

# Accuracy and Precision Performance of the Accu-Chek Mobile System

## I. ACCURACY

The accuracy of the system was assessed according to ISO 15197.

### Introduction

The purpose of this study was to determine the accuracy of the Accu-Chek Mobile blood glucose system using one Accu-Chek Mobile 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 Mobile glucose test strips. Two Accu-Chek Mobile 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:

<b>% Samples</b>	<b>Glucose concentration (mmol/L)</b>	<b>Glucose concentration (mg/dL)</b>
<b>5</b>	< 2.8	< 50
<b>15</b>	≥ 2.8 – 4.3	≥ 50 – 80
<b>20</b>	> 4.3 – 6.7	> 80 – 120
<b>30</b>	> 6.7 – 11.1	>120 – 200
<b>15</b>	> 11.1 – 16.6	> 200 – 300
<b>10</b>	> 16.6 – 22.2	> 300 – 400
<b>5</b>	> 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).

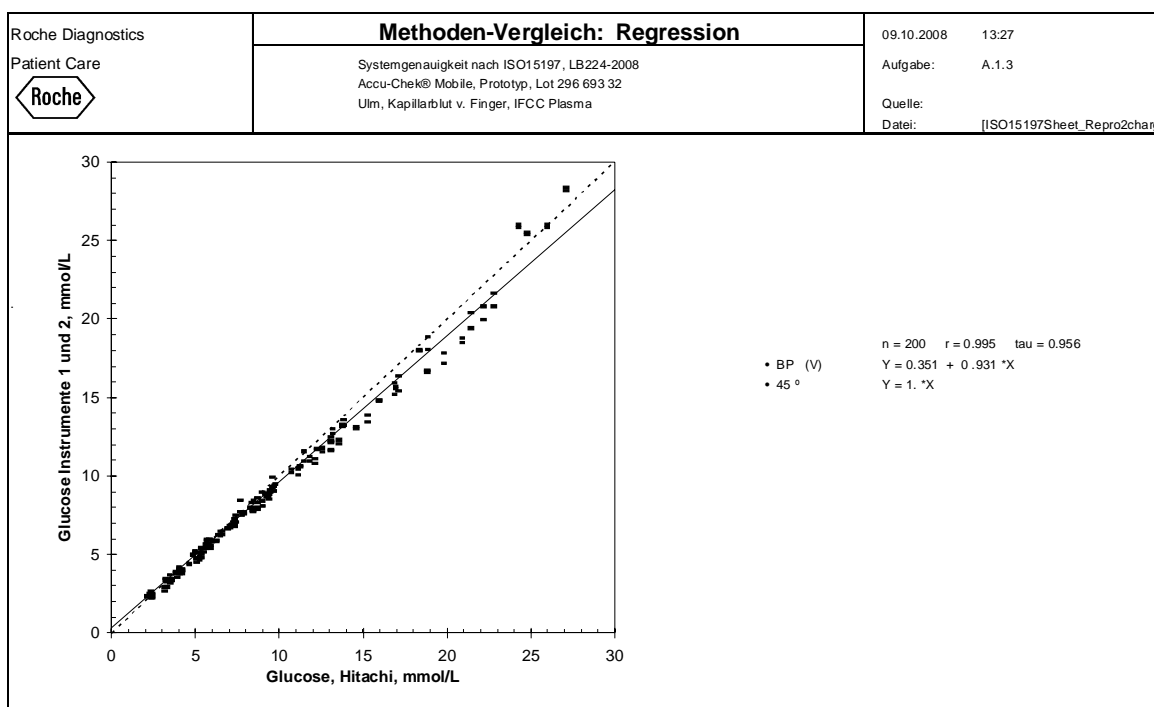
## Results

The Accu-Chek Mobile blood glucose test lot was analyzed by regression analysis according to Bablok/Passing and is summarized in the following table for lot number 296 693 32.

N	Slope	Intercept	Correlation	Slope CI	Int. CI
		(mmol/L)			(mmol/L)
200	0.931	0.351	0.995	(0.918, 0.944)	(0.270, 0.440)
		(mg/dL)			(mg/dL)
200	0.931	6.3	0.995	(0.918, 0.944)	(4.9, 7.9)

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

The capillary data for Accu-Chek Mobile lot # 296 693 32 was analyzed by regression analysis according to Bablok/Passing and is summarized as follows: for the Accu-Chek Mobile Blood Glucose Monitoring System, the regression shows a slope of 0.931 with a 95% confidence interval of (0.918, 0.944). The intercept is 0.351 mmol/L (6.3 mg/dL). The data presented demonstrate a correlation with a value of 0.995. No data were excluded.



The following tables illustrate the bias for Accu-Chek Mobile using test strip lot number 296 693 32.

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

<b>Within ± 0.28 mmol/L</b> (Within ± 5 mg/dl)	<b>Within ± 0.56 mmol/L</b> (within ±10 mg/dl)	<b>Within ± 0.83 mmol/L</b> (within ± 15 mg/dl)
<b>29 / 40 (73 %)</b>	<b>40 / 40 (100 %)</b>	<b>40 / 40 (100 %)</b>

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

<b>Within ± 5 %</b>	<b>Within ± 10 %</b>	<b>Within ± 15 %</b>	<b>Within ± 20 %</b>
<b>101 / 160 (63 %)</b>	<b>153 / 160 (96%)</b>	<b>160 / 160 (100 %)</b>	<b>160 / 160 (100 %)</b>

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 (75 mg/dL) and within ± 20% of glucose concentrations greater than or equal to 4.2 mmol/L (75 mg/dL).

The Accu-Chek Mobile 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 Mobile blood glucose system using one Accu-Chek Mobile blood glucose strip lot and three levels of Accu-Chek Mobile 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 Mobile 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 Mobile blood glucose meters.

From every 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 Mobile control solutions and Accu-Chek Mobile blood glucose test strips:

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

Control Solution Level	Lot	Mean	Mean SD	95%Confidence Interval (SD)
		(mmol/L)	(mmol/L)	(mmol/L)
1	296 693 32	3.56	0.12	(0.1; 0.13)
		(mg/dL)	(mg/dL)	(mg/dL)
1	296 693 32	64.1	2.1	(1.8, 2.3)

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

Control Solution Level	Lot	Mean	Mean SD	95%Confidence Interval (SD)	Mean CV
		(mmol/L)	(mmol/L)	(mmol/L)	(%)
2	296 693 32	9.46	0.12	(0.11; 0.14)	1.3
3	296 693 32	17.86	0.29	(0.26; 0.33)	1.6
		(mg/dL)	(mg/dL)	(mg/dL)	(%)
2	296 693 32	170.5	2.2	(1.9, 2.6)	1.3
3	296 693 32	321.9	5.2	(4.6, 6.0)	1.6

## III. REPEATABILITY

### Introduction

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

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 Mobile blood glucose meters were assigned to this study. One lot of Accu-Chek Mobile 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)
2.4	0.13	(0.12; 0.16)
(mg/dL)	(mg/dL)	(mg/dL)
42.5	2.4	(2.1, 2.8)

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

Mean (mmol/L)	Mean SD (mmol/L)	95%Confidence Interval (SD) (mmol/L)	Mean CV (%)
4,7	0,13	(0.12, 0.16)	2.9
7,3	0,16	(0,14, 0,19)	2.2
9,6	0,19	(0.17, 0.22)	2.0
16,1	0,48	(0.42, 0.56)	3.0
27,3	0,74	(0.65, 0.85)	
(mg/dL)	(mg/dL)	(mg/dL)	(%)
84.3	2.4	(2.1, 2.8)	2.9
131.7	2.9	(2.5, 3.4)	2.2
172.2	3.4	(3.0, 4.0)	2.0
289.9	8.7	(7.6, 10.1)	3.0
491.9	13.3	(11.7, 15.4)	2.7

## IV. CONCLUSION

- The Accu-Chek Mobile System meets the accuracy requirement for the ISO 15197 standard.

Reference:

Internal Data

Roche Diagnostics GmbH; Technical Documentation Accu-Chek Mobile