International Federation of Clinical Chemistry and Laboratory Medicine

Network on Standardization of HbA1c

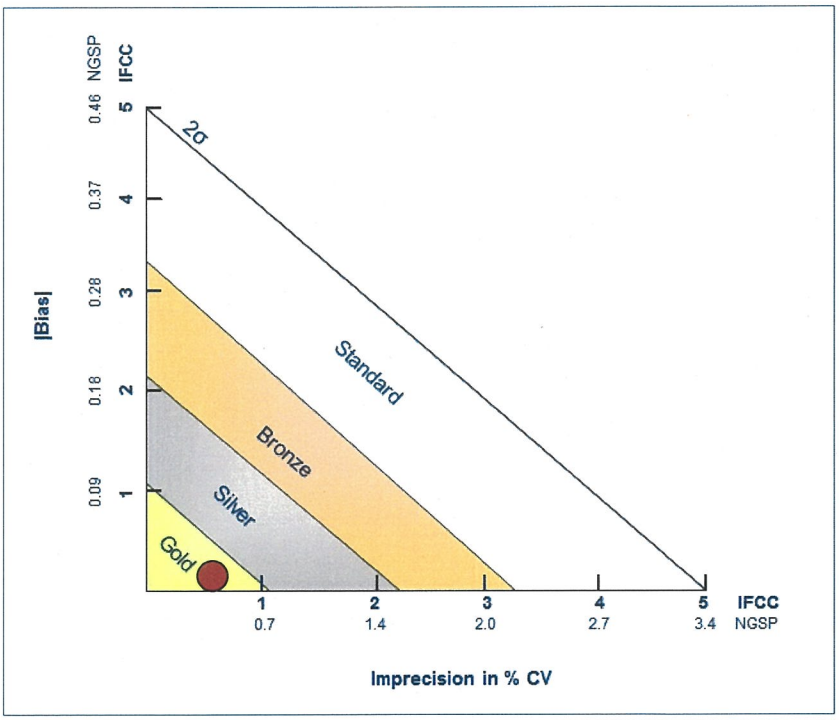
Certificate

Sebia

using

MINICAP Hb A1c

participated in the IFCC HbA1c Certification Programme to demonstrate traceability to the IFCC Reference Measurement Procedure and performed as shown below.



Total Error =	0.7	mmol/mol
Bias =	-0.1	mmol/mol
Imprecision =	0.6	%
Grade =	Gold	

Criteria derived from the IFCC model for Quality Targets HbA1c (Clin Chem 2015;61:752-59)

Date of Certification: 01 January 2018

Date of Expiry: 01 January 2019

IFCC Network Coordinator
Dr. C.W. Weykamp

IFCC HbA1c Certificate 2018

IFCC Certificate

The *design* of the IFCC HbA1c Certificate of Traceability to the IFCC Reference Measurement Procedure (IFCC-RMP) is derived from the Model Quality Targets, developed by the IFCC Task Force on Implementation of HbA1c Standardization (Ref 1).
The *data* on the certificate are calculated from the results in the IFCC Monitoring Programme: manufacturers measure 24 blind samples with HbA1c concentrations covering the relevant analytical range and submit the results to the IFCC Network. The 24 samples are identical two by two ("blind twins" or "blind duplicates").

Performance Parameters on the Certificate

The performance of a measurement is determined by systematic and ad random errors of the assay used to measure HbA1c. The systematic error derives from inappropriate calibration of the assay: results are always too high or too low. The ad random error derives from imprecision of the assay: results are more or less dispersed. The total error is the accumulation of systematic and ad random error. These three parameters are the corner stone of the IFCC Model Quality Targets and shown on the certificate:

a. The systematic error, numerically expressed as "Bias"
b. The ad random error, numerically expressed as "Imprecision"
c. The total error, numerically expressed as "Total Error"
d. The total error, visually expressed as a red dot in the graph
e. The total error, expressed in a grade ranging from "Participated" to "Gold"

Ad a. Bias
Bias is defined as the difference between the concentration measured with the assay of the applicant and the concentration measured with the IFCC-RMP. The calculation is based on the results of all 24 samples in the certification programme. A plot is made: values assigned with the IFCC-RMP on the x-axis and the results of the applicant on the y-axis.
In the relation y = ax + b, 50 is filled for x and y is calculated. The bias on the certificate is the applicant bias at an HbA1c concentration of 50 mmol/mol = (y – 50).
50 mmol/mol is the clinically critical HbA1c concentration.

Ad b. Imprecision
Imprecision is defined as the dispersion of results in multiple measurements in the same sample and expressed as Coefficient of Variation (CV). The CV is calculated from the differences in results in the "blind duplicates" according to

$$CV = \frac{\sqrt{\frac{\sum(\Delta)^2}{n}}}{\bar{x}\sqrt{2}} \times 100\%$$

Δ = difference in the duplicate
n = number of duplicates
$\bar{x}$ = mean of the results for all the submitted duplicates

The blind duplicates in 2017 were samples 2017.01/20, 02/17, 03/15, 04/14, 05/13, 06/19, 07/21, 8/22, 09/18, 10/16, 11/23 and 12/24.

Ad c. Total Error

Total Error is defined as the sum of bias and imprecision according to TE = |B| + 2I

In which:

TE = Total Error

|B| = Absolute Bias at 50 mmol/mol in mmol/mol

I = Imprecision at 50 mmol/mol in mmol/mol (= CV% x 50/100)

Ad d. Total error in the graph

In the graph, bias is plotted on the y-axis and imprecision on the x-axis. The total error of the applicant is drawn with a red dot. Lines and colours in the graph allow grading of the total error. An applicant passes the IFCC sigma metrics criterion (TAE 5 mmol/mol; 2σ) when the red dot is in the triangle between the 2 sigma line and the x- and y-axis. An applicant passes the IFCC biological variation criteria for minimum, desirable, and optimum performance when the red dot is in the amber, grey and yellow zone, respectively.

Ad e. Grading the Performance

For easy understanding, the statistical terminology of the original paper in Clin Chem is simplified: a performance in the 2 sigma triangle is interpreted as “standard pass”, in the amber field as “pass with bronze medal”, in the grey field as “pass with silver medal”, and in the yellow field as “pass with gold medal”. The grade is also printed in a word on the certificate.

Reference

1. Weykamp C, John G, Gillery P, English E, Ji L, Lenters-Westra E, Little R, Roglic G, Sacks D, Takei I, on behalf of the IFCC Task force on implementation of HbA1c Standardization. Investigation of 2 Models to Set and Evaluate Quality Targets for HbA1c: Biological Variation and Sigma-Metrics. Clin Chem 2015;61:752-9.