

Capitainer B, HbA1c

Manufacturer

Capitainer AB

Supplier in Denmark

You Do Bio

Supplier in Sweden

Same as the manufacturer

Supplier in Norway

Same as the manufacturer

Launched in Scandinavia

February 2020



Aim

To assess the analytical performance and user-friendliness of Hemoglobin A1c (HbA1c) measurements of capillary blood, collected with Capitainer B sampling card, analysed on Roche cobas pro with Tina-quant. Sample collection was performed by the intended users (health care personnel and lay persons), and measurements of HbA1c were performed by biomedical laboratory scientists. The first evaluation showed poor accuracy, therefore, a second evaluation was carried out after the manufacturer introduced changes to the pre-analytical procedure, as well as shortening the recommended stability time of the Capitainer B sampling card, from 14 to 5 days after sampling. The second evaluation included only Capitainer B samples collected by lay persons with diabetes, recruited at primary health care centers (PHCCs).

Performance specifications	Results	Conclusions
Repeatability CV $\leq 3,0$ %	First evaluation CV 1,4 – 2,8 %	Fulfilled when samples were collected by health care personnel.
	Second evaluation CV 0,8 – 1,3 %	Fulfilled when samples were collected by lay persons.
Accuracy ≥ 95 % of individual results within $\pm 3,0$ mmol/mol at HbA1c concentration $< 35,3$ mmol/mol and $\pm 8,5$ % at HbA1c concentration $\geq 35,3$ mmol/mol compared to the average result of the comparison method.	First evaluation 74,0 %	Not fulfilled when samples were collected by health care personnel.
	Second evaluation 89,0 %	Not fulfilled when samples were collected by lay persons.
User-friendliness A total rating of "Satisfactory"	First and second evaluation The user-friendliness was rated satisfactory.	Fulfilled

Additional information

Participants and evaluation sites

First evaluation

113 persons with diabetes recruited at a hospital laboratory and 92 persons with diabetes recruited at three primary health care centres.

Second evaluation

115 persons with diabetes recruited at seven primary health care centres.

Evaluated method

Both evaluations

HbA1c on capillary blood samples collected with Capitainer B sampling card, analysed on cobas pro c503 with Tina-quant.

Comparison method

Both evaluations

cobas pro c503 with Tina-quant. HbA1c on venous whole blood samples.

Bias

Both evaluations

When samples were collected by health care personnel in the first evaluation, a positive bias of 2,1 to 3,0 mmol/mol was observed between the evaluated method and the comparison method. When samples were collected by lay persons in the second evaluation, a positive bias of 0,7 to 2,1 mmol/mol was observed between the methods.

A letter with comments from Capitainer AB is attached to the report.

Further information about the evaluation and the organisation of SKUP can be found on www.skup.org.

This summary is also published in Danish, Norwegian and Swedish at www.skup.org.

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