

MATERIALS AND METHODOLOGY

The TRUEbalance™ System from Nipro Diagnostics, Inc. is a new biosensor system that requires one microliter of blood and gives results in ten seconds. The patented TRUEfill® technology test strip design offers fully touchable test strips, beveled-tip design for easy identification of sampling target area and a hydrophilic coating over the chamber which promotes absorption of sample into the chamber. A patented quad-electrode technology ensures proper fill of sample chamber and signals transmission via electrodes to a sensor. Audible fill detection is a safety feature that alerts a user via an audible beep that the required sample has been applied and that the test is counting down. If there is no audible beep, then the test will not start, preventing a false start and/or erroneous results.

For this lab study, 16 meters were used in random sequence, and three lots of TRUEbalance™ Test Strips were evaluated in the laboratory setting. The Yellow Springs Instrument (YSI) was used as the reference device. All required quality controls were reported on meter, strips and reference method.

PARKES ERROR GRID

Parkes et al. developed an error grid to analyze the clinical significance of the bias between blood glucose meter results and lab results.⁴ Accuracy is evaluated by performing a test on the glucose meter and comparing it to the result obtained using the YSI laboratory instrument. For analysis, data points are assigned into one of the five Zones (A-E) on the error grid. Results, or data points, falling into Zones A and B are defined as clinically acceptable, and the observed difference in results would not lead to treatment decisions that may put a patient at risk. As the bias, or difference, increases between the results (Zones C, D and E), there is a greater risk in terms of undertreating or overtreating a patient based on the meter glucose result.

ISO STANDARD 15197:2003

An ISO Standard is developed in response to an identified need in the community that will eventually be suitable for implementation on as broad a basis as possible. ISO developed a standard for blood glucose monitoring performance – 15197:2003 – based on a consensus of professionals around the world. It is recognized as the standard in many countries and is a U.S. FDA-recognized consensus standard.

Standard Reference Results	ISO Bias Limit	Criteria for Accuracy
Less than 75 mg/dL	+/- 15 mg/dL from laboratory reference result	95% of all results
Greater than or equal to 75 mg/dL	+/- 20% from laboratory reference result	

1. Raine CH. Self-monitored blood glucose: a common pitfall. *Endocr Pract.* 2003 Mar-Apr; 9 (2): 137-9.
2. Kristensen G, Nerhus K, Thue G, Sandberg S. Standardization evaluation of instruments for self-monitoring of blood glucose by patients and a technologist. *Clin Chem.* 2004 Jun; 50 (6): 1068-71.
3. Raine CH, Schrock LE, Edelman SV, Mudaliar SR, Zhong W, Proud LJ, Parkes JL. Significant insulin dose errors may occur if blood glucose results are obtained by miscoded meters. *J of Diabetes Science and Technology.* 2007 March; 1 (2): 205-210.
4. Parkes JL, Slatin SL, Pardo S, Ginsberg BH. A new consensus error grid to evaluate the clinical significance of inaccuracies in the measurement of blood glucose. *Diabetes Care.* 2000; 23(8):1143-1148.

FOR ADDITIONAL INFORMATION OR QUESTIONS, ADDRESS WRITTEN REQUESTS TO:

Douglas E. Bell, Ph.D., Senior Director Product Development and Support
Teri A. Sasse, R.N., M.S., Director of Clinical Services

Nipro Diagnostics, Inc.
2400 NW 55th Ct.
Ft. Lauderdale, FL 33309

www.niprodiagnostics.com

NIPRO
DIAGNOSTICS™

**Accuracy of the New
TRUEbalance™
Blood Glucose Monitoring System**

NIPRO
DIAGNOSTICS™

OVERALL EVALUATION OBJECTIVES

- Evaluate the accuracy of the TRUEbalance™ blood glucose monitoring system in comparison to the laboratory reference method (Yellow Springs Instrument [YSI])
- Demonstrate the TRUEbalance™ System is clinically accurate as defined by the criteria developed for the Parkes Error Grid
- Evaluate the TRUEbalance™ System against the International Standardization Organization – ISO 15197:2003 criteria for accuracy

INTRODUCTION

Diabetes self care involves regular blood glucose monitoring to understand the effects of medications, meal planning, and physical activity on blood glucose results, and to make adjustments when glycemic goals are not met. As the cornerstone of diabetes care, blood glucose meters must be easy for patients to use and must provide accurate results – especially for patients who make daily adjustments in insulin based on these results.

Most meters utilize a coding process that requires the user to match the meter to the test strips. The coding step is critical for the system to perform accurately. Coding is required when using the meter and strips for the first time and again when opening a new box of test strips. The coding process involves manually using a button on the meter to scroll through different codes to match the test strips, inserting a code strip (similar to a test strip) until the meter is coded, or inserting a code chip (or code key) into the meter that stays in place until the user finishes the current test strips and opens a new vial.

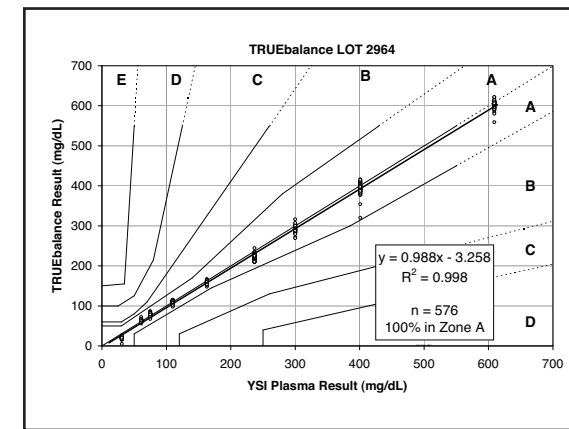
In studies by Raine and Kristensen et al, approximately 16% of people failed to code their blood glucose meters properly.^{1,2} In 2007, Raine et al. published a study that evaluated the significance of inaccuracies in blood glucose results from miscoded meters and outlined how these inaccurate results could affect the dosage of insulin that a patient administered.³ The conclusion supported the fact that improperly coded meters may significantly affect the dosage of insulin taken, and that auto-coded meters showed enhanced performance, even versus meters that were correctly manually coded.

Today, Nipro Diagnostics, Inc. and other manufacturers of blood glucose monitoring systems strive to design easy-to-use blood glucose meters that help to eliminate the possibility of user error. One major advancement is the development of no coding blood glucose monitoring systems with additional user-friendly enhancements, such as larger displays, bold numbers, limited buttons, and ergonomic design. The TRUEbalance™ System from Nipro Diagnostics employs a no-coding technology and test strip design features that promote first-test success and accurate results.

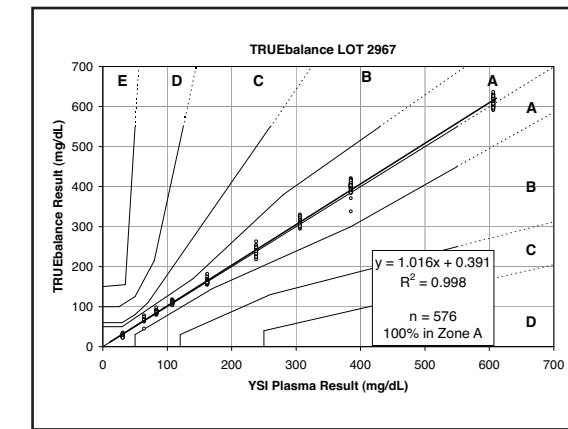
Other features incorporated into test strip design have eliminated additional sources of user error. Enhancements in this area include: touchable test strips; smaller blood samples (1.0 µL or less); and a transition from top dosing of blood to end sampling, allowing the blood sample to more easily enter the chamber. Auto-fill detect, audible beepers and visual fill indicators now confirm sufficient sample size for accurate results.

TOPLINE RESULTS USING PARKES ERROR GRID

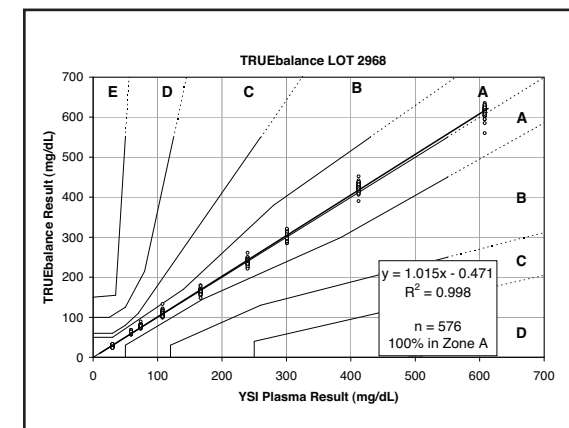
Laboratory evaluations and comparisons were conducted to demonstrate the accuracy of the TRUEbalance™ System. A total of 576 glucose-testing results were recorded and evaluated across three lots of TRUEbalance™ Test Strips at nine different glucose levels. Accuracy was evaluated by performing tests on the glucose meter and comparing it to the results obtained by the YSI laboratory instrument.



	% Results In Zone
Zone A	100%
Zones B, C, D, E	0%



	% Results In Zone
Zone A	100%
Zones B, C, D, E	0%

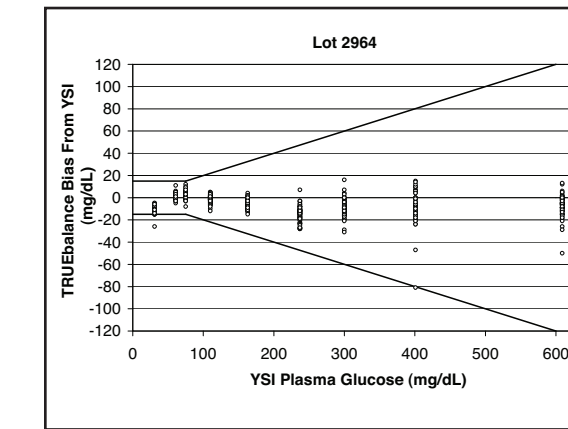


	% Results In Zone
Zone A	100%
Zones B, C, D, E	0%

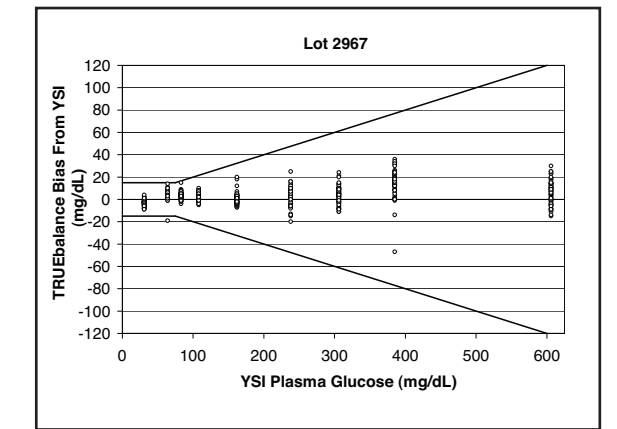
Note: The original Parkes error zone lines extend to 550 mg/dL. The dashed lines are extrapolations of the zone boundaries to accommodate results > 550 mg/dL.

TOPLINE RESULTS USING ISO GUIDELINES

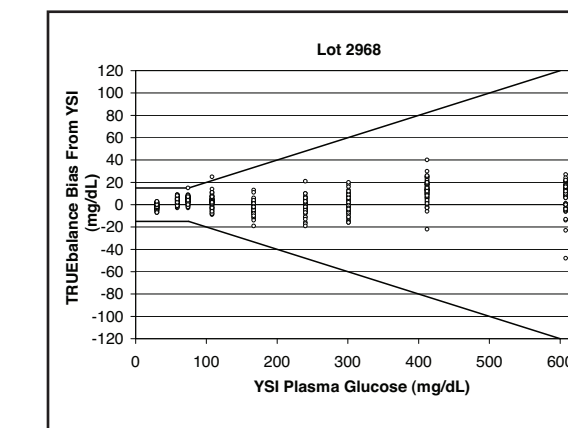
Lab comparisons using the TRUEbalance™ System demonstrated that the meter results exceed the minimum criteria for accuracy set forth by ISO 15197:2003.



Total Data Points	Number of Points Outside of Minimum Criteria	% of Points Inside Minimum Criteria
576	2	99.6%



Total Data Points	Number of Points Outside of Minimum Criteria	% of Points Inside Minimum Criteria
576	2	99.6%



Total Data Points	Number of Points Outside of Minimum Criteria	% of Points Inside Minimum Criteria
576	2	99.6%

CONCLUSION

- Data collected and analyzed from the TRUEbalance™ System showed excellent correlation to the YSI standard and the Parkes Error Grid.
- Using ISO 15197:2003 acceptance criteria for accuracy, the TRUEbalance™ results exceed the minimum criteria for accuracy.
- TRUEbalance™, a no coding system, offers ease of use and simplicity and can be used for all patients with diabetes.