

Evaluation of Accuracy of
TRUENESS™ Blood Glucose Monitoring Systems

Summary

Objectives:

To demonstrate that the TRUENESS™ and TRUENESS™ AIR Blood Glucose Monitoring Systems using TRUENESS™ Test Strips meet the ISO (International Organization for Standardization) EN ISO 15197:2015 Standard for accuracy and FDA Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use, September 2020 Guidance for accuracy.

Methods:

This clinical study was designed in accordance with the above EN ISO Standard and FDA 2020 Self-Monitoring Blood Glucose (SMBG) Guidance. Clinical accuracy was determined by comparing TRUENESS fingerstick blood sample results, obtained by both healthcare professionals and lay users (self-testers), to the ABL90 FLEX PLUS laboratory reference instrument for the measurement of glucose in whole blood samples.

Results:

The TRUENESS System exceeded the minimum ISO standard for accuracy, with 99.8% of healthcare professionals' results falling within limits defined by the EN ISO 15197:2015 Standard. Additionally, 100% of the results were within Zone A of a Consensus Error Grid analysis. The TRUENESS System was also found to exceed the FDA 2020 SMBG Guidance minimum criteria for accuracy with 97.5% of results within $\pm 15\%$ and 99.7% of results within $\pm 20\%$, with 100% of the results within Zones A and B of a Consensus Error Grid analysis.

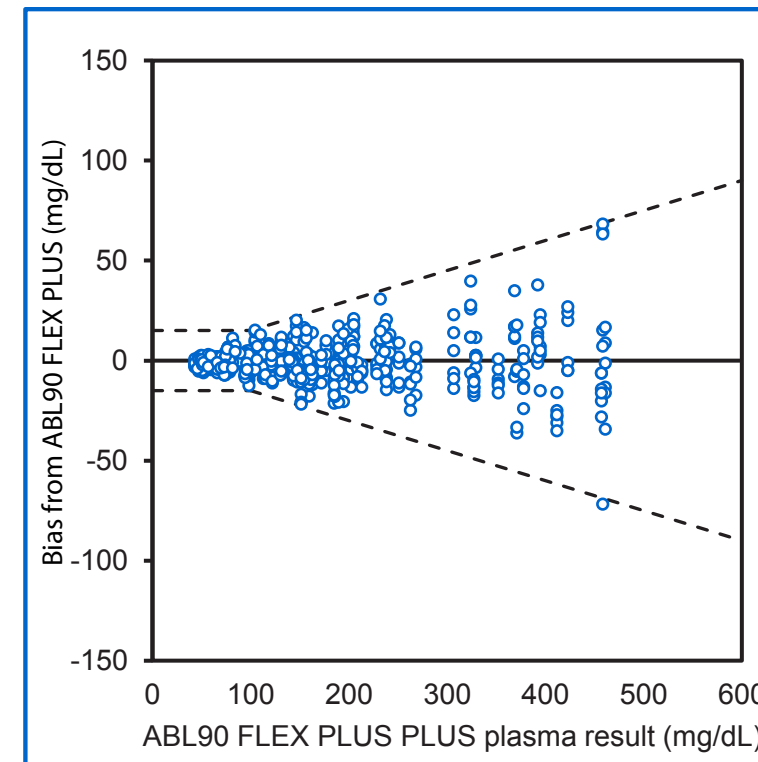
Conclusion:

The TRUENESS and TRUENESS AIR Blood Glucose Meters using TRUENESS Test Strips, exceed the EN ISO 15197:2015 Standard and FDA 2020 SMBG Guidance minimum criteria for accuracy.

REVIEW OF ACCURACY USING THE EN ISO 15197:2015 STANDARD

The TRUENESS™ and TRUENESS™ AIR Meters, featuring TRUENESS™ Test Strips, **exceed the minimum EN ISO 15197:2015 accuracy requirements.**

	EN ISO 15197:2015
Acceptance Range	± 15 mg/dL < 100 mg/dL and $\pm 15\%$ ≥ 100 mg/dL
Acceptance Criteria	$\geq 95\%$ of the data for each of the 3 lots must be within range



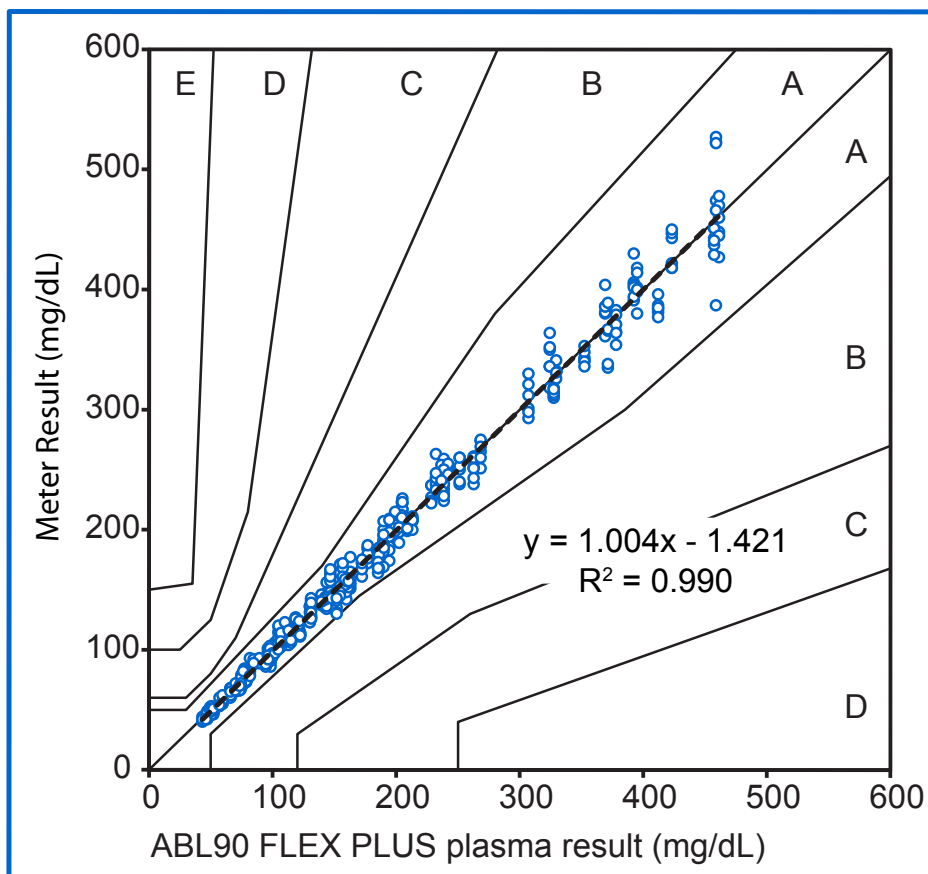
The TRUENESS™ and TRUENESS™ AIR Systems **exceed the EN ISO 15197:2015 minimum criteria** for accuracy with 99.8% of results within ISO limits*

*Data on file.

TRUENESS and TRUENESS AIR HCP Finger vs ABL90 FLEX PLUS: EN ISO 15197:2015 Table		
Results < 100 mg/dL*		
Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
137 / 168 (81.5%)	166 / 168 (98.8%)	168 / 168 (100%)
Results > 100 mg/dL*		
Within ± 5%	Within ± 10%	Within ± 15%
304 / 432 (70.4%)	411 / 432 (95.1%)	431 / 432 (99.8%)

The TRUENESS™ and TRUENESS™ AIR Meters, featuring TRUENESS™ Test Strips, in the hands of healthcare professionals are proven to provide accurate fingerstick results when compared to the ABL90 FLEX PLUS reference method.

EN ISO 15197:2015 requires 99% of all data to fall within Zones A and B of the Consensus Error Grid.



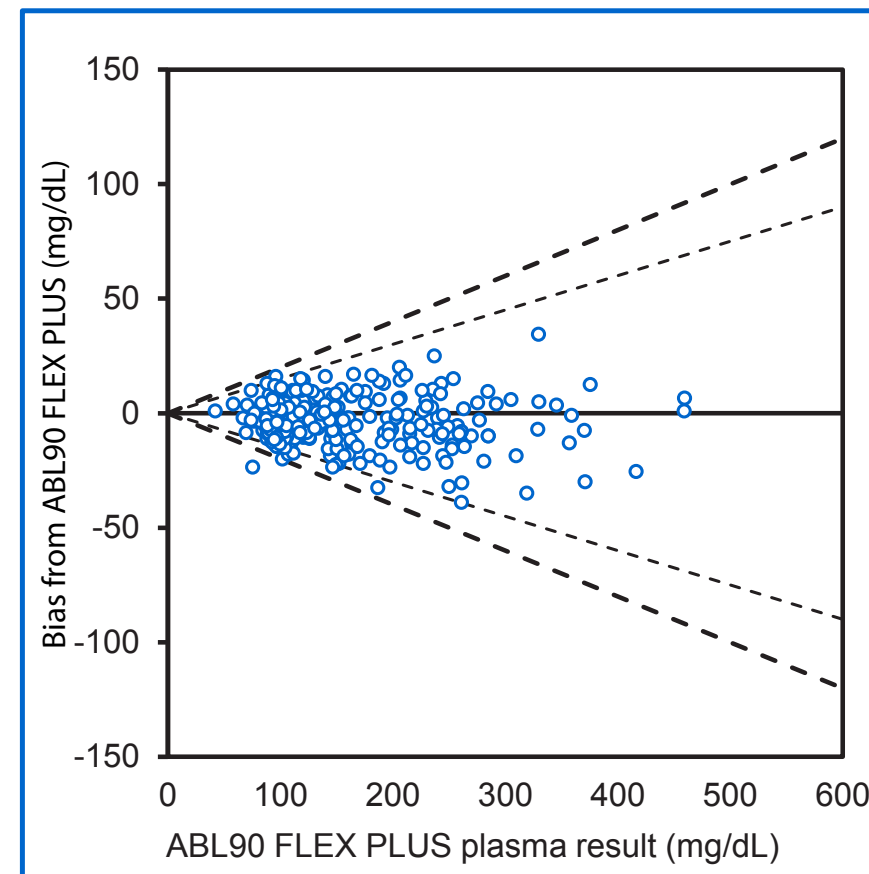
100% of results fell within Zone A of the Consensus Error Grid analysis of HCP results for the TRUENESS™ and TRUENESS™ AIR Systems verses ABL90 FLEX PLUS reference method.*

*Data on file.

REVIEW OF ACCURACY USING THE FDA 2020 SMBG GUIDANCE

The TRUENESS™ and TRUENESS™ AIR Meters, featuring TRUENESS™ Test Strips, **exceed the minimum US FDA 2020 SMBG Guidance** accuracy requirements.

	FDA 2020 SMBG Guidance
Acceptance Range	±15% and ± 20% for the full measurement range
Acceptance Criteria	≥ 95% of the data must be within ±15% and ≥ 99% of the data must be within ± 20%



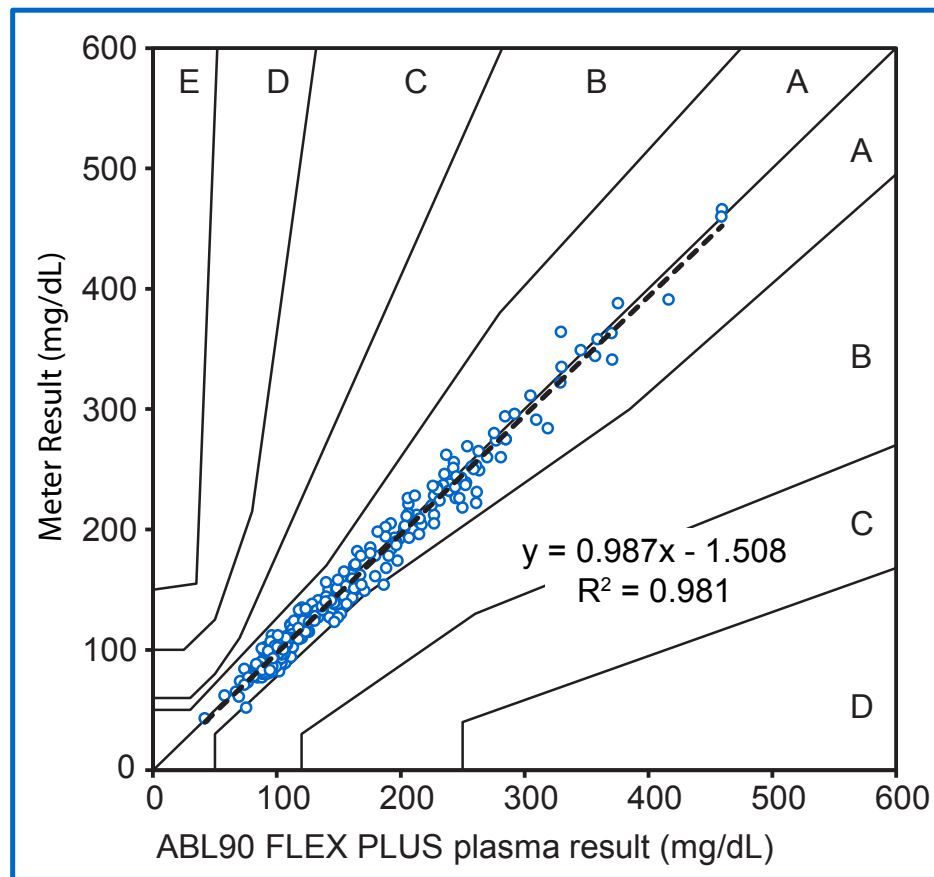
The TRUENESS™ and TRUENESS™ AIR Systems **exceed the FDA 2020 SMBG Guidance minimum criteria** for accuracy with 97.5% of results within ±15% and 99.7% of results within ±20%.*

*Data on file.

TRUENESS™ and TRUENESS™ AIR HCP Finger vs ABL90 FLEX PLUS: FDA 2020 SMBG Guidance Table			
All Results*			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
185 / 354 (52.3%)	291 / 354 (82.2%)	345 / 354 (97.5%)	353 / 354 (99.7%)

The TRUENESS™ and TRUENESS™ AIR Meters, featuring TRUENESS™ Test Strips, in the hands of self-test users are proven to provide accurate fingerstick results when compared to the ABL90 FLEX PLUS reference method.

The FDA 2020 SMBG Guidance does not have any Consensus Error Grid requirements, however for comparison:



100% of results fell within Zones A and B of the Consensus Error Grid analysis of self-test user results for the TRUENESS™ and TRUENESS™ AIR Systems verses ABL90 FLEX PLUS reference method.*

*Data on file.

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