Summary | cobas b 101 for measuremen of HbA1c

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Manufacturer: Roche Diagnostics GmbH
Supplier: In Denmark; Roche Diagnostics Danmark, Abena, OneMed og Mediq
In Norway; Roche Diagnostics Norway, Norengros

Summary of an evaluation provided by SKUP

Conclusion

- **The quality goal for repeatability was fulfilled based on an assessment of the results performed in one health care centre**
- **The quality goal for accuracy was not fulfilled neither under optimal condition nor by intended users.**
- **The quality goal for user-friendliness was fulfilled**

Background

The **cobas b** 101 system is an in vitro diagnostic device for quantitative measurement of Haemoglobin A1c (HbA1c), C-reactive protein (CRP) and lipids. The product is intended for professional use. The sample material for HbA1c measurements can be capillary whole blood, venous ethylenediaminetetraacetic acid (EDTA) or lithium-heparinised venous whole blood. The system is produced by Roche Diagnostics GmbH and was launched into the Scandinavian market April 2013. The SKUP evaluation was carried out in summer 2019 at the request of Roche Diagnostics Denmark and Roche Diagnostics Norway.

The aim of the evaluation

The aim of the evaluation was to assess the analytical quality and user-friendliness of **cobas b** 101 HbA1c, when used both under optimal conditions by experienced laboratory personnel and under real-life conditions by intended users in primary health care.

Materials and methods

Fresh capillary whole blood samples from 111 patients were measured on **cobas b** 101 HbA1c under optimal conditions in a hospital laboratory. Under real-life conditions in two primary health care centres (PHCC1 and PHCC2), fresh capillary whole blood samples from 50 and 40 patients, respectively, were measured on **cobas b** 101 HbA1c. Venous whole blood samples from the same patients were analysed with a comparison method in one of two hospital laboratories (capillary electrophoresis in free solution, Capillarys 3, Sebia and high performance liquid chromatography, TOSOH G8, TOSOH Bioscience, Inc). The analytical quality and user-friendliness were assessed according to pre-set quality goals. The quality goal for precision was a repeatability CV (coefficient of variation) ≤3,0 %. The quality goal for accuracy was that ≥95 % of the results should be within ±8,5 % in relation to the results of the comparison method. The results and limits for the quality goals are presented in mmol/mol. The user-friendliness was assessed using a questionnaire with three given ratings; satisfactory, intermediate and unsatisfactory, and with the quality goal of a total rating of "satisfactory".

Results

The CV achieved under optimal conditions was between 1,4 and 3,4 % depending on the concentration level. The CV achieved under real-life conditions for PHCC1 was between 2,4 and 4,0 %. The calculated CVs achieved under optimal conditions and by PHCC1 include instrument-to-instrument variation and was therefore carried out under "intermediate precision conditions", hence the repeatability from these evaluation sites have not been assessed. The CV for PHCC2 was between 1,3 and 1,7 and was obtained under repeatability conditions.
Under optimal conditions 83 % of the results were within the allowable deviation limits for accuracy and when handled by intended users 57 % of the results were within the limits. In the clinically relevant HbA1c interval ≥38 mmol/mol 85 % and 61 %, respectively, were within the

limits. A statistical significant positive bias was seen between **cobas b** 101 and the comparison method both under optimal conditions and under real-life conditions by the intended users. The user-friendliness was rated as satisfactory.

Comments from Roche Diagnostics
A letter with comment from Roche Diagnostics is attached to the report.

This summery will also be published in Danish, Norwegian and Swedish at www.skup.org