Eurolyser smart 700/340 C-reactive protein (CRP)

Summary of an evaluation under the direction of SKUP
Report SKUP/2013/92

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Background
The measurement of C-reactive protein (CRP) with the Eurolyser smart 700/340 instrument has previously been evaluated by SKUP (SKUP/2011/70*). That evaluation was performed in a hospital laboratory and included capillary samples and control materials. Since that evaluation, the lid on the cuvettes has been reconstructed to include a sample collector device. The supplier for Eurolyser in Denmark, HaemoMedtec, has requested this evaluation.

The aim of the evaluation was to
- examine the analytical quality of Eurolyser smart CRP when measuring venous whole blood samples in a hospital laboratory
- examine the analytical quality of Eurolyser smart CRP when measuring capillary blood samples at two primary health care centres
- evaluate the Eurolyser control material
- evaluate the user-friendliness of Eurolyser smart CRP at two primary health care centres

Materials and methods
Three Eurolyser smart instruments and three lots of Eurolyser test cuvettes were used. 100 venous whole blood EDTA patient samples in a hospital laboratory were included as well as capillary samples from 86 patients in two primary health care centres. In addition two levels of control materials were analysed.

Results
Capillary samples at two primary health care centres: A coefficient of variation (CV) <10,0% was obtained for capillary blood CRP concentrations ≥3,2 mg/L in both primary health care centres, n=62. For CRP concentrations <3,2 mg/L the CV was higher than 10%. (For the mean concentrations 4,4 – 9,0 – 34,1 and 38,6 mg/L the CV% was 15,4-8,3-8,6 and 8,3% and bias was −17%, −11,2%, −4,8% and –8,6%). 96,4% of the sample results fulfilled the quality goal of a deviation less than ±1mg/L or <26% from the comparison method.
Venous EDTA samples in a hospital laboratory: The CV and the upper confidence interval for CV were <10,0% in the range CRP 1,8 to 281 mg/L. The bias was negative for concentrations <16,7 mg/L and positive for higher concentrations. 98% of the results had a deviation less than ±1,0 mg/L or <26% from the comparison method.
User-friendliness: The quick manual, the time factors and the operation were rated as satisfactory by the four evaluators. All evaluators had difficulties with the *control material*, which had a CV <10,0% in the hospital laboratory evaluation and ≥20% in the two primary health care centres.
Technical errors: There were in total three technical errors.

Conclusion
The Eurolyser smart CRP fulfilled the quality goals for imprecision with venous EDTA whole blood samples in the hospital laboratory and with capillary CRP results above 3,2 mg/L in the primary health care centres. CRP concentrations <3,2 mg/L do not fulfil the quality goal. The quality goal for accuracy was fulfilled with venous EDTA samples in the hospital evaluation and with capillary samples at both primary health care centres.
User-friendliness: Both primary health care centres found the instrument easy to use. The control materials were not useful in the primary health care centres as the CV was ≥20%.
The fraction of technical errors: was less than 1,0%

Comments from Eurolyser
A letter with comments from Eurolyser is attached to the report.

The complete report is found at www.skup.nu.