Evaluation of POC measuring systems for Glucose and HbA1c in the hands of the intended users – a Scandinavian cooperation

A. Stavelin[1], E. Eriksson Boija[2], C. Morken[1], D.K. Kur[3], G. Henriksen[3], A. Karlsson[2], S. Ekehaug[1], G. Gidske[1], S. Sandberg[1]

[1]Noklus, Haraldsplass Deaconess Hospital, Bergen, Norway, [2]Equalis AB, Uppsala, Sweden, [3]DEKS, Rigshospitalet Glostrup, Denmark

BACKGROUND – AIM

Scandinavian evaluation of laboratory equipment for point of care testing (SKUP) is a cooperation between Equalis (Sweden), DEKS (Denmark) and Noklus (Norway). SKUP provides objective and supplier-independent information about analytical quality and user-friendliness of point-of-care (POC) measuring systems. The reports are valuable tools when selecting fit-for-purpose POC equipment. We present here an overview of the performance of ten POC glucose and five POC HbA1c measuring systems when operated by the intended users.

METHODS

The evaluations were conducted according to a standard protocol, both by experienced lab personnel and under real-life conditions; the measurements on the POC systems for self-monitoring of blood glucose (SMBG) were conducted by lay persons with diabetes, whereas the POC HbA1c measurements were performed in primary healthcare. Native samples from 100 (glucose) and 180 (HbA1c) patients were analysed in each evaluation, and the POC results were compared with a selected comparison method. The POC measuring systems were assessed against pre-defined analytical performance specifications (APSs) for imprecision and accuracy. The user-friendliness was assessed by the intended users, persons with diabetes and healthcare personnel, respectively.

RESULTS

Table 1. Results overview of **SMBG** evaluated against the updated APSs (ISO 15197:2013) and the previous APSs (ISO 15197:2003).

Evaluated against updated APSs

SMBG system	Manufacturer	SKUP evaluation	Measurements performed by	Fulfilling APS for imprecision	Fulfilling APS for accuracy	User-friendliness
Actiste	Brighter AB	2021/120	BLSs	No	No	Unsatisfactory
			People with diabetes	No	No	
Accu-Chek Instant	Roche Diagnostics	2017/113	BLSs	Yes	Yes	Satisfactory
			People with diabetes	No	Yes	
Accu-Chek Guide	Roche Diagnostics	2017/112	BLSs	Yes	Yes	Satisfactory
			People with diabetes	Yes	Yes	
Accu-Chek Aviva	Roche Diagnostics	2014/105	BLSs	Yes	Yes	Satisfactory
			People with diabetes	Inconclusive	Yes	
mylife Unio	Bionime Corporation	2013/100	BLSs	Yes	Yes	Satisfactory
			People with diabetes	Yes	Yes	

Evaluated against previous APS

SMBG system	Manufacturer	SKUP evaluation	Measurements performed by	Fulfilling APS for imprecision	Fulfilling APS for accuracy	User-friendliness
Accu-Chek Mobile	Roche Diagnostics	2013/99**	BLSs	Yes	Yes	Evaluated in SKUP/2009/74
Mendor Discreet	Mendor Oy	2012/95	BLSs	Yes	Yes	Inconclusive
			People with diabetes	Inconclusive	Yes	
Contour XT	Bayer Healthcare	2012/94	BLSs	Yes	Yes	Satisfactory
			People with diabetes	Yes	Yes	
Accu-Chek Performa	Roche Diagnostics	2011/93[3]	BLSs	Yes	Yes	Satisfactory
OneTouch Verio	LifeScan, Johnson & Johnson	2011/86	BLSs	Yes	Yes	Inconclusive
			People with diabetes	Yes	Yes	

Table 2. Results overview of **POC HbA1c** evaluated against various APSs. Note that the results are not directly comparable between all evaluations as the APSs have been updated over the years.

HbA1c system	Manufacturer	SKUP evaluation	Measurements performed by	Fulfilling APS for imprecision	Fulfilling APS for accuracy	User-friendliness
Atellica DCA	Siemens Healthcare Diagnostics, Inc.	2025/121	BLSs	Inconclusive	No	Satisfactory
			Personnel in PHCC	Inconclusive	No	
cobas b 101 HbA1c	Roche Diagnostics	2022/129	Personnel in PHCC	Yes	No	Inconclusive
Afinion 2 Analyzer HbA1c	Abbott Diagnostics Technologies	2021/126	BLSs	Yes	Yes	Satisfactory
			Personnel in PHCC	Yes	Yes	
cobas b 101 HbA1c	Roche Diagnostics	2020/117	BLSs	Inconclusive	No	Satisfactory
			Personnel in PHCC	Yes	No	
InnovaStar analyzer	DiaSys Diagnostic Systems	2014/101	BLSs	Yes	No	Satisfactory
			Personnel in PHCC	Inconclusive	No	
Quo-Test A1c	Quotient Diagnostics Ltd	2012/91	BLSs	Inconclusive	Yes	Satisfactory
			Personnel in PHCC	Inconclusive	Yes	

BLS; Biomedical Laboratory Scientist, PHCC; Primary Health Care Centre,
SMBG; Self-monitoring of blood glucose, APS; Analytical Performance Specification

Glucose:
Of the ten SMBG, only Actiste did not fulfill the APSs for imprecision and accuracy. Actiste was also the only system rated as unsatisfactory on user-friendliness, while no clear conclusion could be reached for Mendor Discreet and OneTouch Verio.

HbA1c:
Of the five POC systems, only the Afinion 2 Analyzer fulfilled the APSs for both imprecision and accuracy. Atellica DCA, cobas b 101 HbA1c and InnovaStar Analyzer did not meet the accuracy criterion, whereas Quo-Test was inconclusive for imprecision. All POC systems were rated satisfactory on user-friendliness, except cobas b 101 where it was difficult to reach a conclusion.

CONCLUSION – WHY SKUP IS IMPORTANT

SKUP performs comprehensive evaluations of POC measuring systems under real-life conditions. The reports are valuable tools in selecting the appropriate equipment and can thus contribute to improved patient care.

Contact information:

anne.stavelin@noklus.no

For more results, see

www.skup.org