Summary of an evaluation provided by SKUP | cobas b 101 for measurement of HbA1c

Manufacturer	Roche Diagnostics GmbH
Supplier	Roche Diagnostics Norge AS in Norway* Roche Diagnostics A/S in Denmark*
Launched in Scandinavia	April 2013

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Aim

The aim of the evaluation was to assess the analytical quality and user-friendliness of **cobas b** 101 HbA1c, when used under real-life conditions by intended users in primary health care centres (PHCCs). Assessment under optimal conditions was performed under a former evaluation (SKUP/2020/117). The quality goal for repeatability was fulfilled under optimal conditions (CV 1,4-3,4%), while the quality goal for accuracy was not (83%).

Evaluated parameters	Quality goals	Conclusions and results
Repeatability	CV ≤3,0 %	**Fulfilled under real-life conditions** (CV 1,4-2,6 %)
Accuracy	≥95 % of the results should be within ±3,0 mmol/mol from the results of the comparison method at HbA1c concentration <35,3 mmol/mol and within ±8,5 % at HbA1c concentration ≥35,3 mmol/mol	**Not fulfilled under real-life conditions** (83 %)
User-friendliness	A total rating of "Satisfactory"	**Not fulfilled**

Background

Measurement system	In vitro diagnostic device for measurement of C-reactive protein (CRP), Haemoglobin A1c (HbA1c) and a Lipid Panel
Intended users	Health care professionals
Sample material	Capillary whole blood, or venous ethylenediaminetetraacetic acid (EDTA) or lithium-heparinised venous whole blood. Capillary whole blood was evaluated.

Material and methods

Participants	106 patients in PHCC's
Comparison method	A high performance liquid chromatography (HPLC) method implemented on D-100 HbA1c System (Bio-Rad Laboratories, Inc.)
Analytical procedure	The PHCC's received a demonstration of **cobas b** 101 HbA1c by Roche Diagnostics Norway. Analysis of fresh capillary whole blood samples from each participant on **cobas b** 101 HbA1c. The measurements were performed in duplicate, i.e. two separate finger sticks. Three lots of test discs were used. Analysis of venous samples (K_2-EDTA sample tubes) from the same individuals were measured in duplicate on the comparison method. The evaluation was carried out from June to December 2021.
User-friendliness	Assessed using a questionnaire with three given ratings; satisfactory, intermediate and unsatisfactory

Additional findings

Bias	Bias (≈+2 mmol/mol) between **cobas b** 101 HbA1c and the comparison method
Technical errors	None

* Requesting company