The Quo-Test HbA1c analyzer; the right choice in a point-of-care setting

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Quo-Test vs 2 market leading competitors

The aim of this study was to compare different HbA1c POCT devices and established HbA1c laboratory methods. The advantage of POCT methods over traditional laboratory testing is the real-time estimation of the results, which enables a clinician to give patients their test results immediately during a single consultation. This type of testing has significant clinical implications for the patient, allowing them to take control of their disease management in a quicker and more effective manner.

The products

Competitor A - low-cost point-of-care instrument designed for rapid and reliable measurements of HbA1c as well as three other biomarkers. The analyzer uses boronate affinity reflectance technology with either capillary or venous blood.

Competitor B - simple and fast POC analyzer suitable for use with whole blood, plasma, serum and urine. The analyzer provides measurements of HbA1c as well as three other parameters based on boronate affinity chromatography methodology.

Quo-Test (EKF Diagnostics) - dedicated fully automated HbA1c analyzer that uses patented boronate fluorescence quenching technology. A 4µl sample taken from a finger prick or venous whole blood is required and results are available in four minutes.

The methodology

Each test was performed using EDTA treated whole blood samples provided with known HbA1c levels by a local medical laboratory (Dr. Heuchel, Saalfeld, Germany). Measurement of HbA1c levels in the laboratory by HPLC was performed using a Variant II (Bio-Rad Lab, Hercules, USA) under standard operating conditions. Levels of HbA1c were also determined immunologically in the laboratory using the HbA1c Beckman Coulter/AU480 (Beckman Coulter, USA), performed on site in parallel to the tests with the POCT systems.

HPLC analysis was carried out using 100 different EDTA blood samples ranging from 4.4 to 14.6% DCCT. The below table shows the coefficient of correlation and average difference (%DCCT) of each POCT device when compared to the HPLC laboratory method.

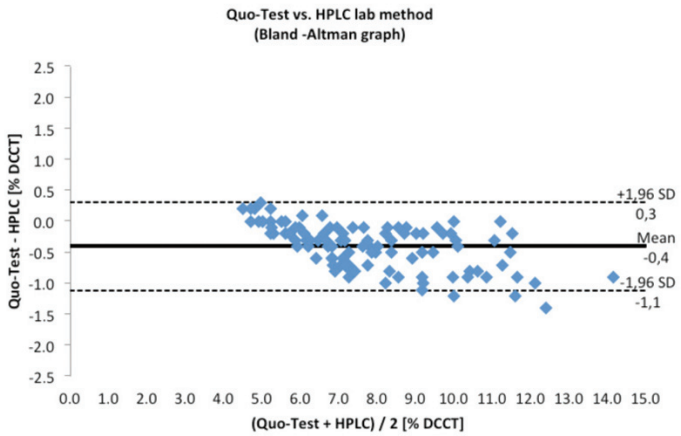
The results

Table.1 Summary of statistical data of the three POCT systems compared to the HPLC laboratory method.

POCT SYSTEM	COEFFICIENT OF CORRELATION (R)	AVERAGE DIFFERENCE (% DCCT)
Competitor A	0.9653	-0.3
Competitor B	0.9850	0.0
Quo-Test	0.9897	-0.4

The Bland-Altman graph in figure. 1 demonstrates the variation in calculated HbA1c level from the HPLC to the Quo-Test device.

Figure. 1 Comparison of Quo-Test with the HPLC laboratory method



It can be seen that both Competitor A and the Quo-Test compare well with 63% of results within 6% of the determined mean HPLC values and all results are within 12% of the HPLC values for the Quo-Test.

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Table. 2 System accuracy of the three POCT systems compared to the HPLC lab method

POCT SYSTEM	% OF RESULTS WITH RELATIVE DEVIATIONS TO THE HPLC LAB METHOD		
	within +6%	within +12%	within +18%
Competitor A	63/100 (63%)	92/100 (92%)	99/100 (99%)
Competitor B	73/100 (73%)	96/100 (96%)	99/100 (99%)
Quo-Test	63/100 (63%)	100/100 (100%)	100/100 (100%)

In addition to being tested against HPLC laboratory testing each device was also tested against a leading immunoassay large scale laboratory analyzer to assess how each compares in the estimation of HbA1c levels from whole blood samples.

As with the HPLC comparison, 100 different EDTA blood samples were assessed using the immunological laboratory method covering a range of 4.9 to 14.1% DCCT HbA1c.

Table. 3 Summary statistical data of the POCT systems compared to the immunological laboratory method

POCT SYSTEM	COEFFICIENT OF CORRELATION (R)	AVERAGE DIFFERENCE (% DCCT)
Competitor A	0.9645	-0.1
Competitor B	0.9891	+0.2
Quo-Test	0.9929	-0.2

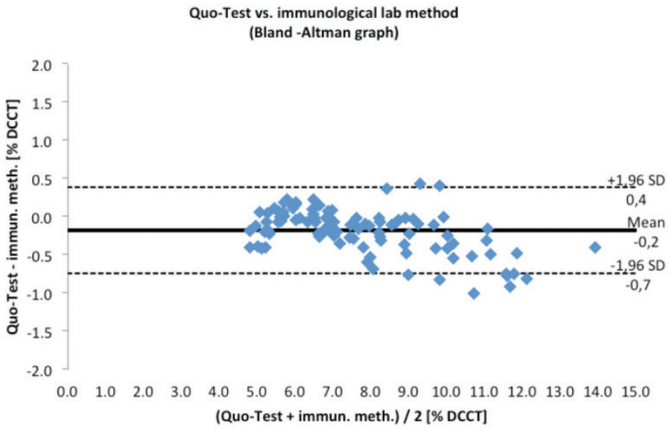

Figure. 3 Comparison Quo-Test with the immunological laboratory method (Bland-Altman graph)

Evaluation of repeatability of the three POCT methods was carried out using three EDTA blood samples at three different HbA1c concentrations (L1 to L3), with 20 repetitions for each concentration level.

Table 4 contains the single test results, as well as the averages in % DCCT, standard deviation (SD) in % DCCT and the coefficients of variations in %.

Table. 4 Summary of statistical data for within-run precision examination of HbA1c determination with four POCT systems

SYSTEM	COMPETITOR A			COMPETITOR B			QUO-TEST		
Test	L1	L2	L3	L1	L2	L3	L1	L2	L3
AVG	5.4	7.3	10.5	5.6	7.6	11.1	5.5	7.6	10.5
SD	0.12	0.14	0.17	0.16	0.12	0.18	0.10	0.11	0.12
% CV	2.2	1.9	1.6	2.8	1.6	1.6	1.9	1.5	1.2

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The discussion

Since POCT is often based in the clinical or primary care setting it is important that non-laboratory trained users can easily handle and correctly operate the analyzers. In Germany the requirements of the German Medical Association guidelines for quality assurance of laboratory medical tests must be fulfilled.

Competitor B and Quo-Test stood out as being the most suitable choice for a point-of-care setting given their ease of use, since they both use simple cassette-based technology.

All systems demonstrated satisfactory system accuracy. Except for two outliers (once each Competitor A and Competitor B) all systems show an accordance with both lab methods within a +18%-range. The maximum deviation of the Quo-Test compared to both laboratory methods is notably below 12%. The Quo-Test was, therefore, found to have the best agreement with the two laboratory methods.

The results of the intra-run precision examination demonstrate good repeatability for all the POCT systems. The coefficients of variation (CV) between 1.6 and 2.2% (Competitor A), 1.6 and 2.8% (Competitor B), 1.2 and 1.9 % (Quo-Test), display only marginal differences between all systems. Regarding the assessment of the precision between the days with control material, only data from five study days was collected with the POCT systems and four days with the laboratory methods. Within this short period all systems demonstrated CVs between 0.5 and 4.5% which represents satisfactory precision. All control test results were within the targets given by the manufacturer.

The Quo-Test system tends to report higher values at low concentrations, but within the maximum range of +12%, fulfilling the requirements of the guidelines of the German Medical Association.

The conclusion

In summary, it can be stated that all POCT systems meet the requirements of HbA1c determination in practice and those set by the German Medical Association. Competitor B and Quo-Test were particularly easy to use and represent the best choice for a point-of-care setting. Regarding analyzer accuracy, it was found that the best agreement with both laboratory methods was achieved when using the Quo-Test analyser.

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