i-CHROMA/2011/90

Background
The *i*-CHROMA™ CRP test was evaluated by SKUP in 2008. Due to several product changes, SKUP performed a new evaluation of *i*-CHROMA™ CRP in 2009. In this second evaluation, the analytical quality goal for accuracy was not fulfilled with venous whole blood samples. With plasma samples the quality goal was fulfilled, despite a bias of -16,5%. The user-friendliness was assessed as satisfying. As a consequence of the results achieved in this second evaluation, the manufacturer adjusted the calibration of the method, and Medic24 applied for a third evaluation of the *i*-CHROMA system in 2010.

The aim of the evaluation
- To examine the imprecision of *i*-CHROMA achieved with whole blood samples, at least100 venous and at least100 capillary patient samples in a hospital laboratory
- To examine if the instrument measures equally correct at both low and high P—CRP concentrations.
- To compare the instrument with an established hospital laboratory method for P—CRP
- To examine the imprecision achieved with 40 patient samples in each of two primary health care centres
- To evaluate the user-friendliness of *i*-CHROMA in hospital laboratory and primary health care centres
- To examine the influence of hematocrit on the results from i-Chroma
- To evaluate the Medic24 control material

Materials and methods
Bias and repeatability of *i*-CHROMA were calculated from duplicate results. Venous whole blood samples and capillary samples from 100 individuals were examined in the hospital, and capillary samples from 80 patients were tested in primary health care centres. The selected comparison method was a Cobas Integra C-Reactive Protein (Latex) method from Roche, using serum as sample material. This immunoturbidi-metric method was operated according to the instructions from Roche using reagents, instrument, and calibrators from Roche. The results were adjusted with a factor (0,943) to be aligned with the Certified Reference Material (CRM) 470.

Results
114 samples (mean 54,8 mg/L, range 1,0-264 mg/L) were measured using four lots of *i*-CHROMA test strips. The results were compared to duplicate results from the comparison method. In the hospital evaluation, >95% of the *i*-CHROMA whole blood sample results, both capillary and venous, were within ±26% from the comparison method results. The bias was less than ±10% in all three concentration levels and the repeatability (CV) was 4,3% for capillary samples and 3,9% for venous samples. In the primary health care evaluation, only capillary samples were analysed in duplicates. In one primary health care centre the repeatability was 5,7% whereas it was 15,0% in the other. This means that the quality goal of <10% was fulfilled only in one of the primary health care centres. According to two of the evaluators the instrument is best suited for users with laboratory experience. The reproducibility achieved with control material was 3,1% in the hospital evaluation and 16% and 20% in the two primary health care centres, respectively.

Conclusion
In the hospital laboratory evaluation the analytical quality goals were fulfilled with both capillary and venous whole blood samples. One primary health care centre achieved the goal for repeatability while the other did not. The CV was 5,7% and 15%, respectively. Two of the evaluators mentioned, that the instrument might have some pitfalls for un-skilled users.

Comments from Medic24
A letter (attachment 8) with comments from Medic24 is attached to the report