

Quo-Test SKUP/2012/91

Triolab, Denmark turned to SKUP for an evaluation of Quo-Test HbA1c in September 2010. The evaluation was performed in the Department of Clinical Biochemistry, Hillerød Hospital and in two primary health care centres in Farum and Birkerød, respectively in the period January to May 2011.

The aim of the evaluation

- To examine the repeatability, trueness and accuracy of Quo-Test in a hospital laboratory achieved with capillary and venous samples from 100 individuals
- To examine the repeatability, trueness and accuracy of Quo-Test in two primary health care centres achieved with capillary samples from 40 patients in each of the two centres
- To evaluate the performance of control materials on the Quo-Test instrument
- To evaluate the user-friendliness of Quo-Test in a hospital laboratory and in two primary health care centres

Materials and methods

Venous whole blood samples and capillary samples from 102 individuals were examined in the hospital. Capillary samples from 84 patients were tested in primary health care centres. Bias and repeatability of Quo-Test were calculated from duplicate results for three levels of HbA1c. Three lots of test cartridges were used. All HbA1c results in this evaluation are presented in DCCT % units.

Results

In both the hospital laboratory and in the two primary health care centres, for capillary as well as venous samples, 95% of the single results had a deviation of less than $\pm 10\%$ from the comparison method. For capillary samples, a bias within $\pm 4,0\%$ was reached in both hospital laboratory and primary health care centres. For the venous samples at the hospital laboratory the bias was within $\pm 4,0\%$ for HbA1c levels above 5,6%, and $-4,6\%$ for samples with lower HbA1c values.

At the hospital laboratory the repeatability varied between 2,0 and 5,2% for capillary samples and between 1,6% and 4,6% for venous samples. For capillary HbA1c levels above 5,6% and venous HbA1c levels above 6,8% the repeatability was less than 4,0%. At the two primary health care centres the repeatability varied between 3,3% and 5,1%. For HbA1c levels above 6,1% in one primary health care centre and above 4,7% in the other primary health care centre, the repeatability was less than 4,0%.

The percentage of technical errors was 2,2%.

The user-friendliness was satisfying, based on the manual and inserts, the time factors of both measurement and preparation, performing of internal and external quality control and for operational ease of use in both primary health care centres and hospital laboratory.

Conclusion

In the hospital laboratory: Quo-Test fulfilled the analytical quality goal for accuracy with both capillary and venous sample. The bias goal (within $\pm 4,0\%$) was fulfilled with capillary samples. For venous results below 5,6% the goal was not fulfilled, but above this level the trueness was satisfactory. The goal for repeatability was fulfilled with venous and capillary sample results above 5,6% and 6,8%, respectively. For HbA1c below these levels the goal for repeatability was not fulfilled.

In the primary health care centres: The quality goals for accuracy and bias were fulfilled in both centres. One primary healthcare centre fulfilled the goal of repeatability $< 4,0\text{ CV}\%$ for all samples; the other fulfilled the goal for HbA1c levels above 6,1%.

The error frequency was 2,2% and just above the goal of $\leq 2,0\%$.

The user-friendliness was satisfactory.

Comments from the requesting company

A letter with comments and additional information from the manufacturer is attached to the report.