

Evaluation of a Glucose Meter with Negligible Hematocrit or Chemical Interference

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Abstract:

Objective: To compare precision and accuracy data from a new meter strip technology to 3 other commercially available meter strip technologies and a reference plasma hexokinase procedure.

Relevance: Considerable concern has been expressed in the literature regarding point-of-care (POC) glucose testing devices (meter-strip) and the considerable error they have demonstrated when compared to reference (plasma-hexokinase) methods.

Methodology: We compared the analytical performance of the newly introduced Nova Biomedical Statstrip glucose monitoring system and three other strip-meters systems (Roche Aviva, Abbott Precision Freestyle, LifeScan SureStep Flexx) to a laboratory plasma hexokinase reference method (Roche Hitachi 912). We determined within-run precision for the four meter strip systems using a freshly prepared whole blood sample spiked with concentrated glucose to give three glucose concentrations and day-to-day precision using aqueous control materials supplied by each vendor. Common interferences, including hematocrit, maltose and ascorbate, were tested alone and in combination with one another on each of the four strip-meter systems at low, medium and high blood glucose concentrations.

Results: Within-run imprecision of the StatStrip in spiked whole blood samples, as determined by the coefficient of variation, was < 4.5% for glucose concentrations between 4.14-20.70 mmol/L. Day-to-day imprecision using control materials was < 6%. Increasing hematocrit values, while significantly lowering the glucose values obtained from the Aviva, Precision Freestyle and the SureStep Flexx systems, had virtually no effect on the StatStrip system. Of the four strip-meter systems tested for interference, only the StatStrip remained within 5% of its initial value following the cumulative addition of ascorbate, and/or maltose at low and high hematocrit levels for the three glucose concentrations tested.

Conclusions: The StatStrip glucose meter gave precision (within-run and day-to-day) comparable to that determined on the other three meter-strip systems tested. The StatStrip system was not susceptible to hematocrit, ascorbate or maltose interferences, either alone or in combination with one another. The other strip meter systems tested were significantly influenced by these interferences

Acknowledgements:

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Introduction:

The current study was designed to evaluate the analytical performance of four commercially available glucose meters. In an attempt to mimic the complexity seen with critical care patients, common interferences such as hematocrit, maltose and ascorbate, were tested alone and in combination with one another at low, medium and high blood glucose concentrations. Accuracy of glucose analyses was established by comparing all values to a reference plasma hexokinase method and determining whether differences exceeded the ISO 15197 guidelines.

Objective:

To compare precision and accuracy data from a new strip meter technology to three other commercially available strip meter technologies and a reference plasma hexokinase procedure.

Methods:

Glucose Strip-Meter Systems Evaluated

- Nova Biomedical Stat Strip
- Roche Aviva
- Abbott Precision Freestyle
- Lifescan Sure Step Flexx

Parameters Measured:

1. Within run precision using the four strip-meter systems using freshly prepared whole blood spiked with concentrated glucose to give three glucose concentrations. Day to day precision using aqueous control materials supplied by each vendor.

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Methods Con't.

2. Interferences, including hematocrit, maltose and ascorbate, were tested alone and in combination with one another on each of the four strip-meter systems as low, medium and high blood glucose concentrations.

3. Patient blood gas results (hematocrit and glucose) (n= 154) were compared with those obtained with the four glucose meters.

Results:

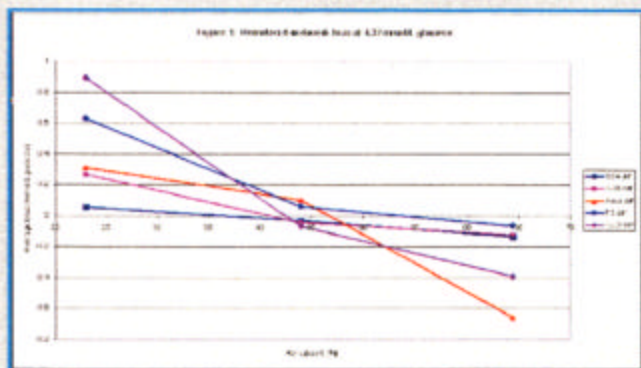


Figure 1. Hematocrit-induced bias at 4.32 mmol/L glucose. SSA & SSB = Nova, Aviva = Roche, FS = Abbott, SuSt = LifeScan

Strip/Meter System	Glucose Conc.		
	Low	Medium	High
Nova	4.14±0.13 (3.08%)	11.18±0.36 (3.19%)	20.79±0.54 (2.59%)
Abbott	4.39±0.33 (7.59%)	10.09±0.66 (6.55%)	19.55±0.72 (3.66%)
Roche	4.33±0.12 (2.82%)	11.06±0.33 (2.96%)	21.86±0.51 (2.36%)
LifeScan	4.31±0.13 (3.09%)	9.80±0.17 (1.69%)	19.82±0.18 (0.89%)

Table 1: Within Run Precision [mean glucose concentration (mmol/L) ± standard deviation (coefficient of variation)]

Strip/Meter System	Glucose Conc.	
	Low	High
Nova	8.15±0.12 (3.92%)	16.32±0.17 (1.04%)
Abbott	6.09±0.20 (4.34%)	
Roche	2.38±0.10 (4.20%)	17.19±0.20 (1.06%)
LifeScan	2.67±0.14 (5.31%)	20.45±0.48 (2.39%)

Table 2: Day to Day Precision [mean glucose concentration (mmol/L) ± standard deviation (coefficient of variation)]

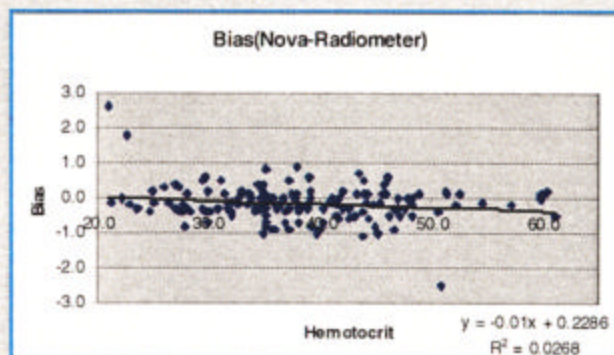


Figure 2. Hematocrit effect in patient samples with hematocrit adjustment. Glucose concentration measured using the Nova Stat Strip Meter and the Radiometer 725 blood gas analyzer.

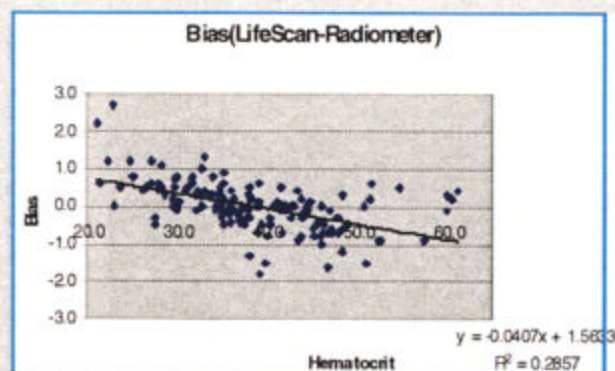


Figure 3. Hematocrit effect in patient samples with hematocrit adjustment. Glucose concentration measured using the Lifescan Sure Step Flex Meter and the Radiometer 725 blood gas analyzer.

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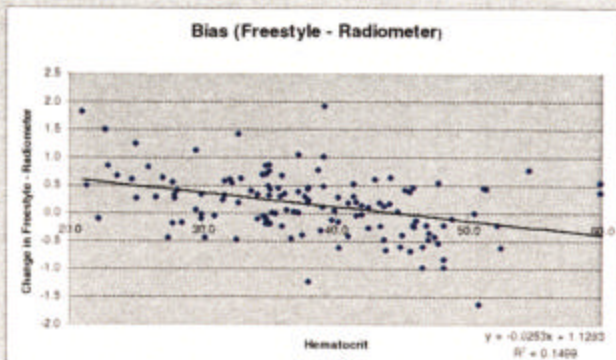


Figure 4. Hematocrit effect in patient samples with hematocrit adjustment.
Glucose concentration measured using Abbott Precision Freestyle and the
Radiometer 725 blood gs analyzer.

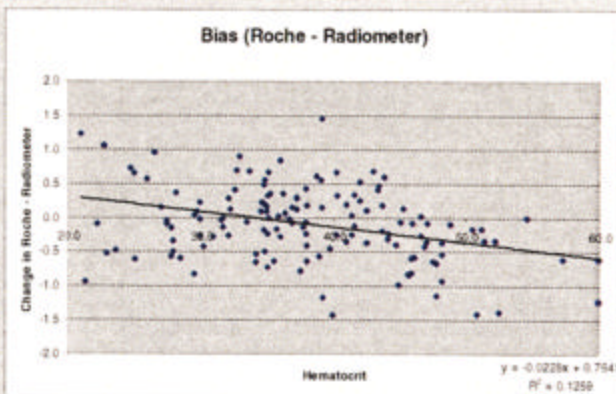


Figure 5. Hematocrit effect in patient samples with hematocrit adjustment.
Glucose concentration measured using Roche Aviva and the
Radiometer 725 blood gs analyzer.

Conclusion:

The Nova glucose meter gave precisions (within-run and between-day) comparable to that determined on the other three meter systems tested. The Nova system was not susceptible to hematocrit, ascorbate or maltose interferences, either alone or in combination with one another. The other strip meter systems tested were significantly influenced by these interferences.

Literature Cited:

References: 1. Soldin SJ, Brugnara C, Wong EC. Pediatric Reference Intervals Fifth Edition. Washington, DC USA: AACC Press; 2005. 2. Holub M, Tuschl D, Ratschmann R, Stmadova KA, Muhl A, Heinze G, Sperl W, Bodamer OA. Influence of hematocrit and localisation of punch in dried blood spots on levels of amino acids and acylcarnitines measured by tandem mass spectrometry. Clin Chim Acta 2006;Nov373(1-2):27-31. 3. Adam BW, Alexander JR, Smith SJ, Chace DH, Loeber JG, Elvers LH, Hannon WH. Recoveries of Phenylalanine from Two Sets of Dried-Blood-Spot Reference Materials: Prediction from Hematocrit, Spot Volume, and Paper Matrix. Clinical Chemistry 2000;46:126-128.