

A NEW POINT-OF-CARE ANALYZER FOR RAPID AND PRECISE DETERMINATION OF LIPID PROFILE AND HbA1c.

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Background. A portable whole-blood analyzer **cobas b 101** (Roche Diagnostics) for determination of full lipid profile (total cholesterol, HDL-cholesterol and triglyceride, LDL-cholesterol calculated by the Friedewald equation up to triglyceride 4.5 mmol/L) as well as glycated haemoglobin HbA1c reported in both DCCT (%), IFCC (mmol/mol) and estimated average glucose (eAG, mmol/L) units, was recently launched. Usable patient materials are <20 µL capillary as well as LiHep or EDTA anticoagulated whole-blood. Turnaround time is 5-6 minutes. We evaluated the analytical performance of this new point-of-care equipment.

Methods. 79 venous blood samples from as many unselected non-fasting out-patients were drawn for routine determination of lipid profile and HbA1c on the instruments Modular E170 (Roche Diagnostics) and Tosoh G8 (Tosoh Bioscience), respectively. Parallel EDTA test tube samples were drawn for **cobas b 101**. A single lotno. test cartridges was used for assaying lipid profile and HbA1c, respectively, within two hours of collection. The analyzer's analytical imprecision (CVa) was calculated from the differences in duplicate determinations. Deviation from perfect accuracy (bias) was assessed by direct comparison with the routine methods.

Results.

	Cholesterol	HDL	LDL	Triglyceride
Mean	5.1 mmol/L	1.3 mmol/L	3.0 mmol/L	1.7 mmol/L
Range	2.3-9.2 mmol/L	0.4-2.6 mmol/L	1.1-6.9 mmol/L	0.6-5.8 mmol/L
CVa	1.2%	2.4%	2.3%	1.2%
Bias	+ 5.0%	+ 0.2%	- 5.6%	+ 5.6%
	HbA1c DCCT	HbA1c IFCC	HbA1c eAG	
Mean	6.3%	45.0 mmol/mol	7.9 mmol/L	
Range	4.4% - 10.1%	25 - 85 mmol/mol	5.3 - 13.4 mmol/L	
CVa	1.3%	1.9%	1.8%	
Bias	No method comparison	- 2% in normal range (< 44 mmol/mol) +1.8% within abnormal range	No method comparison	

Conclusions. **cobas b 101** provides rapid, accurate and highly precise measurements of lipid profile and HbA1c. Slight biases in some settings were unimportant for clinically reliable use of **cobas b 101** at the point of patient care.