

NT-proBNP on Cobas h 232 POC system

Summary of an evaluation under the direction of SKUP Report SKUP/2013/97

Background

The Cobas h 232 POC system (Cobas h 232) was launched onto the Scandinavian market in 2007. The system is produced by Roche Diagnostics GmbH. The test strips for the meter support diagnosis and assessment of cardiovascular diseases. This evaluation was ordered by Roche Diagnostics Norway and was performed with test strips for NT-proBNP.

The aim of the evaluation

- compare Cobas h 232 results achieved with heparinised venous whole blood in a hospital laboratory and in three primary health care centres with results from serum samples achieved with an established hospital laboratory method for NT-proBNP
- compare the analytical quality of Cobas h 232 with the manufacturer's specifications for imprecision ($CV \leq 15\%$), trueness versus Elecsys (bias $\leq \pm 20\%$) and accuracy versus Elecsys (a deviation for 95% of the results less than 14 pmol/L in concentration range 7 – 27 pmol/L, less than 52% in concentration range 28 – 142 pmol/L and less than 61% in concentration range 143 – 1062 pmol/L)
- examine the variation between three lots of NT-proBNP test strips
- evaluate the user-friendliness of Cobas h 232 and the user manual

Materials and methods

The evaluation of NT-proBNP on Cobas h 232 was carried out without any specific quality goals set by SKUP. Heparinised venous whole blood samples from 107 hospitalised patients were measured on Cobas h 232 in the hospital laboratory. A total of 95 heparinised venous whole blood samples were tested in three primary health care centres (PHCC). Three lots of NT-proBNP test strips were used. All results from Cobas were compared with the routine method for quantitative determination of NT-proBNP in serum at the hospital laboratory (Elecsys proBNP-II method on Modular Analytics E170). All samples were handled according to the given information about NT-proBNP stability.

Results

- The repeatability CV was approximately 10% in the hospital laboratory and between 5% and 10% in PHCC. The achieved precision fulfils the manufacturer's specifications.
- In the hospital laboratory NT-proBNP on Cobas h 232 showed results in agreement with the comparison method. At the PHCC the Cobas results showed between 14% and 24% higher NT-proBNP results than the comparison method. The bias has so far not been explained. The manufacturer's specification for maximum bias versus the Elecsys proBNP method was not fulfilled for results from PHCC in the concentration range 66-250 pmol/L.
- 100% of the results obtained in the hospital laboratory and 94% of the results obtained by the PHCC were within the manufacturer's specifications for accuracy. The fraction of results inside deviation limits of $\pm 25\%$ were 75% and 58%, respectively.
- The three lots of test strips used in the evaluation seem to give similar results.
- The users were satisfied with the user manual. The time factors and quality control possibilities were assessed as intermediate. This was partly due to the 12 minutes analysis time, the storage conditions for the test strips (refrigerator) and the control material

(freezer). The operation facilities were assessed as both satisfactory and intermediate. The needle on the Cardiac pipette makes up a potential risk of injury. It is difficult to avoid air bubbles in the pipette.

- The fraction of technical errors was <2%.

Conclusion

It must be underlined that SKUP had no specific quality goals for this evaluation, and the performance was therefore compared to the manufacturer's specifications. The repeatability CV was between 5% and 10%, and fulfils the manufacturer's specifications ($CV \leq 15\%$). The results from the hospital laboratory were within the manufacturer's specifications for accuracy. PHCC achieved 94% within these specifications. It was discovered a bias of approximately +20% between the Cobas h 232 results with heparinised whole blood from PHCC and the results from the serum samples sent to the hospital laboratory. This bias was unexpected because the Cobas h 232 results (heparinised whole blood) from the hospital laboratory were in agreement with the comparison method. The response from the evaluation sites about the user-friendliness was acceptable.

Comments from the manufacturer

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