

DiaSpect Hemoglobin T System SKUP/2013/96

Background

DiaSpect Hemoglobin T System is intended for the determination of haemoglobin concentration in whole blood. The instrument uses a photometric method with compensation for turbidity. No reagents are involved. The system, manufactured by DiaSpect Medical GmbH, has been launched in many countries including Scandinavia.

The aim of the evaluation was to

- examine the imprecision of haemoglobin results measured with DiaSpect Hemoglobin T
- compare capillary and venous results in a hospital laboratory and in two primary health care centres with an established hospital laboratory method for haemoglobin (Sysmex XE-5000)
- evaluate the control materials for DiaSpect Hemoglobin T
- evaluate the user-friendliness of DiaSpect Hemoglobin T at two primary health care centres

Materials and methods

Four DiaSpect Hemoglobin T instruments and three lots of cuvettes were used. 102 patients from a hospital and 82 patients visiting two primary health care centres were included for capillary sampling. 222 venous samples and three levels of control material were also analysed.

Results

Capillary samples: At two primary health care centres the imprecision (CV) was between 3,0 and 3,9%. The results were inconclusive on fulfilling the quality goal $\leq 3,0\%$; most likely the quality goal was not fulfilled. 72% of the sample results fulfilled the quality specifications of $< \pm 5,0\%$ from the comparison method. When used in the hospital laboratory, the quality goal was 'fulfilled' for high, 'inconclusive most likely fulfilled' for medium and 'not fulfilled' for the low haemoglobin concentrations.

Venous samples: The quality goal for imprecision was fulfilled both when the instrument was used in the hospital laboratory (CV = 0,7%) and in the primary health care centres (CV = 0,7% and 0,9%). With samples stored less than 24 h the bias from the comparison method was $-2,0\%$ in the hospital laboratory and $-0,4$ to $+1,8\%$ at the two primary health care centres. In the hospital laboratory 95%, and at the primary care centres 98%, of the results from samples stored less than 24 hours were within the quality specifications for allowable deviation.

The control materials at three concentration levels showed a CV $\leq 1,0\%$.

User-friendliness: The manual, the time factors and the quality control were rated as satisfactory by both primary health care centres. One centre also rated 'operation' as satisfactory. The other centre was less satisfied because they had to use blood drop number four and five for the measurement.

Technical errors: There were in total three technical errors of 963 results.

Conclusion

Capillary samples: The quality specifications for imprecision was fulfilled for the capillary samples with high concentrations, but not for low concentrations in the hospital laboratory. In the primary health care the quality specifications for imprecision was most likely not fulfilled.

Venous samples: Results from samples stored less than 24 hours fulfilled the quality goals for precision and trueness, both in the hospital laboratory and in the two primary health care centres.

The control materials can be used as indicators of the function of the instruments.

User-friendliness: One primary health care centre was satisfied with the instrument. The other did not normally discard the first three drops of blood and found it difficult to use blood drop number four.

The percent of technical errors: was less than 1,0%.

Comments from the manufacturer

None