in2it, a system for measurement of B-haemoglobin A1c

Summary of an evaluation under the direction of SKUP
Report SKUP/2010/78

Conclusion
In the hospital laboratory: in2it fulfilled the quality goals for imprecision (<4 CV%) and total error of <±10% with both capillary and venous samples.
In the primary care centres: in2it fulfilled the goals for imprecision (<4 CV%) for the combination of one capillary and one venous samples and total error of <±10% in one centre. In the other primary care centre the imprecision CV was 5,2% and only 89,5% of the samples fulfilled a deviation less than ±10%.
The user friendliness was satisfying; however, there were unfavourable comments on too much noise, when the instrument was rotating the test cartridge.

Background
Bio-Rad turned to SKUP for an evaluation of in2it HbA1c in 2009. The testing was performed under optimal conditions in the Department of Clinical Biochemistry, Odense University Hospital and Hillerød Hospital. The end-users were represented by the two primary care centres Gribskov Lægecenter, Vejby and Noer-Hansen and Søndergård, Hillerød, both sending samples to Hillerød. The comparison method was Tosoh G8 in Odense and Tosoh G7 in Hillerød.

In2it has existed for several years; however it was improved during 2008.

The aim of the evaluation
- Determination of the imprecision with 100 venous and 40 capillary patient samples in a hospital laboratory
- Determination of the imprecision with 40 patient samples at two primary care centres. The duplicate measurement consisted of one capillary sample and on venous sample
- Comparison with the established Tosoh method for HbA1c. Determination of trueness and accuracy
- Evaluation of user-friendliness
- Investigation of possible interference of carbamide (urea) and haemolysis

Materials and methods
Four in2it instruments, four cartridge lots, and samples from 180 patients were tested.

Results
The quality goals, a total error of less than ±10% and a repeatability CV of less than 4,0% were fulfilled in the hospital laboratory evaluation and in one of the two primary care centres for venous and capillary samples. An imprecision CV of 3,1% was achieved with venous samples in the hospital and with venous and capillary samples in one primary care centre, while the CV for capillary samples in the hospital laboratory was 4,0%. In the other primary care centre only 89,5% of the samples fulfilled a deviation less than ±10% mainly because of an imprecision CV of 5,2 %. Additional testing revealed that the high imprecision probably was due to low level of buffer in the cartridges caused by leakage loss near the expiry date. The leakage could not be detected visually. An indicator of leakage might prevent this. The user friendliness was satisfying; however, it was mentioned that the instrument did make too much noise when running, and that the test cartridges consume space in the refrigerator. Interference test for haemolysis demonstrated that low grade of haemolysis does not interfere with the test.

Comments from Bio-Rad
A letter with comments from Bio-Rad, with a reply from SKUP, is attached to the report.

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