

Multi-Site Evaluation of Three Blood Glucose Measurement Systems.

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Background: Blood glucose measurement systems are essential for the treatment and management of hospitalized patients' glycemic state. Hospitalized patients present challenges to many glucose meters used in the hospitals and this can lead to poor analytical performance and potential adverse events.

Objective: Evaluate the analytical performance of Nova Statstrip, Roche Accu-Chek Inform I, and Abbott Precision Xceed Pro for the use with adult and pediatric population in a 25 hospital system.

Method: The performance of Nova Statstrip, Roche Accu-Chek Inform I, and Abbott Precision Xceed Pro were compared to the Siemens Vista 1500 central lab analyzer. Both within-run and between-run imprecision was evaluated using 2 levels of QC material and 2 lot numbers of test strips. 131 adult venous samples were collected at two different sites. 21 Adult fingerstick samples were collected in an Intensive Care Unit at a third site. 33 pediatric capillary sample were collected from a nursery unit at a fourth site. All patient samples were tested within 60 minutes of collection. The meters were also evaluated for hematocrit bias and interferences from acetaminophen, ascorbic acid, maltose, and galactose. The CLSI POCT 12A3 criteria were used for evaluation.

Results: Within-run imprecision study results for the three meters were (2.9%-3.4%) for Nova Statstrip, (4.0%-3.3%) for Roche Accu-Chek Inform I, and (4.6%-3.5%) for Abbott Precision Xceed Pro. Between-run imprecision study results for the three meters were (3.7%-4.7%) for Nova Statstrip, (5.9%-4.0%) for Roche Accu-Chek Inform I, and (5.0%-4.1%) for Abbott Precision Xceed Pro. Adult venous correlations for the three meters were ($y = 1.0185x - 0.7286$; $r^2=0.99514$; $N=131$) for Nova Statstrip, ($y = 1.0196x - 5.0238$; $r^2=0.98073$; $N=131$) for Roche Accu-Chek Inform I, and ($y = 0.9644x + 12.122$; $r^2=0.97772$; $N=131$) for Abbott Precision Xceed Pro. Pediatric capillary correlations for the three meters were ($y = 1.0036x - 1.3217$; $r^2=0.9805$; $N=33$) for Nova Statstrip, ($y = 1.007x + 1.0187$; $r^2=0.9628$; $N=33$) for Roche Accu-Chek Inform I, and ($y = 1.0536x + 5.2984$; $r^2=0.9216$; $N=33$) for Abbott Precision Xceed Pro. Adult capillary correlations for the three meters were ($y = 0.9687x + 4.7613$; $r^2=0.9225$; $N=21$) for Nova Statstrip, ($y = 1.1442x - 10.88$; $r^2=0.8965$; $N=21$) for Roche Accu-Chek Inform I, and ($y = 1.1672x - 10.086$; $r^2=0.9331$; $N=21$) for Abbott Precision Xceed Pro. The three meters exhibited no interference from acetaminophen or ascorbic acid at the concentrations tested (5 and 10 mg/dL). The Roche Accu-Chek Inform I exhibited interference from maltose and galactose at the concentrations tested (100 and 200 mg/dL). The Abbott Precision Xceed Pro exhibited significant bias at low and high hematocrits.

Conclusions: The analytical performance of Nova Statstrip meter was superior to Roche Accu-Chek Inform I and Abbott Precision Xceed Pro in our evaluation. The Nova Statstrip meter met the CLSI POCT 12A3 criteria followed by the Roche Inform I meter while the Abbott Xceed Precision Pro failed to meet the criteria.