

Analytic Evaluation of a New Glucose Meter System in 15 Different Critical Care Settings

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Abstract

Background:

Maintaining appropriate glycemic control in critically ill patients reduces morbidity and mortality. The use of point-of-care (POC) glucose devices is necessary to obtain rapid results at the patient's bedside. However, the devices should be thoroughly tested in the intended population before implementation. The use of POC glucose meters in critically ill patients has been questioned both in the literature and by regulatory agencies. The aim of this study was to determine if the ACCU-CHEK® Inform II system (Roche Diagnostics) POC glucose meter demonstrated the desired accuracy and precision, as defined by Clinical and Laboratory Standards Institute guideline POCT12-A3, in a large number of critically ill patients from multiple intensive care settings at two academic medical centers.

Methods:

A total of 1200 whole blood meter results from 600 patients were compared with central laboratory plasma values. Whole blood aliquots from venous samples were used to obtain duplicate meter results with the remaining sample being processed to obtain plasma for central laboratory testing within 5 min of meter testing.

Results:

A total of 1185 (98.8%) of the new meter's glucose values were within $\pm 12.5\%$ (± 12 mg/dl for values ≥ 100 mg/dl) of the comparative laboratory glucose values, and 1198 (99.8%) were within $\pm 20\%$ (± 20 mg/dl for values < 100 mg/dl).

Conclusions:

Considering the large number of patients from numerous critical care units examined, the new glucose meter system appears to have sufficient analytic accuracy for use in critically ill patients.

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Abbreviations: (ED) emergency department, (FDA) Food and Drug Administration, (ICU) intensive care unit, (NICE-SUGAR) Normoglycemia in Intensive Care Evaluation–Survival Using Glucose Algorithm, (POC) point of care, (TGC) tight glycemic control, (UVA) University of Virginia, (WU) Washington University

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