LETTER TO THE EDITOR

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Accuracy Evaluation of GlucoLAB Auto-coding and Finetest Lite Glucose Monitoring Systems Following ISO 15197:2013

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There are several evaluating standards for blood glucose monitoring systems (BGMSs) according to ISO 15197:2013. Amongst the standards, system accuracy is a major aspect to be considered. The international standard ISO 15197:2013 defines system accuracy as the respective comparison of blood glucose (BG) results obtained with a BGMS and reference analyser with a relevant error range [1]. In addition, such standards states procedures and criteria for the evaluation of system accuracy. In the present study, the system accuracy of two BGMSs (GlucoLAB Auto-coding and Finetest Lite: Infopia Co. Ltd., Anyang, Korea), each with three reagent system lots, was evaluated following ISO 15197:2013. GlucoLAB Auto-coding and Finetest Lite are well-established BGMSs available on the European market since 2011 and 2015, respectively. Both systems were procured from the manufacturer.

The study was performed in December 2015 and March 2016 at the Endocrine Division, Hanil General Hospital, Seoul, Korea. The study was conducted with institutional review board approval (KMC-2015-ME-003,004). This study followed the international standards regulated by ISO 15197:2013 to verify the accuracy. Precision of the two BGMSs was evaluated using five samples of venous blood from each glucose concentration interval specified following ISO 15197:2013. Results for the CV (%) fell within the range of 1.9 to 4.9% (Table 1). System accuracy was evaluated with three reagent system lots from capillary blood samples of 100 different subjects. Two hundred microliters of capillary blood was collected from the fingertips of each subject in lithium heparin tubes. Duplicate measurements of blood samples were performed for each reagent system lot of a BGMS and the collected capillary blood was immediately centrifuged

at 3,500 rpm for 5 minutes. Centrifuged capillary plasma was measured in duplicate with a reference method using Glucose Oxidase-based YSI 2300 STAT PLUS (YSI Life Sciences, Yellow Springs, OH, USA). Respective mean YSI 2300 STAT PLUS results were considered as the reference glucose values. Accuracy and precision of the

YSI 2300 STAT PLUS results were verified during the test procedures [2]. For this purpose, regular internal and external quality control measures were performed as recommended in the manufacturer's manual.

The BGMSs fulfilled the accuracy criteria of ISO 15197:2013, which states at least 95% of the results

Table 1. Precision of GlucoLAB Auto-coding and Finetest Lite

ISO 15197:2013 requirement (mg/dL)	Mean (mg/dL)	Repeatability precision (CV %)					
		GlucoLAB Auto-coding			Finetest Lite		
		Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
30 to 50	38.8	4.9	3.8	4.1	4.8	4.5	4.6
51 to 110	86.8	2.3	2.9	2.2	2.3	2.1	1.9
111 to 150	149.5	2.3	2.0	2.2	2.3	2.6	3.2
151 to 250	215.9	2.4	2.7	2.3	2.4	2.2	2.3
251 to 400	352.0	2.1	2.2	1.9	1.9	2.2	2.3

Table 2. System accuracy between GlucoLAB Auto-coding, Finetest Lite BG monitoring systems, and YSI 2300 STAT PLUS Auto analyser (N=200)

BG system	Strip lot	ISO 15197:2013	BG concentration <100 mg/dL			BG concentration ≥100 mg/dL		
			Within±15 mg/dL	Within±10 mg/dL	Within±5 mg/dL	Within±15%	Within±10%	Within±5%
GlucoLAB Auto-coding	Lot 1	200 (99.0)	100.0	94.8	62.1	98.6	89.4	56.3
	Lot 2	200 (98.5)	100.0	98.3	72.4	97.9	89.4	58.5
	Lot 3	200 (98.5)	100.0	96.6	67.2	97.9	82.4	52.8
Finetest Lite	Lot 1	200 (100.0)	100.0	100.0	82.7	100.0	83.8	54.7
	Lot 2	200 (99.0)	100.0	100.0	71.2	98.6	84.5	49.3
	Lot 3	200 (97.0)	98.1	92.3	44.2	96.6	72.3	35.8

Values are presented as number (%) or %.

Abbreviation: BG, blood glucose.

Table 3. Consensus error grid analysis of glucose levels measured by GlucoLAB Auto-coding and Finetest Lite BG monitoring system against YSI 2300 STAT PLUS Auto analyser (N=200)

BG system	Strip lot	Consensus error grid zone				
		Zone A	Zone B	Zone C	Zone D	Zone E
GlucoLAB Auto-coding	Lot 1	200/200 (100.0)	0/200 (0)	0/200 (0)	0/200 (0)	0/200 (0)
	Lot 2	198/200 (99.0)	2/200 (1.0)	0/200 (0)	0/200 (0)	0/200 (0)
	Lot 3	199/200 (99.5)	1/200 (0.5)	0/200 (0)	0/200 (0)	0/200 (0)
Finetest Lite	Lot 1	200/200 (100.0)	0/200 (0)	0/200 (0)	0/200 (0)	0/200 (0)
	Lot 2	200/200 (100.0)	0/200 (0)	0/200 (0)	0/200 (0)	0/200 (0)
	Lot 3	200/200 (100.0)	0/200 (0)	0/200 (0)	0/200 (0)	0/200 (0)

Values are presented as number (%).

Abbreviation: BG, blood glucose.

Fig. 1. System accuracy of three lots of two BG monitoring systems. Absolute differences between the BG concentration results measured with the systems and the respective comparison values measured with YSI 2300 STAT PLUS (200 data, duplicate measurements on a sample with each test strip lot) are shown. Solid lines indicate the limits stipulated in ISO 15197:2013. (A) GlucoLAB Auto-coding lot 1. (B) Finetest Lite lot 1. (C) GlucoLAB Auto-coding lot 2. (D) Finetest Lite lot 2. (E) GlucoLAB Auto-coding lot 3. (F) Finetest Lite lot 3. Abbreviation: BG, blood glucose.

Fig. 2. Consensus error grid analysis of capillary blood glucose results. Each specimen was measured in duplicate by each method. Zone A, clinically accurate (no effect on clinical action); Zone B, clinically acceptable (altered clinical action-little or no effect on clinical outcome); Zone C, altered clinical action-likely to affect clinical outcome; Zone D, altered clinical action-could have significant medical risk; and Zone E, altered clinical action-could have dangerous consequences. (A) GlucoLAB Auto-coding lot 1. (B) Finetest Lite lot 1. (C) GlucoLAB Auto-coding lot 2. (D) Finetest Lite lot 2. (E) GlucoLAB Auto-coding lot 3. (F) Finetest Lite lot 3.

should be within ± 15 mg/dL of the reference glucose values at BG concentration < 100 mg/dL and within $\pm 15\%$ at BG concentrations ≥ 100 mg/dL (for each individual test strip lot), and at least 99% of the results of all three lots together were within zones A and B of the consensus error grid.

For BG values < 100 mg/dL, the GlucoLAB Auto-coding system showed 100% of the results within ± 15 mg/dL and 94.8%–98.3% within ± 10 mg/dL. Finetest Lite showed 98.1%–100% within ± 15 mg/dL and 92.3%–100% within ± 10 mg/dL. At BG concentrations ≥ 100 mg/dL, 97.9%–98.6% of the values measured with the GlucoLAB Auto-coding system were within $\pm 15\%$ and 82.4%–89.4% were within $\pm 10\%$. For Finetest Lite, 96.6%–100% were within $\pm 15\%$ and 72.3%–84.5% were within $\pm 10\%$ in these BG concentrations. Considering all BG concentrations, 98.5%–99% of the GlucoLAB Auto-coding system results and 97%–100% of the Finetest Lite results were within the limits (Table 2, Fig. 1). For both systems, 100% of the values were within zones A and B of the consensus error grid (Table 3, Fig. 2).

In this study, GlucoLAB Auto-coding and Finetest Lite fulfilled the system accuracy criteria of ISO 15197:2013

when evaluated against a glucose oxidase-based reference method. GlucoLAB Auto-coding and Finetest Lite BGMSs provided reliable results and satisfied the ISO 15197:2013 accuracy criteria.

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ISO 15197:2013 지침에 따른 자가혈당측정기 GlucoLAB Auto-coding과 Finetest Lite의 시스템 정확도 성능평가

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