within minutes an accurate and precise test result. In this way, with the value readily available, treatment efficacy can be evaluated right there and then.

Single instrument precision profile

Sample	Normal	Diabetic	Afinion™ HbA1c Control C I	Afinion™ HbA1c Control C II
% HbA1c	5.7	10.3	6.7	9.6
Within run repeatability % CV (n=20)	0.8	0.8	1.0	1.4
Between day imprecision % CV 20 days, (n=4)	0.5	0.8	0.8	1.0
Total imprecision % CV 20 days, (n=4)	1.0	1.2	1.4	1.8



Afinion™ Analyzer System

So simple, so fast, so safe!

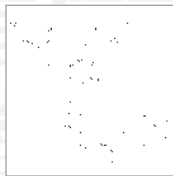
The Afinion™ Test Cartridge is designed with your convenience in mind:

- The single cartridge contains all reagents necessary for analysing HbA1c in the sample.
- The integrated sample collector ensures the correct amount of sample material is collected in a safe and easy way.
- The cartridge has a dedicated field for ID labelling.
- The barcode contains all data necessary for the Analyzer: Test type, lot number, expiry date – they are all there.



The secret lies in

Analysing HbA1c using Afinion™ HbA1c is based on Axis-Shield's patented blue boronic acid conjugate XC-DAPOL-CPBA⁹. The conjugate is designed to allow measurement of the glycosylated hemoglobin only, as the conjugate binds specifically to cis-diols of glycosylated hemoglobin. Combined with a measurement of hemoglobin, the % HbA1c of the sample is calculated and displayed by the Afinion™ AS100 Analyzer.



Standardisation

In January 2004 the ADA/EASD/IDF Working Group agreed that the IFCC Reference Method should become the global reference and that all manufacturers should calibrate their instruments to this new reference. HbA1c values should still be reported in DCCT/UKPDS numbers⁷. For more information see the IWG web site <http://www.ifcchba1c.com/index.asp>

Standardisation of Afinion™ HbA1c is traceable to the IFCC Reference system. Correct standardisation is maintained through collaboration with the European Reference Laboratory for Glycohemoglobin⁸.

- 1 N Eng J Med. 1993; 329:977-986
- 2 Brit Med J. 1998; 317:703-713
- 3 Brit Med J. 1998; 317:713-720
- 4 Lancet. 1998; 352:837-853
- 5 Lancet. 1998; 352:854-865
- 6 Clin Chem Lab Med. 2002; 40(1):78-89
- 7 Diabetologia. 2004; 47(5):R53-54
- 8 <http://www.euroreflab.com/>
- 9 Clin Chem. 1997; 43(12):2390-2396

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