Summary / cobas b 101 for measurement of CRP

Manufacturer: Roche Diagnostics GmbH
Supplier: In Denmark; Roche Diagnostics Denmark, OneMed, ABENA, Mediq
In Norway; Roche Diagnostics Norway, Norengros AS

Summary of an evaluation provided by SKUP

Conclusion
- **The quality goal for repeatability was fulfilled both under optimal conditions and when the measurements were performed by intended users**
- **The quality goal for accuracy was fulfilled both under optimal conditions and 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 C-reactive protein (CRP), Haemoglobin A1c (HbA1c) and lipids. The product is intended for professional use. The sample material for CRP measurements can be capillary whole blood and serum, as well as venous ethylenediaminetetraacetic acid (EDTA) and lithium heparin anticoagulated whole blood and 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 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 CRP, both when used under optimal conditions by experienced laboratory personnel and when used under real-life conditions by intended users in primary health care.

Materials and methods

Capillary whole blood samples from 106 patients were measured on **cobas b** 101 CRP under optimal conditions. Under real-life conditions in each of two primary health care centres (PHCC1 and PHCC2) capillary whole blood samples from 55 and 50 patients, respectively, were measured on **cobas b** 101 CRP. Venous serum samples from the same patients were analysed on a comparison method (CRP Vario immunoturbidimetric assay, Architect plus c16000, Abbott). The analytical results and user-friendliness were assessed according to pre-set quality goals. The quality goal for precision was a repeatability (coefficient of variation, CV) ≤10,0 %. The quality goal for accuracy was that ≥95 % of the results should be within the deviation limits of ±2,0 mg/L for CRP concentrations <10 mg/L and ±20,0 % for CRP concentrations ≥10 mg/L 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

The CV achieved under optimal conditions was between 2,1 and 2,6 % depending on the concentration level. The PHCCs achieved a CV between 1,9 and 2,7 %. All the results were within the allowable deviation limits for accuracy both under optimal conditions and in the PHCCs. At the medical decision point of 40 mg/L there was a small but statistically significant bias between **cobas b** 101 CRP and the comparison method of approximately –3 %. The user-friendliness was rated as satisfactory.

Comments from Roche Diagnostics

Roche Diagnostics has accepted the report without further comments.

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