

Summary of the evaluation of Atellica DCA Analyzer and Atellica DCA HbA1c Reagent Cartridges

Manufacturer	Siemens Healthcare Diagnostics, Inc
Supplier in Denmark	Timik ApS
Supplier in Sweden	Timik AB
Supplier in Norway	Timik AS
Launched in Scandinavia	April 2024



Aim

To assess the analytical performance and user-friendliness of Haemoglobin A1c (HbA1c) measurements with the Atellica DCA HbA1c System performed by the intended users, i.e. experienced laboratory personnel and health care professionals in primary healthcare.

Performance specifications	Results	Conclusions
Repeatability CV $\leq 3,0$ % calculated per site, each with results divided into three concentration interval.	Hospital laboratory: Capillary samples 2,4 – 3,9 CV% Venous samples 1,9 – 5,0 CV%	Inconclusive (fulfilled in clinically relevant interval (39-59 mmol/mol))
	Primary health care centres (PHCCs): Capillary samples 1,9 – 6,0 CV% Venous samples 2,3 – 2,9 CV%	Inconclusive (fulfilled in clinically relevant interval (39-59 mmol/mol))
Accuracy ≥ 95 % of the results should be within $\pm 3,0$ mmol/mol from the results of the comparison method at HbA1c concentrations $< 35,3$ mmol/mol and within $\pm 8,5$ % at HbA1c concentrations $\geq 35,3$ mmol/mol	Hospital laboratory: Capillary samples 88 % Venous samples 89 %	Not fulfilled
	PHCCs: Capillary samples 84 % Venous samples 90 %	Not fulfilled
User-friendliness A total rating of "Satisfactory"	The user-friendliness was rated satisfactory.	Fulfilled

Additional information

Participants	Persons ≥ 18 years coming to the laboratory (n=102) or the PHCCs (n=91) for measurement of HbA1c.
Evaluated method	Atellica DCA HbA1c System on capillary and venous whole blood using three lots of reagent cartridges.
Comparison method	Tosoh Automated Glycohemoglobin Analyzer HLC-723G11 from Tosoh Corporation, Inc., in the department of Laboratory Medicine, Hospital of Västmanland, Västerås, Sweden. Method adjusted with reference materials.
Technical error	1,2 %. The SKUP recommendation of < 2 % was achieved.

A letter with comments from Siemens Healthineers is attached to the report.

Further information about the evaluation and the organisation of SKUP can be found on www.skup.org.

This summary is also published in Danish, Norwegian and Swedish at www.skup.org.