i-CHROMA CRP

Summary of an evaluation under the direction of SKUP
Report SKUP/2008/61

Background
i-CHROMA™ CRP test is a Near Patient Testing system used for measuring the concentration of CRP in human blood, serum or EDTA-plasma. The system is primarily intended for use in the primary health care. The *i*-CHROMA system is based on quantitative immunoassay technology, which is capable of quantifying single or multiple analytes at the same time by measuring laser-induced epifluorescence on a test cassette.

The aim of the evaluation
- Get a measure of the analytical quality of *i*-CHROMA in the CRP-interval of 2.5 to 300 mg/L, achieved under standardised and optimal conditions in a hospital laboratory by an experienced laboratory technologist
- Evaluate the analytical quality of *i*-CHROMA in two Danish primary care centres
- Evaluate the user-friendliness when used in a hospital laboratory and in primary care

Materials and methods
Bias and repeatability were calculated from test results from 100 individuals tested with i-CROMA both with capillary and venous samples (EDTA plasma) in duplicates. After the analysing time was reduced from five to three minutes, an additional 100 samples were analysed in duplicates. The distribution of the measurements covered a CRP concentration range from 2.5 to 300 mg/L. The designated comparison method was an immunoturbidimetric method, using anti-CRP mouse monoclonal antibodies. The agglutination was measured turbidimetrically in a Modular P instrument from Roche. The WHO standard 85/506 was used before, during and after the evaluation to adjust for bias. After a satisfying evaluation in a hospital laboratory the supplier decided to test the system also in the primary health care.

Results
After the analysing time of i-CHROMA was changed to three minutes, 98% of the sample results were within a total error of ±26% from the comparison method results. The bias was less than ±10% in all levels. In the hospital the repeatability of *i*-CHROMA for both capillary and venous samples was 4-7%. In the primary care evaluation the repeatability was between 5,2% and 7,2% for capillary samples and 96% of the results had an acceptable deviation from the comparison method. The user-friendliness was satisfying. Both primary care centres mentioned that it was convenient to do the analysing in one step.

Conclusion
The analytical quality goals, with bias <10%, repeatability <10% and a deviation from comparison method <26%, were fulfilled in the hospital laboratory evaluation for both capillary and venous samples as well as in primary care for the capillary results. The user-friendliness was assessed as satisfying both in the hospital laboratory and in the primary care.