

Accuracy and Precision Performance of the Accu-Chek[®] Compact and Accu-Chek Compact Plus System

I. ACCURACY

The accuracy of the system was assessed per the ISO 15197.

Introduction

The purpose of this study was to determine the accuracy of the Accu-Chek Compact blood glucose system using one Accu-Chek Compact blood glucose strip lot.

Method

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.

Testing was performed using Accu-Chek Compact glucose test strips. Two Accu-Chek Compact 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 (mmol/L)	Glucose concentration (mg/dL)
5	< 2.8	< 50
15	≥ 2.8 – 4.3	≥ 50 – 80
20	> 4.3 – 6.7	> 80 – 120
30	> 6.7 – 11.1	>120 – 200
15	> 11.1 – 16.6	> 200 – 300
10	> 16.6 – 22.2	> 300 – 400
5	> 22.2	> 400

100 values (100 specimen) were used in the analysis per glucose meter, 2 meters were used.

Glucose concentration was artificially altered for samples at less than 2.8 mmol/L (50 mg/dL) and greater than 22.2 mmol/L (400 mg/dL).

Results

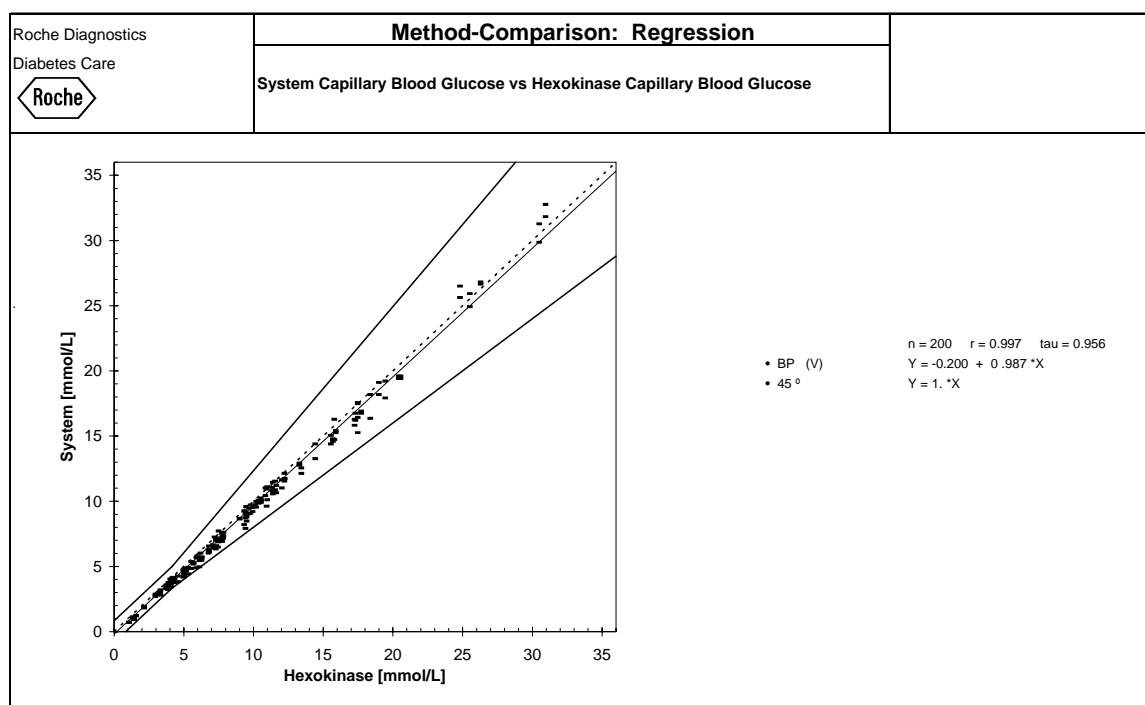
The Accu-Chek Compact blood glucose test lot was analyzed by regression analysis according to Bablok/Passing and is summarized in the following table for lot number 295235.

N	Slope	Intercept	Correlation	Slope CI	Int. CI
		(mmol/L)			(mmol/L)
200	0.987	-0.200	0.997	(0.975, 0.999)	(-0.311, -0.136)
		(mg/dL)			(mg/dL)
200	0.987	-3.6	0.997	(0.975, 0.999)	(-5.6, -2.5)

The results demonstrate excellent correlation with all values near the optimum value of 1.000.

The following figure illustrates the regression graph according to Bablok/Passing.

The capillary data for Accu-Chek Compact lot # 295235 was analyzed by regression analysis according to Bablok/Passing and is summarized as follows: for the Accu-Chek Compact Blood Glucose Monitoring System, the regression shows a slope of 0.987 with a 95 % confidence interval of (0.975, 0.999). The intercept is -0.200 mmol/L (-3.6 mg/dL). The data presented demonstrate excellent correlation with a value of 0.997 with 1.000 as the optimum value. No data were excluded.



The following tables illustrate the bias for the Accu-Chek Compact system using test strip lot number 295235.

Results less than 4.2 mmol/L (75 mg/dL)

Within ± 0.28 mmol/L (Within ± 5 mg/dL)	Within ± 0.56 mmol/L (Within ± 10 mg/dL)	Within ± 0.83 mmol/L (Within ± 15 mg/dL)
29 / 38 (76 %)	38 / 38 (100 %)	38 / 38 (100 %)

Results greater than or equal to 4.2 mmol/L (75 mg/dL)

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
96 / 162 (59 %)	144 / 162 (89 %)	160 / 162 (99 %)	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 ± 0.83 mmol/L (15 mg/dL) of the manufacturer’s measurement procedure at glucose concentrations less than 4.2 mmol/L (75mg/dL) and within ± 20 % of glucose concentrations greater than or equal to 4.2 mmol/L (75 mg/dL).

The Accu-Chek Compact Glucose Monitoring System meets the ISO 15197 requirements for accuracy. All of the 200 samples (100 %) were within the minimum acceptable performance criteria.

II. INTERMEDIATE PRECISION

Introduction

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

Intermediate precision is defined as 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 Compact blood glucose meters were assigned to this study.

The test strips were dosed with control solution and the process was repeated for each meter over ten days for each assigned level of control solution.

Results

For each control solution, daily for a period of ten days ten different determinations were made on ten Accu-Chek Compact blood glucose meters.

From these 100 determinations, the mean value was calculated and is shown below. Nonparametric methods were used to calculate a confidence interval for the mean standard deviation (SD).

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

Results less than 4.2 mmol/L (75 mg/dL)

Control Solution Level	Mean	Mean SD	95 %Confidence Interval (SD)
	(mmol/L)	(mmol/L)	(mmol/L)
1	2.4	0.07	(0.06, 0.08)
	(mg/dL)	(mg/dL)	(mg/dL)
1	43	1.2	(1.1, 1.4)

Results greater than 4.2 mmol/L (75 mg/dL)

Control Solution Level	Mean	Mean SD	95 %Confidence Interval (SD)	Mean CV
	(mmol/L)	(mmol/L)	(mmol/L)	(%)
2	8.2	0.20	(0.18, 0.23)	2.4
3	16.9	0.42	(0.37, 0.48)	2.4
	(mg/dL)	(mg/dL)	(mg/dL)	(%)
2	148	3.6	(3.2, 4.2)	2.4
3	305	7.5	(6.6, 8.7)	2.4

III. REPEATABILITY

Introduction

The purpose of this study was to determine the repeatability of the Accu-Chek Compact blood glucose system using one Accu-Chek Compact blood glucose strip lot.

Repeatability is defined as 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 Compact blood glucose meters were assigned to this study. One lot of Accu-Chek Compact blood glucose test strips was tested.

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.

The test strips were dosed with blood and the process was repeated for each meter ten times ($n = 100$) for each assigned level of spiked venous blood.

Results

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

Results less than 4.2 mmol/L (75 mg/dL)

Mean	Mean SD	95 %Confidence Interval (SD)
(mmol/L)	(mmol/L)	(mmol/L)
1.8	0.09	(0.08, 0.11)
(mg/dL)	(mg/dL)	(mg/dL)
33	1.7	(1.5, 2.0)

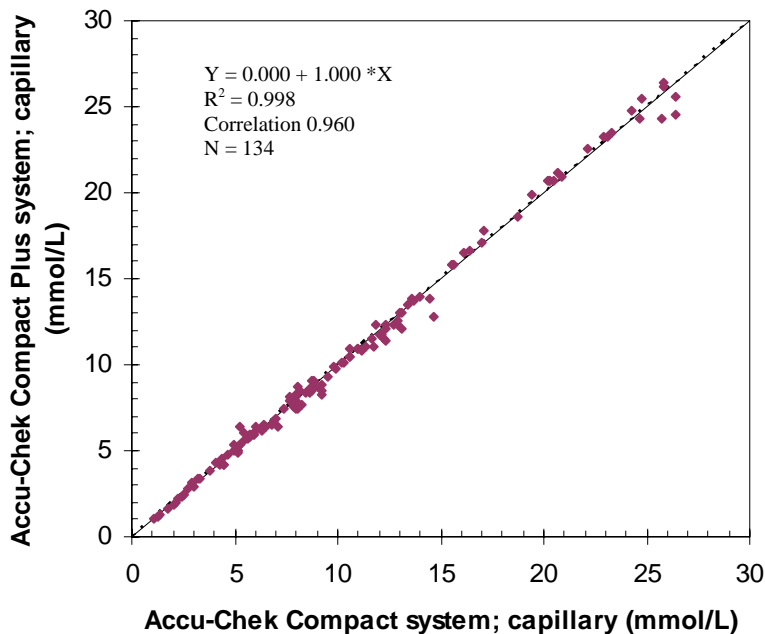
Results greater than 4.2 mmol/L (75 mg/dL)

Mean	Mean SD	95 %Confidence Interval (SD)	Mean CV
(mmol/L)	(mmol/L)	(mmol/L)	(%)
4.6	0.17	(0.15, 0.19)	3.7
7.2	0.22	(0.19, 0.25)	3.0
10.2	0.27	(0.23, 0.31)	2.6
18.8	0.57	(0.50, 0.66)	3.0
(mg/dL)	(mg/dL)	(mg/dL)	(%)
83	3.0	(2.7, 3.5)	3.7
130	3.9	(3.4, 4.5)	3.0
183	4.8	(4.2, 5.6)	2.6
338	10.2	(9.0, 11.9)	3.0

Equivalency Study

Testing was performed at an external site with an Accu-Chek Compact meter and an Accu-Chek Compact Plus meter in direct comparison. The comparison was done with 2 test strip lots. See below for an example of one of the compared lots. After a fingerstick, the blood was applied on each of the 2 systems: Accu-Chek Compact system and the Accu-Chek Compact Plus system. Application was performed by a trained technician with 134 subjects. A comparison of Accu-Chek Compact meter and Accu-Chek Compact Plus meter indicated that both meters produce identical results.

Equivalency Accu-Chek Compact system vs. Accu-Chek Compact Plus system



IV. CONCLUSION

- The Accu-Chek Compact System, and Accu-Chek Compact Plus System meet the accuracy requirement for the ISO 15197 standard.

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