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 ***Polymer Technology Systems Inc.*** using ***A1CNow+***, participates in the Monitoring Programme to demonstrate traceability. In the Monitoring Programme of 2015 the following performance was seen:

Deviation from IFCC-target	at 30 mmol HbA1c/mol Hb :	-3.8
	at 60 mmol HbA1c/mol Hb :	-3.6
	at 90 mmol HbA1c/mol Hb :	-3.4
Reproducibility, coefficient of variation		5.86%
Linearity, correlation coefficient		0.9900

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

Date of issue: 4 December 2015

Certification expires: 31 December 2016

Dr. C.W. Weykamp
IFCC HbA1cNetwork Coordinator

MEMORANDUM

DATE: Dec 12, 2014

TO: A1CNow+™ Customers

FROM: Polymer Technology Systems, Inc.

RE: 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 PTS's A1CNow+™ Multi-Test A1C System. Routine blood samples for this method are from finger stick and do not include EDTA. EDTA bias with PTS'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. PTS recommends the use of heparin anticoagulant instead of EDTA when testing venous samples.

Traceability of PTS'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.