IFCC International Federation of Clinical Chemistry
Network on Standardization of HbA1c

Certificate

Traceability of Manufacturers to the IFCC Reference Measurement Procedure for HbA1c

This certifies that ***Bayer Diabetes Care*** using ***A1CNow+***, uses calibrators supplied by the IFCC Network to get traceable to the IFCC Reference Measurement Procedure and participates in the Monitoring Programme to demonstrate traceability. In the Monitoring Programme of 2010 the following performance was seen:

Deviation from IFCC-target	at 30 mmol HbA1c/mol Hb :	-2.8
	at 60 mmol HbA1c/mol Hb :	-4.4
	at 90 mmol HbA1c/mol Hb :	-6.1
Reproducibility, coefficient of variation		6.34
Linearity, correlation coefficient		0.9869

* Bayer HealthCare Addendum: See attached statement regarding commutability of IFCC traceability samples

Date of issue: 8 December 2010

Certification expires: 31 December 2011

IFCC Network Coordinator

Bayer HealthCare
Diabetes Care

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Memo:

Bayer HealthCare LLC- Diabetes Care, A1CNow™
510 Oakmead Parkway
Sunnyvale, California 94085

Date: January 1, 2011
To: A1CNow+™ Customers

Subject: STATEMENT REGARDING COMMUTABILITY OF IFCC TRACEABILITY SAMPLES

Although the "Deviation from IFCC-target" results listed on our certificate of traceability are considered acceptable per the IFCC standards, they exhibit a negative bias. EDTA in the IFCC traceability samples has been shown to cause artificially low results with Bayer's A1CNow+™ Multi-Test A1C System. Routine blood samples for this method are from finger stick and do not include EDTA. EDTA bias with Bayer's A1CNow+ device varies between A1CNow+ lots and from blood sample to blood sample, thus both the accuracy and reproducibility or precision (coefficient of variation) may be affected. Bayer recommends the use of heparin anticoagulant instead of EDTA when testing venous samples.

A similar qualifying statement is included with the CAP survey results in the US. See http:// http://www.ngsp.org/CAPdata.asp

Traceability of Bayer's A1CNow+™ Multi-Test A1C System is also demonstrated by the performance of our in-house reference instrument, a Tosoh G7. This instrument is used to assign values for samples used to calibrate the A1CNow+™ product. Our Tosoh G7 is also traceable to the IFCC network per the attached certificate and demonstrates excellent accuracy and precision.

IFCC
International Federation of Clinical Chemistry and Laboratory Medicine
Network on Standardization of HbA1c

Certificate

Traceability of Manufacturers to the IFCC Reference Measurement Procedure for HbA1c

This certifies that ***Bayer Diabetes Care*** using ***Tosoh G7***, uses calibrators supplied by the IFCC Network to get traceable to the IFCC Reference Measurement Procedure and participates in the Monitoring Programme to demonstrate traceability. In the Monitoring Programme of 2010 the following performance was seen:

Deviation from IFCC-target	at 30 mmol HbA1c/mol Hb :	-0.6
	at 60 mmol HbA1c/mol Hb :	-0.4
	at 90 mmol HbA1c/mol Hb :	-0.2
Reproducibility, coefficient of variation		1.16
Linearity, correlation coefficient		0.9994

Date of issue: 8 December 2010

Certification expires: 31 December 2011

IFCC Network Coordinator