Quo-Test A1c studies and evaluations

Title	Evaluation of the Quo-Test A1C Assay	Quo-Test A1c. A system for measurement of B-Hemoglobin A1c	The Quo-Test HbA1c analyzer; the right choice in a point-of-care setting	Assessment of Two Point of Care Analysers for Determination of HbA1c	An evaluation of the QuoTest performance against NGSP criteria and sigma-metrics
Date of publication	2009	2011	2013	2014	2016
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Organisation	John Radcliffe Hospital, Oxford, UK	SKUP, Denmark	Imcarmed GmbH, Germany	Diabetes Research Group, Swansea University, UK	European Laboratory for Glycohemoglobin, Isala, Zwolle, Netherlands
Comparator	Menarini HA-8160 affinity chromatography (HPLC method)	Tosoh G7 cation-exchange chromatography (HPLC method)	Bio-Rad Variant II cation-exchange chromatography (HPLC method) Beckman Coulter/AU480 (Immunoassay method) (Immunoassay method) Competitor A Boronate affinity reflectance (POC method) Competitor B Boronate affinity chromatography (POC method)	Biorad D10 cation-exchange chromatography (HPLC method)	Roche Tina-quant Gen.2 HbA1c on Integra 800 (Immunoassay method) Trinity Biotech Premier Hb9210, affinity chromatography (HPLC method) Tosoh G8, cation-exchange chromatography (HPLC method)
Method	Accuracy and bias	Accuracy, precision, bias and user-friendliness	Accuracy, precision, bias and user-friendliness	Accuracy, precision, bias and user-friendliness	Accuracy, precision, bias and Hb interferences
Results	**Accuracy/Bias** 0.987 coefficient of correlation with the HPLC lab method Bias (%A1c) -0.07 95% limits of agreement -0.71 to 0.56%	**Precision** *Hospital lab* 4.6-11.9% DCCT CV 3.6% *Primary care centres* 4.7-10.4% DCCT CV 3.4-4.3% **Accuracy/Bias** *Hospital lab (capillary blood)* 95% of the results were within allowable deviation ±10% with the HPLC lab method Bias 95% limits of agreement 4.6-11.9% DCCT -1.6% 5.0-10.4% DCCT -3.3 - +0.8 % *Primary care centres* 95% of the results were within allowable deviation ±10% with the HPLC lab method Bias 95% limits of agreement 5.0-10.4% DCCT -3.3 - +0.8 %	**Precision** Quo-Test intra-run precision CV 1.2-1.9% **Accuracy/Bias** 0.9897 coefficient of correlation with -0.4% DCCT average difference against the HPLC lab method. 0.9929 coefficient of correlation with -0.2% DCCT average difference against the immunological lab method.	**Precision** Quo-Test Intra-run precision 6.0% DCCT CV 1.0% 7.7% DCCT CV 5.3% 10.9% DCCT CV 1.6% **Accuracy/Bias** 0.9523 coefficient of correlation with -1 mmol/mol average difference against the HPLC lab method.	**Precision** CV in the EP-5 protocol at an HbA1c value of 49 mmol/mol is 2.2% in DCCT. CV in the EP-5 protocol at an HbA1c value of 75 mmol/mol. **Accuracy/Bias** The CVs of the duplicates in the EP-9 were well within the acceptable criteria. The mean bias compared with the mean of the SRMPs was well within the acceptable criteria of <2 mmol/mol. **Hb interference** No interference of the common Hb-variants HbAS, HbAC, HbAD, HbAE, HbAJ, elevated A2 (β-thalassemia) and HbF <8.6%.
Conclusion	The Quo-Test analyzer gave results which were substantially equivalent to the Menarini HA-8160 analyzer in accuracy and with no significant bias. The total error was within the exacting performance criteria of the National Glycohemoglobin Standardisation Program (NGSP).	The accuracy of the Quo-Test analysers was found to be within acceptable limits (95% within ±10%) across capillary and venous blood. The precision of the Quo-Test analyser was found to be above the quality goal with capillary blood and satisfactory for venous blood. The combined precision across both blood types was found to be within acceptable limits. The user-friendliness was satisfactory.	The best agreement with both laboratory methods was achieved when using the Quo-Test analyser. All the POCT systems met the requirements of HbA1c determination in practice and those set by the German Medical Association. Quo-Test was particularly easy to use and represents the best choice for a point-of-care setting.	Agreement between the POCT analyser with an established HPLC reference method was good across a wide range of HbA1c. Use of the Quo-Test POCT analysers provides a rapid, accurate and reproducible method of determination of HbA1c. There is benefit to being able to generate results immediately in the clinical setting, providing greater convenience to the patient.	The Quo-Test met the generally accepted performance criteria for HbA1c. The combined performance in sigma-metrics is very good, if the CVs of the duplicates are examined then it is apparent that one lot number has a sigma >6; this is a class-leading level of performance.
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