

Performance Evaluation of a New Blood Glucose Monitor That Requires No Coding: The OneTouch® Vita™ System

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Abstract

Background:

Improvements to blood glucose monitoring systems aim to simplify the testing process, reduce or eliminate errors, and provide additional information for patients with diabetes. New systems must continue to demonstrate high-quality analytical performance. The new OneTouch® Vita™ System (LifeScan, Inc., Milpitas, CA) offers a no-code testing process and proven technology found in the OneTouch® Ultra® System. Comparative studies were conducted with the new and established systems to evaluate their precision and accuracy.

Methods:

Within-run precision in blood, total precision with controls, and system accuracy were evaluated using three lots of OneTouch Vita Test Strips and one lot of OneTouch Ultra Test Strips. Accuracy was tested across a wide glucose range (38–520 mg/dL, 2.1–28.9 mmol/L) using fingertip blood samples from 139 subjects. Reference plasma glucose values were obtained using the YSI 2300 STAT Plus Glucose & Lactate Analyzer (YSI Inc., Yellow Springs, OH). All studies were designed in accordance with requirements published by the International Organization for Standardization (ISO 15197).

Results:

Precision testing (within-run and total) with both systems produced coefficients of variation (CVs) of <5% for all sample types and glucose levels. Within-run precision testing with blood showed CVs of <3.1% and <4.7% for the OneTouch Vita and OneTouch Ultra Systems respectively. Total precision with control samples gave CVs of <3.0% and <3.6% for the two systems. Consensus error grid analysis showed equivalent clinical accuracy with 98.4% (821/834) and 98.2% (273/278) of results within zone A. Both systems met the ISO acceptability requirements for system accuracy.

Conclusion:

The OneTouch Vita System provides a simple no-code testing process with performance comparable to the OneTouch Ultra and OneTouch Ultra2 Systems.

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Abbreviations: (CV) coefficient of variation, (ISO) International Organization for Standardization

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