

# Precision and agreement of 266 strip-based glucose meters without the involvement of the laboratory medicine

Pedro Louzao, Lydia Pascual, Paloma Oliver, Maria Jose Alcaide, Pilar Fernandez-Calle, Antonio Buno

## Background:

Glucose meters are widely used in a variety of healthcare settings as Point-of-Care Testing (POCT) for the management of hypo and hyperglycemic disorders. However, laboratory medicine is not always involved in managing this POCT activity. Internal quality control (IQC) is a component of quality assurance which checks that patients' results are reliable before running blood samples.

In this study we evaluated the precision and agreement of many glucose meters used in different care settings at our institution when IQC is not performed routinely. This is one of the preliminary steps performed in our hospital before leading a POCT project for glucose meters.

## Material and Methods:

266 glucose meters (Accu-Chek Performa; Roche Diagnostics) were included in the study from 84 different healthcare settings in a 1,300 beds hospital. Two liquid glucose control material solutions were used with low and high glucose levels, 45 and 299 mg/dL respectively. Both levels were measured in duplicate in order to assess the precision of each device (Coefficient of variation; CV%). Test strips that were in use in each setting were utilized. Analyses were performed by three staff from the laboratory. The analytical goal for CV was 5% according to ADA criteria. Also we evaluated the agreement for all devices considering average  $\pm$  2SD (Standard deviation) for each control level.

## Results:

	Glucose meters with CV>5% n (%)	Highest CV (%)	Glucose meters with result> $\pm$ 2SD n (%)	Lowest/Highest glucose concentration (mg/dL)
Low level	12 (4.5)	25	9 (3.4)	40/66
High level	5 (1.9)	11	27 (10.2)	264/343

A total of 17 (6.4%) glucose meters showed a CV>5%, being the highest CV 25%. Regarding the agreement, we observed 34 (12.8%) glucose meters with result> $\pm$ 2SD. The difference between the highest and lowest result was x1.65 and x1.3 fold for low and high level respectively.

## Conclusions:

A relevant percentage of glucose meters did not fulfill the requirement of the precision study established by ADA. In the agreement study, particularly at high level of glucose, we also observed a large percentage of devices with results outside the acceptance limits. The range of the results obtained for each studied level varies significantly.

In our opinion, this study evidence that POCT must be led by laboratory medicine and a quality assurance program including QC management and operator's training should be established for these tests.