

Accuracy and Precision Performance of the Accu-Chek[®] Advantage and Accu-Chek[®] Comfort Curve System

Introduction

- The accuracy of the system was assessed per the ISO 15197:2003 standard.
- Capillary blood from subjects diagnosed with diabetes was obtained at one external diabetes clinic. These results were compared to reference values obtained by using the hexokinase reference method adjusted to give plasma like results.

I. ACCURACY

Method

Testing was performed using Accu-Chek Comfort Curve glucose test strips. Two Accu-Chek Advantage blood glucose meters were assigned for testing with one lot of blood glucose test strips.

Per the ISO standard, blood glucose meter results must lie within the following ranges for each meter tested as stated in the table below:

% Samples	Glucose concentration (mg/dL)
5	< 50
15*	50-75
20	76-120
30	120-200
15	201-300
10	301-400
5	> 400

***Note:** The upper limit for this range was modified from 80 to 75 mg/dL.

Two Accu-Chek Advantage meters were used and 102 results were collected on one meter and 98 results were collected on the other. Glucose concentration was artificially altered for samples less than 50 mg/dL and greater than 400 mg/dL.

Results

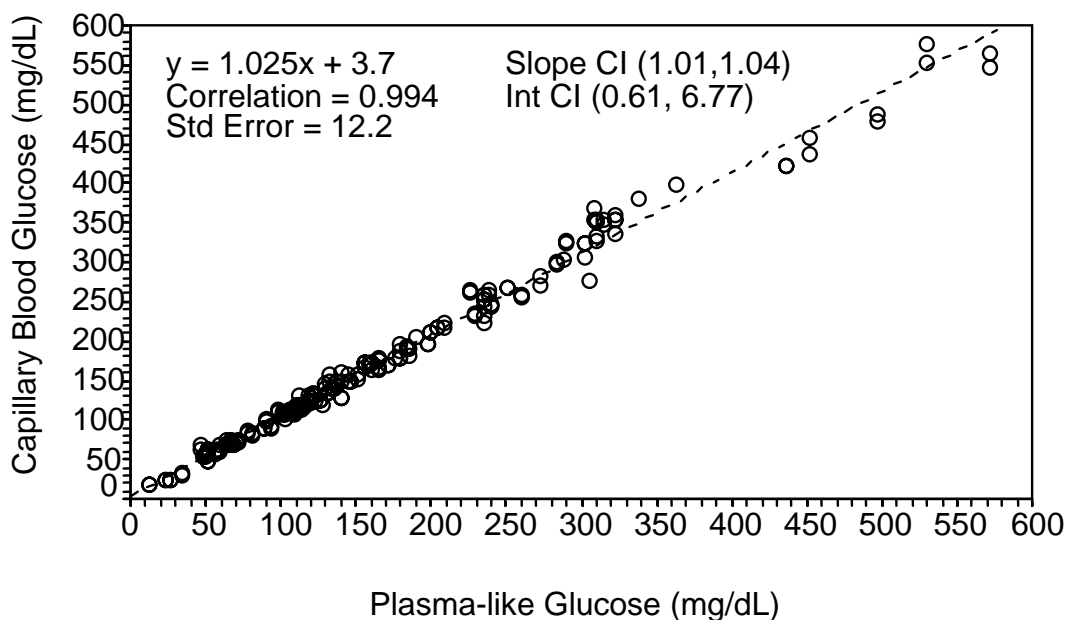
The Accu-Chek Comfort Curve blood glucose test lot was analyzed by linear regression and is summarized in the following table for lot number 546926.

Figure	N	Slope	Intercept	Correlation	Std. Error	Slope CI	Int. CI
1	200	1.025	3.7	0.994	12.2	(1.01,1.04)	(0.61, 6.77)

The lot demonstrates excellent correlation with all values near the optimum value of 1.000.

The following figure illustrates the linear regression graph.

Capillary Blood Glucose (mg/dL) versus Plasma-like
Glucose using Accu-Chek Comfort Curve Test Strip
Lot # 546926 (N = 200)



The capillary data for Accu-Chek Comfort Curve test strip lot # 546926 was analyzed by linear regression and is summarized as follows: for the Accu-Chek Comfort Curve Blood Glucose Monitoring System, the regression shows a slope of 1.025 with a 95% confidence interval of (1.01, 1.04). The intercept is 3.7 mg/dL. The data presented demonstrate excellent correlation with a value of 0.994 with 1.000 as the optimum value.

No statistical outliers were found.

The following tables illustrate the bias for the Accu-Chek Comfort Curve test strip using test strip lot number 546926.

Results less than 75 mg/dL

Within \pm 5 mg/dL	Within \pm 10 mg/dL	Within \pm 15 mg/dL
26 / 38 (68%)	35 / 38 (92 %)	37 / 38 (97 %)

Results greater than or equal to 75 mg/dL

Within \pm 5 %	Within \pm 10 %	Within \pm 15 %	Within \pm 20 %
82/162 (51%)	137/162 (85%)	156/162 (96 %)	162/162 (100 %)

The minimum acceptable accuracy for results produced by a glucose monitoring system shall be as follows:

- Ninety-five percent (95%) of the individual glucose results shall fall within \pm 15 mg/dL of the results of the manufacturer's measurement procedure at glucose concentrations less than 75 mg/dL and within \pm 20% at glucose concentrations greater than or equal to 75 mg/dL.

The Accu-Chek Comfort Curve Glucose Monitoring System meets the ISO 15197:2003 requirements for accuracy. Overall, 199 of the 200 samples (99.5%) were within the minimum acceptable performance criteria.

The range of plasma like hexokinase values was 13.1 to 572.1 mg/dL.

II. INTERMEDIATE PRECISION

Introduction

The purpose of this study was to determine the intermediate precision of the Accu-Chek Comfort Curve blood glucose system using three Accu-Chek Comfort Curve blood glucose strip lots and three levels of Accu-Chek Comfort Curve control solution.

Intermediate precision is defined as the following:

“Precision under conditions where test results are obtained with the same method on identical test items in the same location, but where other variables such as operators, equipment, calibration, environmental conditions and/or time intervals differ.”

Method

Ten Accu-Chek Advantage blood glucose meters were assigned to this study. Three Accu-Chek Comfort Curve test strip lots were used with ten vials from each strip lot assigned to this study.

One blood glucose test strip was removed from each vial and placed into the designated meter. The test strip was dosed with control solution and the process was repeated for each meter over ten days for each assigned level of control solution and strip lot.

Results

For each control solution, ten different determinations were made on ten Accu-Chek Advantage blood glucose meters. Over three strip lots, this gave a total of thirty different determinations.

From these thirty determinations, the median SD or CV was selected and a nonparametric method was used to place a confidence interval around the median SD.

The following table lists the intermediate precision results using Accu-Chek Comfort Curve control solutions and Accu-Chek Comfort Curve blood glucose test strips:

Results less than 75 mg/dL

Control Solution Level	Mean (mg/dL)	Median SD	95%Confidence Interval (SD)
1	30	1.5	(1.3,1.7)

Results greater than 75 mg/dL

Control Solution Level	Mean (mg/dL)	Median SD	Median CV (%)	95%Confidence Interval (SD)
2	125	3.3	2.6	(3.0, 4.1)
3	315	7.6	2.4	(6.9, 9.0)

III. REPEATABILITY

Introduction

The purpose of this study was to determine the repeatability of the Accu-Chek Comfort Curve blood glucose system using three Accu-Chek Comfort Curve blood glucose strip lots.

Repeatability is defined as the following:

“Precision under conditions where independent test results are obtained with the same method on identical test items in the same location by the same operator using the same equipment within a short interval of time.”

Method

Ten Accu-Chek Advantage blood glucose meters were assigned to this study.

The glucose in a venous blood sample was allowed to degrade and concentrated glucose solution was added to this blood to achieve varying blood glucose concentrations. Once the manipulated blood sample had achieved stability, testing was performed on each of the ten blood glucose meters and the results were recorded. All blood testing occurred in one day.

One blood glucose test strip was removed from each vial and placed into the designated meter. The test strip was dosed with blood and the process was repeated for each meter ten times for each assigned level of spiked venous blood. This process was then repeated for the other two strip lots providing thirty different determinations.

Results

From the thirty different determinations, the median SD or CV was calculated and a nonparametric method was then used to calculate a confidence interval for the SD.

The following table lists the repeatability results using manipulated venous blood:

Results less than 75 mg/dL

Mean (mg/dL)	Median SD	Median %CV	95%Confidence Interval (SD)
41	1.7	N/A	(1.4, 2.0)

Results greater than 75 mg/dL

Mean (mg/dL)	Median SD	Median %CV	95%Confidence Interval (SD)
76	2.6	3.4	(2.0, 3.0)
133	5.0	3.8	(4.2, 5.6)
214	6.6	3.1	(5.3, 7.1)
318	11.4	3.6	(9.4, 12.5)

CONCLUSION

- The Accu-Chek Comfort Curve System meets the accuracy requirement for the ISO 15197:2003 standard.
- No requirements are listed by the ISO 15197:2003 standard for intermediate precision and repeatability.

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