Summary | cobas b 101 for measurement of Lipid Panel

(cholesterol, HDL- and LDL-cholesterol and triglycerides)

Manufacturer: Roche Diagnostics GmbH

Supplier: In Denmark: Roche Diagnostics Denmark, Abena, OneMed and Mediq Danmark
In Norway: Roche Diagnostics Norway, Norengros

Summary of an evaluation provided by SKUP

Conclusion

- **The quality goal for repeatability was fulfilled for cholesterol and HDL-cholesterol both under optimal conditions and by intended users.**
- **The quality goal for repeatability was not fulfilled for LDL-cholesterol and triglycerides neither under optimal conditions nor by intended users.**
- **The quality goal for accuracy was fulfilled for cholesterol and HDL-cholesterol both under optimal conditions and by intended users.**
- **The quality goal for accuracy was not fulfilled for LDL-cholesterol and triglycerides neither under optimal conditions 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 Lipid Panel measurements can be capillary whole blood, as well as venous ethylenediaminetetraacetic acid (EDTA) and lithium heparin anticoagulated whole blood or plasma. The system is produced by Roche Diagnostics GmbH and was launched into the Scandinavian market April 2013. The SKUP evaluation was carried out in spring/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 Lipid Panel, both when used under optimal conditions by experienced laboratory personnel and under real-life conditions by intended users in primary health care.

Materials and methods

Capillary whole blood samples from 111 patients were measured on **cobas b** 101 Lipid Panel under optimal conditions. Under real-life conditions in two primary health care centres (PHCC1 and PHCC4), fresh capillary whole blood samples from 48 and 40 patients, respectively, were measured on **cobas b** 101 Lipid Panel. Venous plasma samples from the same patients were analysed on a comparison method **cobas** 8000, Roche Diagnostics. The analytical results and user-friendliness were assessed according to pre-set quality goals. The quality goal for precision was a repeatability (CV) for cholesterol ≤3,0 %, for HDL- and LDL-cholesterol ≤4,0 % and for triglycerides ≤5,0 %. The quality goal for accuracy was that ≥95 % of the results should be within the deviation limits of ±9,0 % for cholesterol, ±13,0 % for HDL- and LDL-cholesterol and ±16,0 % for triglycerides in relation to the comparison method.
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

Cholesterol: The CV achieved under optimal conditions was between 1,3 and 2,0 % depending on the concentration level and the PHCCs achieved a CV between 0,8 and 2,4 %.
Under optimal conditions 98 % of the results were within the allowable deviation limits for accuracy and in the PHCCs 95 % of the results were within the allowable deviations limits.
A small but statistical significant bias was seen at medium and high levels under optimal condition (+0,03 – +0,11 mmol/L) and in the PHCCs (+0,13 – +0,23 mmol/L).

HDL-cholesterol: The CV achieved under optimal conditions was between 0,8 and 0,9 % depending on the concentration level and the PHCCs achieved a CV between 1,0 and 2,2 %.
Under optimal condition 99 % of the results were within the allowable deviation limits for accuracy and in the PHCCs 98 % of the results were within the allowable deviation limits.
Under optimal condition a small but statistically significant bias was seen at the low level (-0,04 mmol/L). No statistically significant bias was seen at the medium and high levels.
For PHCC1 a small but statistically significant bias was seen at the low level (-0,04 mmol/L). No statistically significant bias was seen at the medium and high levels.
In PHCC4 no statistically significant bias was seen.

Triglycerides: The CV achieved under optimal conditions was between 4,0 and 8,0 % depending on the concentration level. The PHCCs achieved a CV between 1,4 and 8,5 %.
Under optimal conditions 50 % of the results were within the allowable deviation limits for accuracy and in the PHCCs 54 % of the results were within the allowable deviation limits.
Both under optimal condition and in PHCCs a statistically significant bias was seen at all three levels (+0,22 – +0,40 mmol/L).

LDL-cholesterol: The CV achieved under optimal conditions was between 1,9 and 10,3 % depending on the concentration level. The PHCCs achieved a CV between 1,9 and 5,1 %. Under optimal conditions 91 % of the results were within the allowable deviation limits for accuracy and in the PHCCs 91 % of the results were within the limits.
Under optimal condition a negative bias was seen at all three levels (-0,10 and -0,07 mmol/L). The bias was statistically significant at the low and high level. For the PHCCs no statistically significant bias was seen. The user-friendliness for the instrument was rated as satisfactory.

Comments from Roche Diagnostics

A letter with comments from Roche Diagnostics is attached to the report.
See the full report and letter on www.skup.org.

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