

## Hemo\_Control haemoglobin measuring system

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### Summary of an evaluation organised by SKUP Report SKUP/2004/29

Hemo\_Control haemoglobin measuring system (Hemo\_Control) is intended for determination of the haemoglobin concentration in human blood. Hemo\_Control consists of an absorption photometer and microcuvettes that contain dried reagents. In the cuvette, haemoglobin is converted to azide methaemoglobin, a coloured product that is measured bichromatically in the photometer. The sample volume is 10 µL. The sample can be drawn directly into the Hemo\_Control Microcuvette from a capillary puncture. The cuvette is read directly in the Hemo\_Control Photometer. The measuring range is 0 – 256 g/L (0.00 – 15.89 mmol/L).

Hemo\_Control is manufactured by EKF-diagnostic GmbH in Germany. The evaluation was ordered by MEDimport AS in Norway. The first part of the evaluation was performed under standardised and optimal conditions by experienced laboratory technologists in a hospital laboratory in Sweden. The second part was performed under real life conditions by staff at two primary care centres in Norway. The analytical quality goal derived from biological variation was set to allow a total error of up to  $\pm 5\%$ .

#### Results

The within-series precision with venous EDTA samples in the hospital laboratory was good. The CV was around 1 %. When the imprecision was measured between days the CV figures did not increase. There was a small, but negligible, negative bias relative to the Comparison Method on Coulter LH 750. The total error was less than  $\pm 5\%$ . The results achieved in the hospital laboratory fulfil the analytical quality goal.

The precision with venous samples at the primary care centres was also good. The CV was 0.7 and 1.5 % respectively. There was a positive bias, but negligible small, relative to the Comparison Method. These results also fulfil the analytical quality goal with a total error of less than  $\pm 5\%$ .

Using capillary samples taken in the finger the imprecision was higher, as expected. At Centre B the imprecision was acceptable, with CV 2.8 %. At Centre A the imprecision was too high, with CV 5.5 %. The quality goal was therefore not attained with capillary samples. It is a complicating fact that the haemoglobin concentration in capillary blood is not representative for the haemoglobin concentrations in venous blood. These pre-analytical sources of error are not only valid for Hemo\_Control, but for all instruments using capillary samples for measuring B-Haemoglobin.

#### Practical points of view

All personnel involved in the evaluation summarised their opinion about the Hemo\_Control system as being quick and easy to use. They also thought the instrument was small and neat.

#### Conclusion

Hemo\_Control showed, when using venous samples, good precision and only small deviations from the results of the Comparison Method. The bias was small and negligible. The total error was less than  $\pm 5\%$ . The quality goal is attained with venous samples. The quality goal was not attained with capillary samples, mainly due to non-representative haemoglobin concentrations in capillary puncture blood and to poor precision. Acceptable precision can be obtained with skilful sample collection, but the non-representative concentrations appear impossible to avoid. These pre-analytical sources of error with capillary samples are valid not only for Hemo\_Control, but for all instruments measuring haemoglobin.

Hemo\_Control is quick and easy to use and well suited for the Primary health care.

The complete Hemo\_Control evaluation report is available at [www.SKUP.nu](http://www.SKUP.nu)