

**Clinical Study on the Accuracy  
and Ease of Use of the New,  
No Coding TRUEresult® System,  
Featuring TRUEtest™ Strips**

Advanced Performance System Exceeds Minimum Criteria  
for Accuracy As Defined by  
FDA-Recognized Consensus Standard ISO 15197:2003

# CLINICAL STUDY SUMMARY

## EVALUATION OBJECTIVES

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This clinical study was specifically designed to meet five specific clinical objectives:

1. Prove that the TRUEresult® System provides equal, or superior, accuracy compared to the Roche ACCU-CHEK® Aviva blood glucose testing system.
2. Prove that the TRUEresult® System exceeds the minimum criteria for accuracy as defined by ISO Standard 15197:2003.
3. Prove that lay users, using the TRUEresult® System, obtain test results consistent with those obtained by healthcare professionals.
4. Prove that the TRUEresult® System accurately measures forearm capillary blood samples.
5. Prove that first-time users of the TRUEresult® System found it easy to use and were able to obtain accurate results.

## ISO STANDARD 15197:2003

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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 the 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	<b>95% of all results</b>
Greater than or equal to 75 mg/dL	+/- 20% from laboratory reference result	

## PARKES ERROR GRID

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Parkes et al. developed an error grid to analyze the clinical significance of the bias between blood glucose monitor results and lab results. 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 any 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 under-treating or over-treating a patient based on the glucose result.

## SITES AND SUBJECTS

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Clinical evaluations of the TRUEresult® System were conducted at four clinical institutions across the U.S.:

- Diabetes & Glandular Disease Clinic; San Antonio, TX
- St. Vincent Hospital; Leadville, CO
- Clearwater Valley Hospital; Orofino, ID
- Philadelphia College of Osteopathic Medicine (PCOM); Philadelphia, PA

Three of the sites were assigned the evaluation of the TRUEresult® versus a predicate device in fingerstick, alternate site accuracy evaluations, as well as ISO user performance evaluations. The San Antonio, TX site had the specific purpose of determining ISO accuracy of fingerstick testing.

Four lots of TRUEtest™ Strips were used during these evaluations; a different lot at each of the four locations. Two lots of ACCU-CHEK® Aviva Test Strips were used in the study.

In total, 317 subjects completed the protocol across the four evaluation sites. The subjects were diversified in age, ethnicity and education, with slightly more females than males. The ages ranged from 18 to 85 years old.

## EVALUATION AND COMPARATIVE METHODS

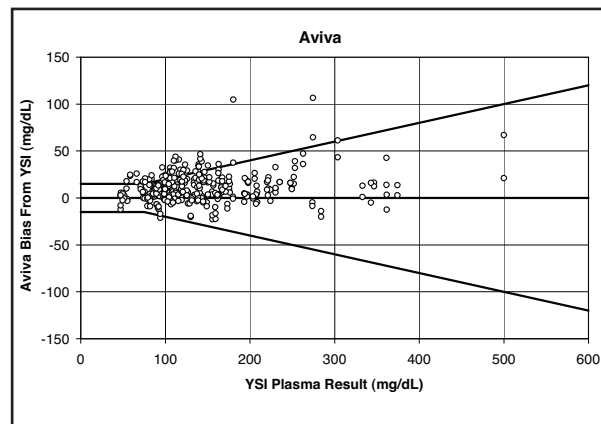
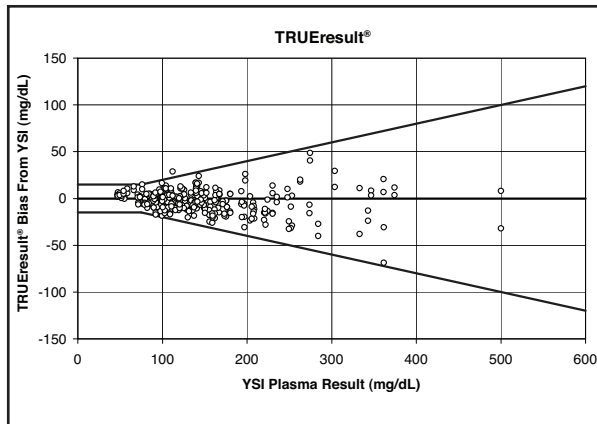
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Numerous clinical evaluations and comparisons were conducted to determine the accuracy and ease of use of the TRUEresult® System.

Site	Number of Subjects	Purpose	Origin of Tested Blood	
			Finger	Forearm
DGDC	126	1. ISO accuracy of fingerstick testing.	✓	
St. Vincent	65	1. Comparison to predicate for fingerstick. 2. Alternate site validation. 3. ISO user performance evaluation. 4. Altitude validation.	✓	✓
Clearwater Valley	62	1. Comparison to predicate for fingerstick. 2. Alternate site validation. 3. ISO user performance evaluation.	✓	✓
PCOM	64	1. Comparison to predicate for fingerstick. 2. Alternate site validation. 3. ISO user performance evaluation.	✓	✓

# TOPLINE RESULTS USING ISO CRITERIA

The TRUEresult® System, in the hands of healthcare professionals, is proven to provide accurate fingerstick results that exceed the ISO minimum criteria for accuracy. In this clinical evaluation, results obtained with the ACCU-CHEK® Aviva did not meet the ISO minimum criteria for accuracy.



	Total Data Points	Number of Points Outside of Minimum Criteria	% of Points Outside Minimum Criteria
TRUEresult®	346	1	0.2%
ACCU-CHEK® Aviva	346	52	15.0%

Summary of TRUEresult® accuracy against the YSI reference method for **meter readings below 75 mg/dL**

Within +/- 5 mg/dL	Within +/- 10 mg/dL	Within +/- 15 mg/dL
28/44 or 64%	42/44 or 95%	44 of 44 or 100%

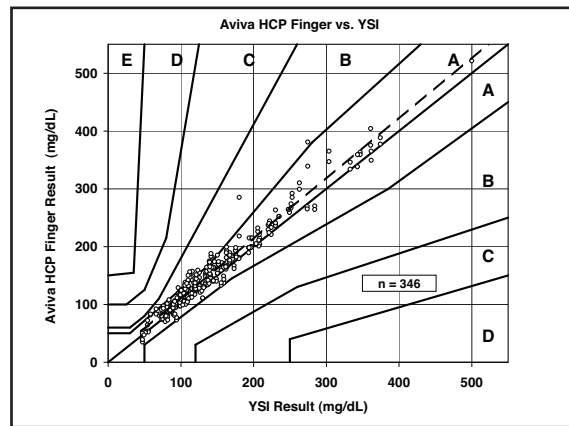
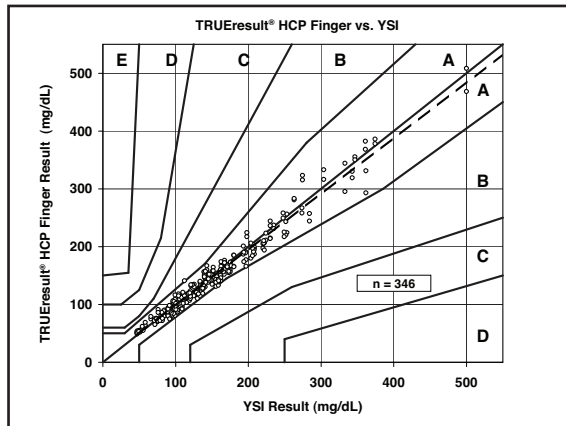
Summary of TRUEresult® accuracy against the YSI reference method for **meter readings at 75 mg/dL and above**

Within +/- 5%	Within +/- 10%	Within +/- 15%	Within +/- 20%
139/270 or 51%	227/270 or 84%	260/270 or 96%	268/270 or 99%

The TRUEresult® System exceeds the ISO minimum criteria for accuracy with 99.4% of results within range.

# TOPLINE RESULTS USING PARKES ERROR GRID — FINGERSTICK

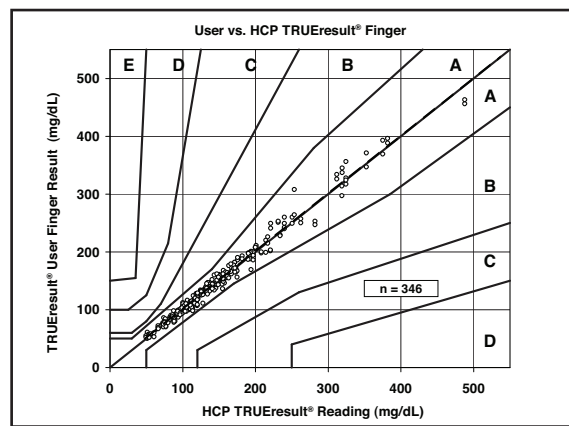
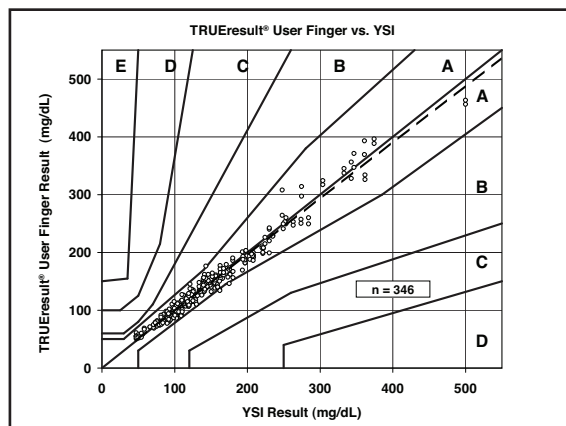
The TRUeResult® System, in the hands of healthcare professionals, is proven to provide accurate fingerstick results that are equivalent to both the YSI reference method and fingerstick results obtained with the ACCU-CHEK® Aviva.



	% Results In Zone
Zone A	99.4%
Zone B	0.6%
Zones C, D and E	0%

	% Results In Zone
Zone A	92.8%
Zone B	7.2%
Zones C, D and E	0%

The TRUeResult® System, in the hands of lay users, is proven to provide accurate fingerstick results when compared to both the YSI reference method and fingerstick results obtained by healthcare professionals.

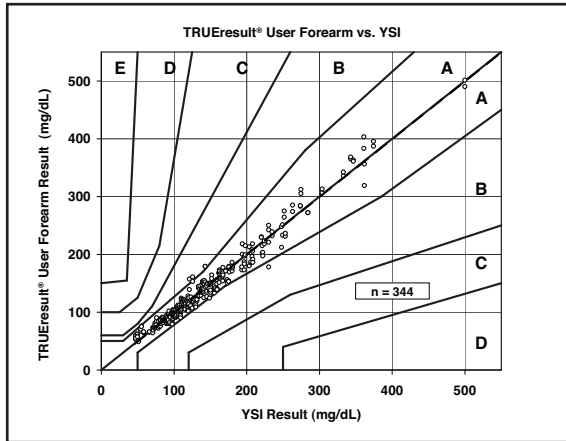


	% Results In Zone
Zone A	98.8%
Zone B	1.2%
Zones C, D and E	0%

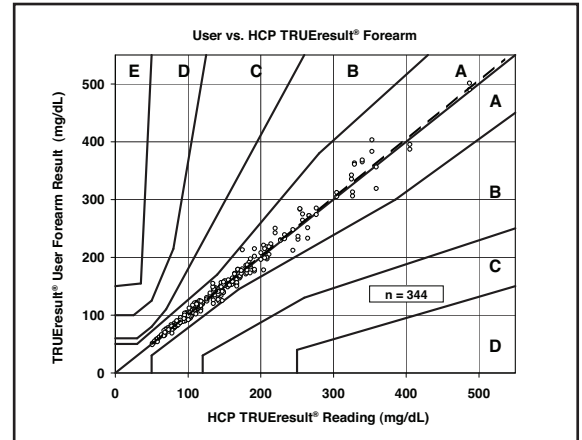
	% Results In Zone
Zone A	100%
Zone B	0%
Zones C, D and E	0%

# TOPLINE RESULTS USING PARKES ERROR GRID — FOREARM

The TRUEresult® System, in the hands of lay users testing on their forearms, is proven to provide accurate results when compared to both the YSI reference method and results obtained by healthcare professionals from user forearms.

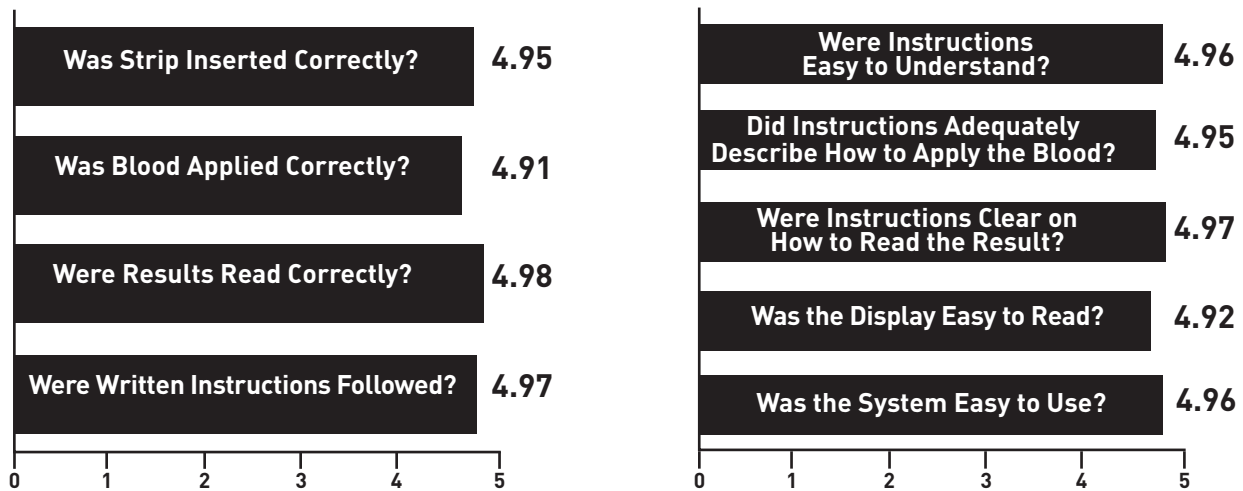


	% Results In Zone
<b>Zone A</b>	<b>98.8%</b>
<b>Zone B</b>	<b>1.2%</b>
<b>Zones C, D and E</b>	<b>0%</b>



	% Results In Zone
<b>Zone A</b>	<b>100%</b>
<b>Zone B</b>	<b>0%</b>
<b>Zones C, D and E</b>	<b>0%</b>

Healthcare professional observations and lay user evaluations prove that first-time users of the TRUEresult® System found it easy to use, and were able to obtain accurate and precise results.



The HCP ranked first-time users' compliance with the instructions of the TRUEresult® System on a scale of 1 to 5, where 5 is perfect compliance.

First-time users ranked different aspects of the instructions and the TRUEresult® System on a scale of 1 to 5, where 5 indicates "total agreement" and 1 is "strongly disagree."

## CONCLUSION

- The TRUEresult® System performed as well as an FDA-cleared device with fresh capillary blood from a fingerstick and provided results that are well within ISO Standard 15197:2003.
- The TRUEresult® System gave equivalent results with capillary blood from a forearm sample as from a fingerstick.
- Users found the instructions easy to understand, and users were judged to use the system correctly by the observing healthcare professionals.

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**FOR ADDITIONAL INFORMATION OR QUESTIONS, ADDRESS WRITTEN REQUESTS TO:**

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