Smart CRP

Summary of an evaluation under the direction of SKUP
Report SKUP/2011/70*

Background
The Eurolyser ***smart*** system (**S**ingle **M**ethode **A**utomated **R**eading **T**echnology) is a family of near- patient testing instruments which can be used for several different tests. This evaluation is about the Eurolyser *smart* 546 instrument together with the *smart* CRP test (*smart* CRP system) used for measuring the concentration of CRP in whole blood, serum or plasma. The system is primarily intended for use in primary health care. The system is based on kinetic determination of the concentration of CRP by turbidimetric measurement at 546 nm (or at 700 nm in other Eurolyser instruments) of the antigen-antibody reaction between antibodies to human CRP, bound to polystyrene particles, and CRP present in the sample.

The aim of the evaluation
- To get a measure of the analytical quality of the *smart* CRP system in the concentration interval of 2,0 to 302 mg/L achieved under standardised and optimal conditions in a hospital laboratory by an experienced laboratory technologist.
- To assess the achieved analytical quality with the quality goals specified by SKUP: Bias <±10%, repeatability <10 CV% and total error <±26%.
- To evaluate the user-friendliness when used in a hospital laboratory

To investigate the influence of haematocrit was not part of the protocol; however it was measured because hospitalised patients were used in order to get a wide range of CRP-concentrations.

Materials and methods
Bias and repeatability were calculated from the test results from 101 individuals tested with both capillary whole blood samples and venous samples (EDTA-whole blood) in duplicates. The designated comparison method was an immunoturbidimetric plasma method, using mouse monoclonal Anti-CRP antibodies. The agglutination was measured turbidimetrically in a Modular P instrument from Roche. To check the calibration of the comparison method the 1st international standard of human C-Reactive Protein 85/506 was used before and after the evaluation. The comparison method needed no adjustment.

Results
97% of the venous whole blood sample results >4,0 mg/L were within the total error goal while 84% of the capillary blood sample results were within the goal. With venous whole blood samples the bias goal was fulfilled for CRP >4 mg/L. With capillary whole blood samples the bias goal was not fulfilled. The repeatability of *smart* CRP system in the range 4,5 to 36 mg/L was lower in venous sample results (5 CV%) than in capillary blood sample results (10 CV%). The user-friendliness was satisfactory; however there were comments about how to prepare the sample in order to get the correct volume.

Conclusion
With venous whole blood samples the CRP results between 4,0 to 302 mg/L fulfilled the analytical quality goals specified by SKUP. With capillary whole blood samples the quality goal for bias was not fulfilled. The total error goal was fulfilled between 8 and 302 mg/L. The user-friendliness was assessed as satisfactory; however, there were comments about application of the sample. As the *smart* CRP system was evaluated in a hospital laboratory, it is so far unknown how the system performs under less standardised conditions in the primary health care.

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