



Report Finale

Valutazione dell'Accuratezza di GLUCOCARD™ **SM**

Riferimento ISO 15197:2013 § 6.3
Valutazione dell'Accuratezza del Sistema



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Study Site / Investigator /Laboratory

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Aim

The aim of the present study was to evaluate the clinical accuracy of the new **GLUCOCARD™ SM** SMBG system (hereinafter "**SM**").

The accuracy evaluation was performed referring to the norm EN ISO 15197:2013.

Material & Methods

A number of 600 glucose measurements on capillary and venous blood samples were performed using the **SM** system. Measurements were performed using three different lots of sensors (i.e. 200 measurements per lot).

Fresh capillary whole blood samples were obtained directly from finger-pricks of different subjects, i.e. patients undergoing the oral glucose tolerance test and the previous relative SMBG control.

In order to achieve a significant number of measurements in the hypoglycemic (<70 mg/dL) and hyperglycemic ranges (>180 mg/dL), and thus to ensure a wide distribution of glucose concentration values, a certain number of determinations were performed using manipulated heparinised venous blood: samples were supplemented with glucose for achieving high glucose levels, while glucose in venous samples was deliberately depleted for achieving low glucose values.

These measurements were performed within the temperature range 21°C - 23°C.

The strips lots used for the present study were the following:

- GLUCOCARD™ SM Test Strips:
 - lot **SAM060030-A** (lot #A), expiry date 2017-01
 - lot **SAM060030-B** (lot #B), expiry date 2017-01
 - lot **SAM060030-C** (lot #C), expiry date 2017-01

The S/N of the meters used in the present study were the following:

- GLUCOCARD™ SM meters:
 - EAM250000114, EAM250000116 (used with lot #A);
 - EAM250000115, EAM250000120 (used with lot #B);
 - EAM250000113, EAM250000112 (used with lot #C);

The measurement results obtained with the investigated system were then compared with those obtained with a reference method: COBAS c-501, Roche Diagnostics ("GLUC3", Hexokinase).

Accuracy was evaluated referring to the requirements reported in EN ISO 15197:2013¹:

- a. 95% of individual glucose results shall fall within ± 15 mg/dL of the results of the manufacturer's measurement procedure at glucose concentrations < 100 mg/dL, and within ± 15 % at glucose concentrations ≥ 100 mg/dL.
- b. 99% of individual glucose results shall fall within zones A and B of the Consensus Error Grid².

¹ EN ISO 15197:2014 In vitro diagnostics test systems – Requirements for bloodglucose monitoring systems for self-testing in managing diabetes mellitus, paragraph 6.3 (System accuracy).

² Parkes JL, Slatin SL, Pardo S, Ginsberg BH. *A New Consensus Error Grid to Evaluate the Clinical Significance of Inaccuracies in the Measurement of Blood Glucose*. Diabetes Care. 2000; 23:1143-1148.

Results & Discussions

The accuracy of the **SM** system was evaluated through the following analyses:

- Bias Plot (Bland-Altman), referring to EN ISO 15197:2013 requirements
- Consensus Error Grid (Parkes), as required by EN ISO 15197:2013

The Consensus Error Grid and the Bias Plots are reported in Fig.1-4.

GLUCOCARD™ SM – Lot #A – EN ISO 15197:2013

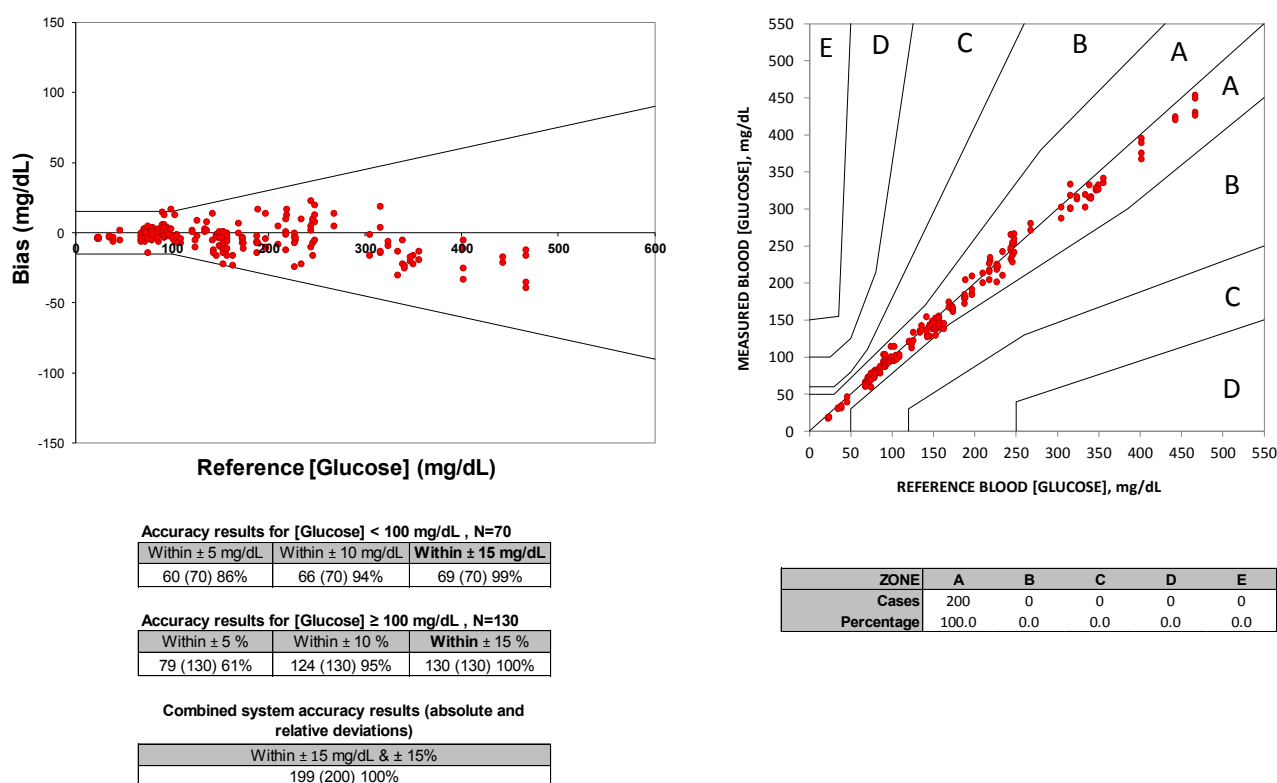


Figure 1 – GLUCOCARD™ SM, lot #A. On the left: Bias Plot graph and the relative summary table. On the right: Consensus Error Grid graph and the relative summary table.

Clinical Accuracy Evaluation of GLUCOCARD™ SM

GLUCOCARD™ SM – Lot #B – EN ISO 15197:2013

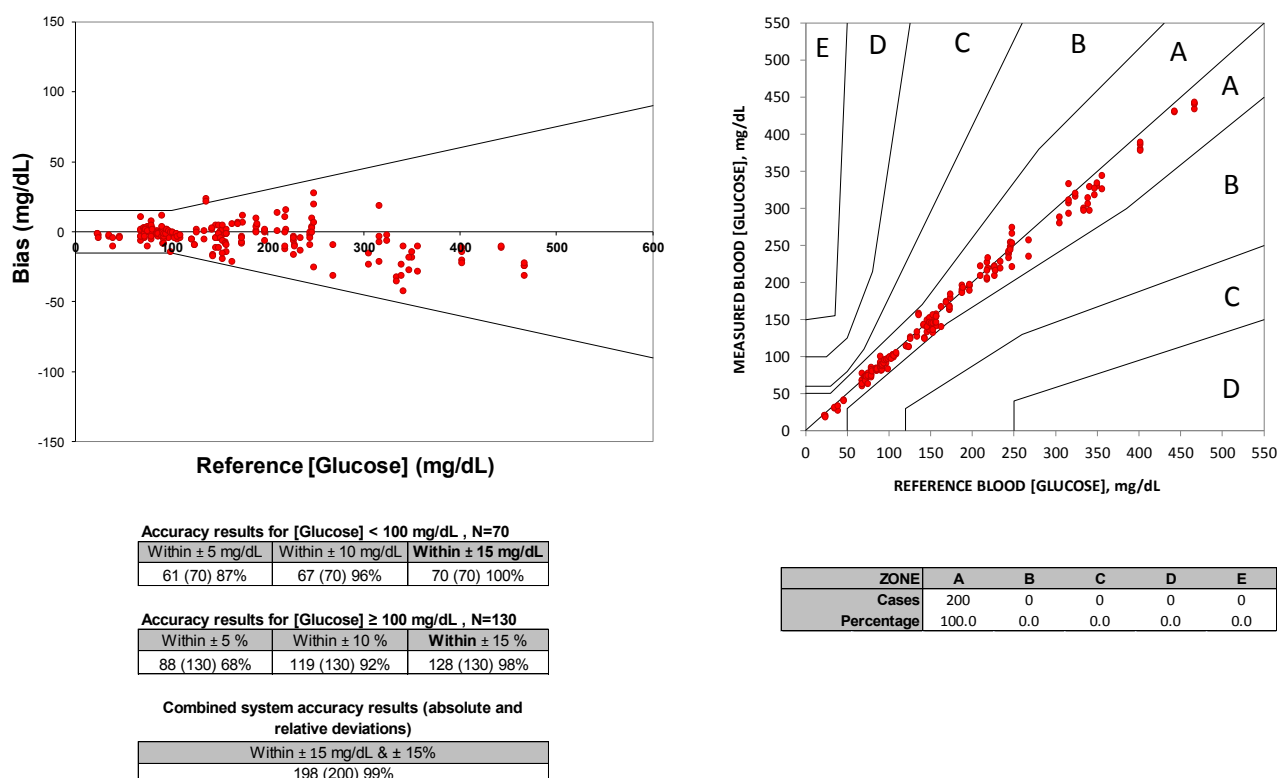


Figure 2 - GLUCOCARD™ SM, lot #B. On the left: Bias Plot graph and the relative summary table. On the right: Consensus Error Grid graph and the relative summary table.

GLUCOCARD™ SM – Lot #C – EN ISO 15197:2013

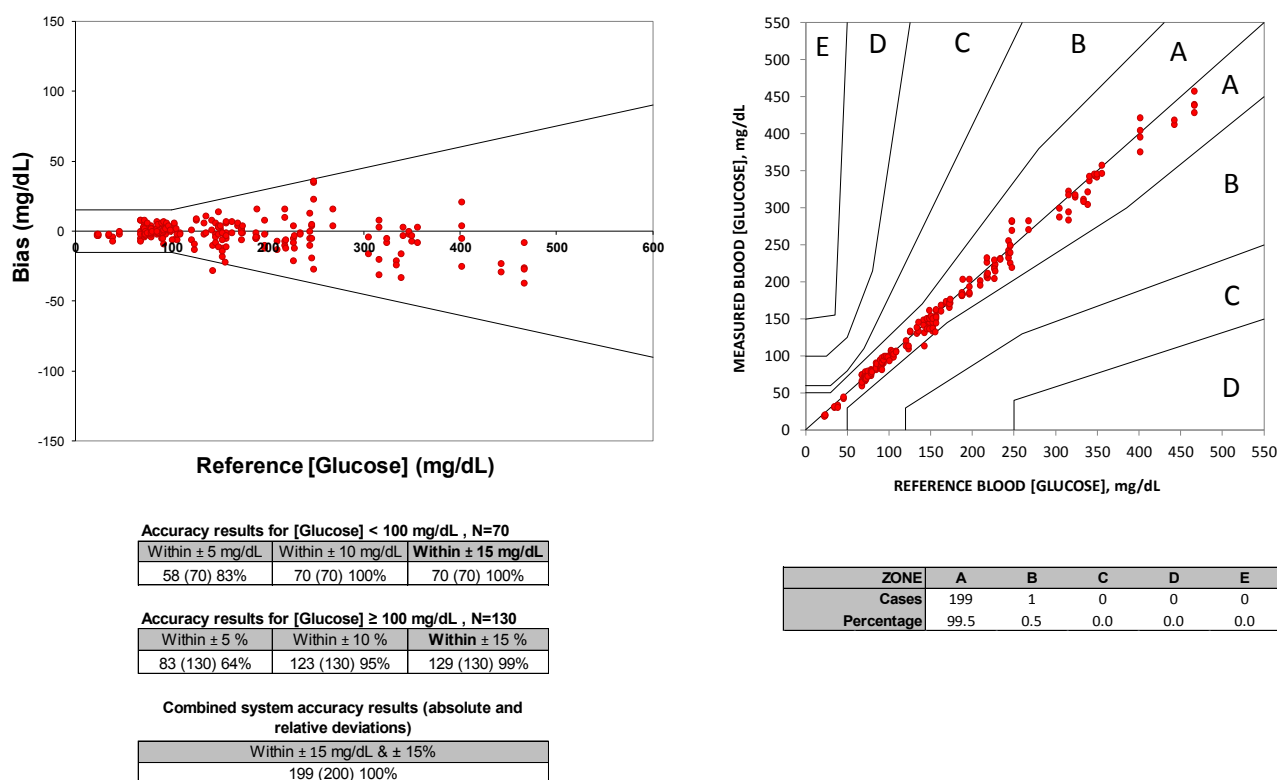


Figure 3 - GLUCOCARD™ SM, lot #C. On the left: Bias Plot graph and the relative summary table. On the right: Consensus Error Grid graph and the relative summary table.

GLUCOCARD™ SM – All Lots – EN ISO 15197:2013

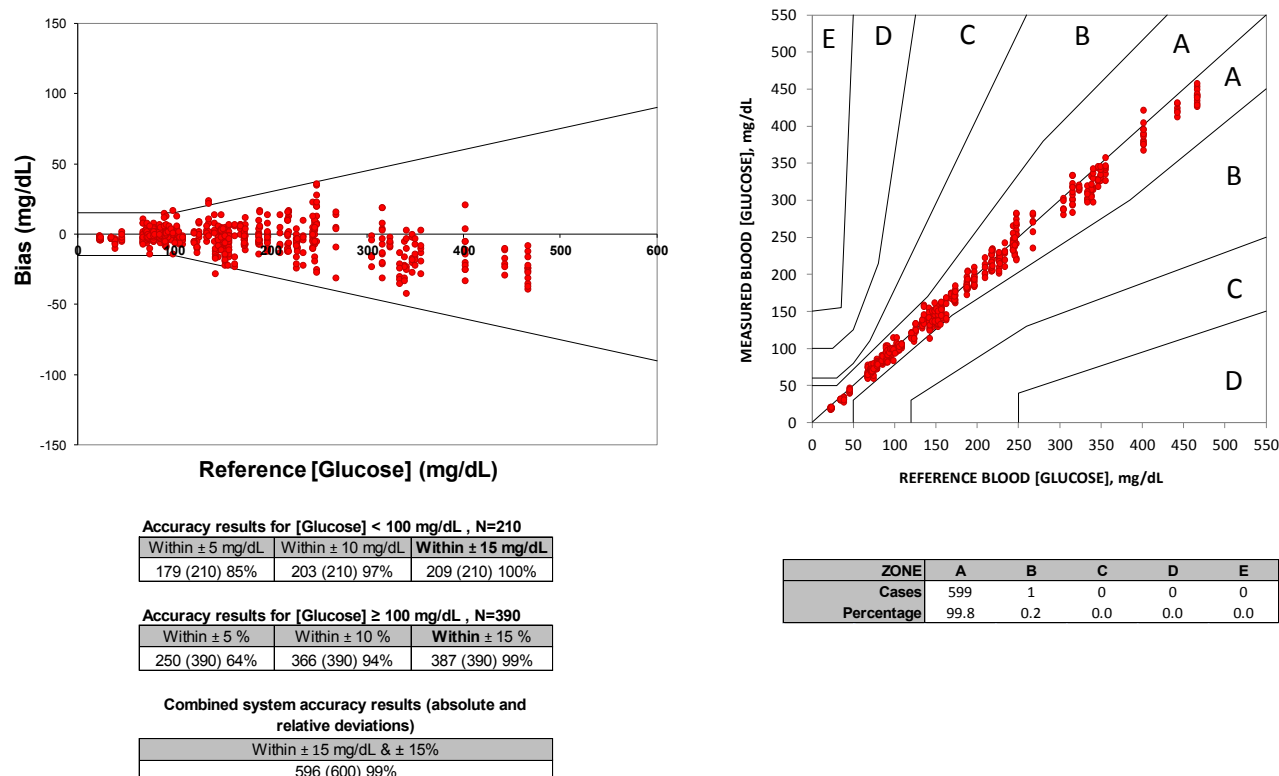


Figure 4 - GLUCOCARD™ SM, All lots. On the left: Bias Plot graph and the relative summary table. On the right: Consensus Error Grid graph and the relative summary table.

Conclusions

The **GLUCOCARD™ SM** system resulted to be highly accurate in glucose measurement and compliant with EN ISO 15197:2013.

All the strips lots tested resulted to be compliant with both Bias Plot and Consensus Error Grid accuracy requirements.

Investigator:

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