ACCU-CHEK® Guide Me

SYSTEM EVALUATION

Accu-Chek® Guide Me: System Evaluation

Contents

The Accu-Chek® Guide Me system

Introduction

The Accu-Chek Guide Me blood glucose monitoring system is a unique solution designed to meet the diverse needs of people with diabetes and their healthcare professionals. The system features a proprietary, spill-resistant vial, which lets patients remove a single strip without spilling, and a strip that lets patients place a tiny drop anywhere along the end of the strip, providing a simple solution that can help make blood glucose testing easier.[1] The easy-to-navigate meter interface and intuitive features support simple diabetes management. *Bluetooth®* connectivity to a smartphone app offers quick insights virtually anytime and anywhere, as well as access to additional diabetes management tools.

The system provides excellent accuracy and precision using Accu-Chek Guide test strips, which have undergone a wide range of testing, including studies at external sites and extensive internal testing. Study results demonstrate that the test strips provide accurate and reliable blood glucose measurements under varied conditions, exceeding the performance requirements of the *ISO 15197:2013/EN ISO 15197:2015* standard.[2] This document describes key features of the Accu-Chek Guide Me system and summarises study results for accuracy, precision, haematocrit, and interfering substances.

[1] **Harvey, Craig, Richard Koubek, Vanessa Bégat, and Stephan Jacob. "Usability Evaluation of a Blood Glucose Monitoring System With a Spill-Resistant Vial, Easier Strip Handling, and Connectivity to a Mobile App: Improvement of Patient Convenience and Satisfaction." *Journal of Diabetes Science and Technology* 10, no. 5 (2016): 1136–1141.**

[2] **Roche data on file.**

System features

With a spill-resistant vial, a larger blood application area on the strip, and results automatically logged to an app, the Accu-Chek Guide Me system leads patients to a simple testing experience.[3]

Spill-resistant vial

The strip vial design protects against spills and makes it easy to remove just one strip.

Test strip dosing

The full-end application area allows a tiny drop to be placed anywhere along the yellow edge of the test strip and is the largest dosing area among leading brands.[4]

Fast test time

The test result appears in less than 4 seconds after dosing the strip.

Proven accuracy

The Accu-Chek Guide Me system fulfills the *ISO 15197:2013/EN ISO 15197:2015* standard.[5]

Automatic coding

No coding is needed, resulting in fewer steps in testing.

Intuitive design and user-friendly navigation

The three-button, user-friendly interface is designed for users who want a simple test.

Display

The meter's large, easy-to-read display makes it simple to see test results.

Memory

The meter automatically stores up to 720 blood glucose results in memory with the time and date of the test. Arrow buttons make it easy to access and review stored blood glucose results.

The meter automatically stores up to 30 control results in memory, which can be transferred to compatible software for viewing.

Averages

The system calculates averages from results for the last 7, 14, 30, or 90 days.

Failsafes

Before starting a test and during testing, the system performs extensive quality checks to ensure accurate results.

Bluetooth® connectivity

Bluetooth connectivity can wirelessly transmit results to healthcare apps, displaying data in helpful trends and graphs that can be shared with a healthcare professional.

USB connectivity

If desired, data can be transferred by USB cable from the meter to diabetes management software on a PC or on the web.

[3] **Harvey, Craig, Richard Koubek, Vanessa Bégat, and Stephan Jacob. "Usability Evaluation of a Blood Glucose Monitoring System With a Spill-Resistant Vial, Easier Strip Handling, and Connectivity to a Mobile App: Improvement of Patient Convenience and Satisfaction." *Journal of Diabetes Science and Technology* 10, no. 5 (2016): 1136-1141.**

[4] **Roche data on file.**

[5] **Roche data on file.**

System specifications

The tables below describe the specifications for the Accu-Chek Guide Me meter and Accu-Chek Guide test strips.

System specifications

Category	Specification
Measurement principle	FAD glucose dehydrogenase (GDH), electrochemical
Range of measurement	0.6 to 33.3 mmol/L
Measuring time	Less than 4 seconds
Operating temperature	4°C to 45°C (39°F to 113°F)
Operating humidity	10% to 90%
Test strip expiration	18 months after production date. Test strips remain stable up to the expiration date printed on test strip vial, even after opening (test strip container must be tightly closed after each test strip is removed).
Sample volume	0.6 µL
Hematocrit range	10% to 65%
Altitude	Up to 3,094 meters (10,150 feet) above sea level
Sample types	Capillary, venous, arterial, neonatal
Test sites	Fingertip, palm, forearm, upper arm
Reference method	Hexokinase with deproteinisation, converted into plasma values according to IFCC recommendation

Meter specifications

Category	Specification
Meter storage temperature	-25°C to 70°C (-13°F to 158°F)
Memory capacity	720 blood glucose results viewable on meter with time and date 30 control results with time and date
Automatic off	90 seconds after performing a test, 15 seconds after a test strip is removed
Power supply	Two 3-volt lithium batteries (coin cell type CR2032)
Display	LCD
Dimensions	76 mm length × 48 mm width × 16 mm height
Weight	Approximately 43 g (with batteries)
Construction	Hand-held
Protection class	III
Meter type	Suitable for continuous operation
Interfaces Continua CERTIFIED	USB: micro-B connector; Bluetooth Low Energy; Continua Certified® to a Continua Certified manager
Radio frequency connectivity	Bluetooth low energy technology operating in the frequency band of 2.4 GHz (2.402 GHz to 2.480 GHz) with a maximum transmitted power of 0 dBm (1 mW)

Strip technology

Measurement principle

When an Accu-Chek Guide test strip is inserted into the Accu-Chek Guide Me meter, a small alternating current (AC) is applied until the application of blood causes a sharp increase in the conductivity observed at the measurement and sample-sufficiency electrodes on the test strip. Both electrodes are used to assure an adequate sample has been applied.

Once a sufficient sample has been detected, the meter applies a series of AC voltages at four frequencies and reads the AC responses. These responses carry information about the sample type and environmental temperature, and also allow the system to perform various internal quality checks.

After the AC measurements are completed, a series of four ramped direct current (DC) pulses are applied and the current is observed, which is proportionate to the glucose. The AC and DC information are then combined to provide a haematocrit and temperature-compensated glucose result.

Dosing area

The Accu-Chek Guide test strip design allows a small blood sample to be placed anywhere along the yellow edge on the end of the test strip. It is the widest application area among leading brands.[6]

Accu-Chek Guide Test Strip

[6] **Roche data on file.**

Performance Evaluation

Capillary whole blood accuracy (technician)

Study design

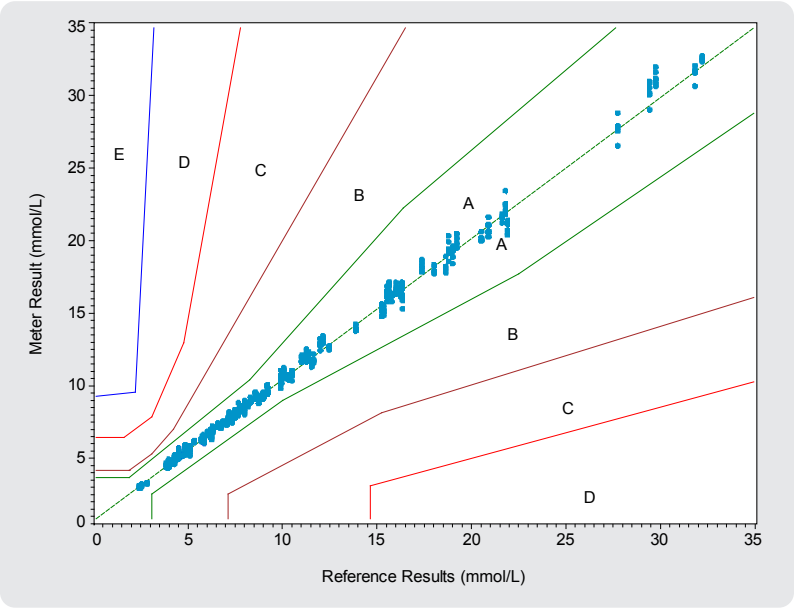
Technicians at one participating facility performed capillary finger sticks on patients. Two glucose test strips from three individual strip lots were dosed for each subject, for a total of 200 glucose meter results per lot. Meter results were compared to whole blood reference samples.[7]

Acceptance Criteria *(ISO 15197:2013/EN ISO 15197:2015)*:

- ≥95% of the individual glucose measured values shall fall within ±0.83 mmol/L of the reference results at glucose concentrations <5.6 mmol/L or within ±15% at glucose concentrations ≥5.6 mmol/L.
- ≥99% of individual glucose measured values shall fall within zones A and B of the Consensus Error Grid (CEG) for Type 1 diabetes.

Results (pooled strip lots)

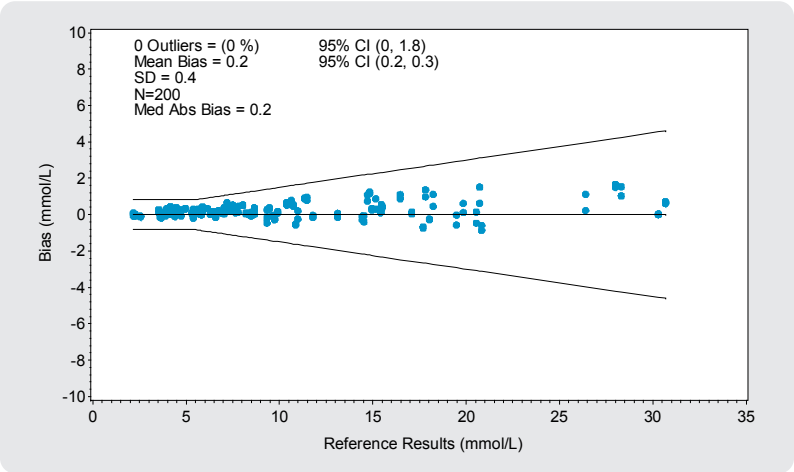
Subjects	100
Glucose Range (Reference)	2.2 to 30.7 mmol/L
Haematocrit Range (Reference)	32% to 51%



Zone	Description	Results
A	No effect on clinical action	**100% (600/600)**
B	Altered clinical action—little or no effect on clinical outcome	0% (0/600)
C	Altered clinical action—likely to affect clinical outcome	0% (0/600)
D	Altered clinical action—could have significant medical risk	0% (0/600)
E	Altered clinical action—could have dangerous consequences	0% (0/600)

[7] **Testing performed with Accu-Chek Guide meters. Roche data on file showing equivalency of Accu-Chek Guide Me meter to Accu-Chek Guide meter.**

Results (strip lot 1)



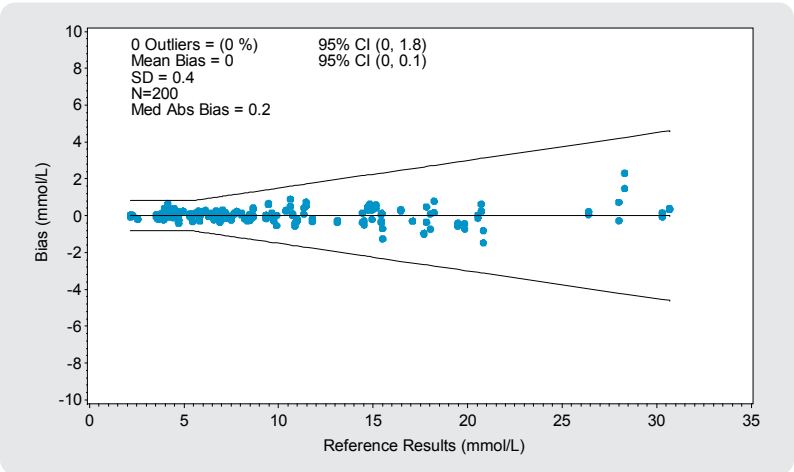
Results <5.6 mmol/L

Within ±0.28 mmol/L	Within ±0.56 mmol/L	Within ±0.83 mmol/L
83.3% (50/60)	100.0% (60/60)	100.0% (60/60)

Results ≥5.6 mmol/L

Within ±5%	Within ±10%	Within ±15%
75.0% (105/140)	100.0% (140/140)	100.0% (140/140)

Results (strip lot 2)



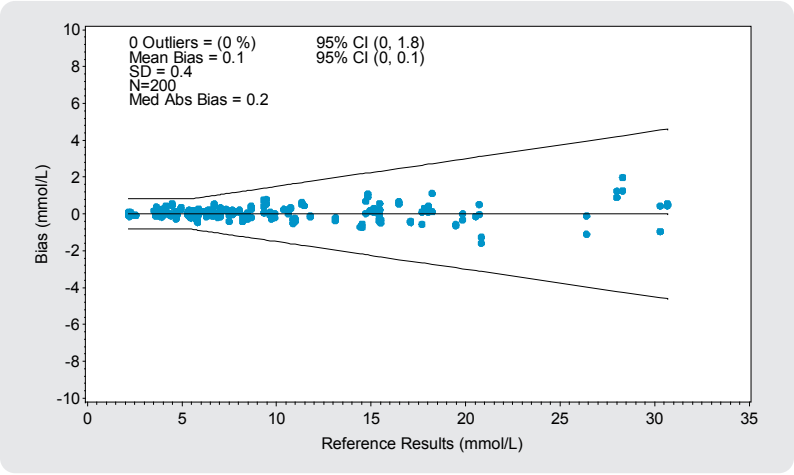
Results <5.6 mmol/L

Within ±0.28 mmol/L	Within ±0.56 mmol/L	Within ±0.83 mmol/L
86.7% (52/60)	98.3% (59/60)	100.0% (60/60)

Results ≥5.6 mmol/L

Within ±5%	Within ±10%	Within ±15%
90.0% (126/140)	100.0% (140/140)	100.0% (140/140)

Results (Strip lot 3)



Results <5.6 mmol/L

Within ±0.28 mmol/L	Within ±0.56 mmol/L	Within ±0.83 mmol/L
90.0% (54/60)	98.3% (59/60)	100.0% (60/60)

Results ≥5.6 mmol/L

Within ±5%	Within ±10%	Within ±15%
87.9% (123/140)	100.0% (140/140)	100.0% (140/140)

Conclusion

100% of the data are within the bias requirements, and 100% of the results fall within Zone A of the Consensus Error Grid, clearly exceeding the acceptance criteria. These data demonstrate that the system provides accurate results with capillary blood and results meet *ISO 15197:2013/EN ISO 15197:2015* requirements.

Capillary whole blood accuracy (patient)

Study design

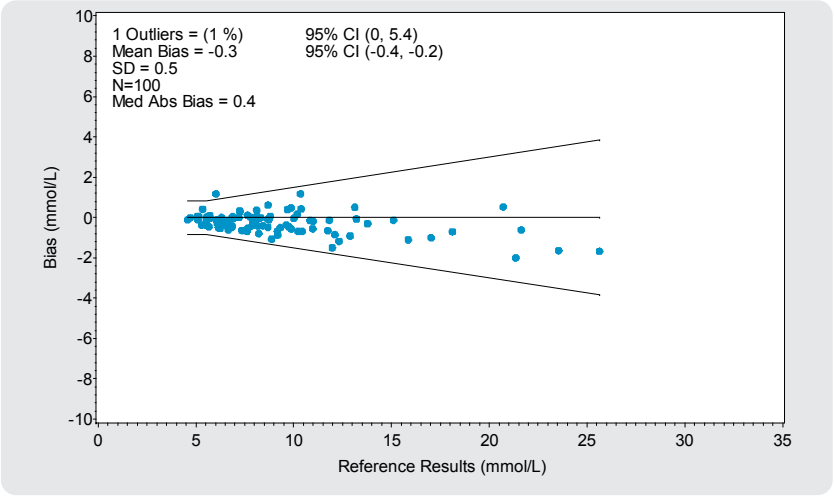
Patients at one facility were asked to read the labeling provided with the system and to subsequently perform a finger stick and dose a test strip from one strip lot. The patients were given no instruction by a trained technician. The subjects' results were compared to whole blood reference samples. [8]

Acceptance Criteria *(ISO 15197:2013/EN ISO 15197:2015)*:

- ≥95% of the individual glucose measured values shall fall within ±0.83 mmol/L of the reference results at glucose concentrations <5.6 mmol/L and within ±15% at glucose concentrations ≥5.6 mmol/L.

Results

Subjects	100
Glucose Range (Reference)	4.6 to 25.6 mmol/L
Haematocrit Range (Reference)	34% to 50%



Results <5.6 mmol/L

Within ±0.28 mmol/L	Within ±0.56 mmol/L	Within ±0.83 mmol/L
66.7% (6/9)	100.0% (9/9)	100.0% (9/9)

Results ≥5.6 mmol/L

Within ±5%	Within ±10%	Within ±15%
58.2% (53/91)	95.6% (87/91)	98.9% (90/91)

Conclusion

99% of the data are within the bias requirements, clearly exceeding the acceptance criteria. These data demonstrate that the untrained user can obtain accurate results with capillary blood, and results meet *ISO 15197:2013/EN ISO 15197:2015* requirements.

[8] **Testing performed with Accu-Chek Guide meters. Roche data on file showing equivalency of Accu-Chek Guide Me meter to Accu-Chek Guide meter.**

Venous whole blood accuracy

Study design

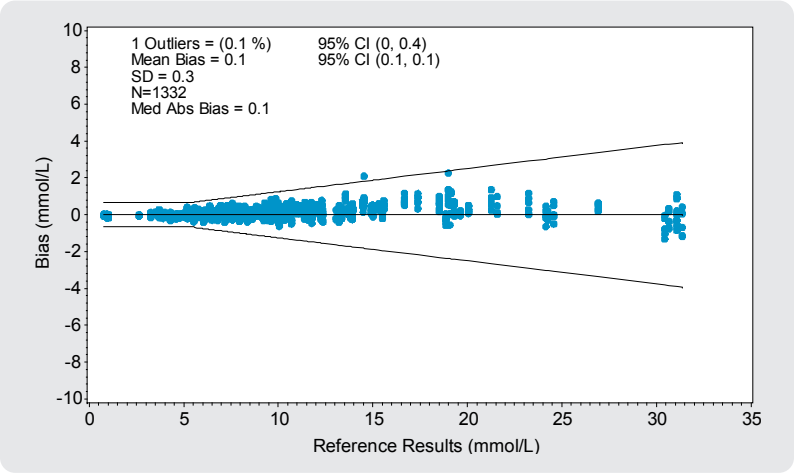
Technicians at one clinical site collected blood via venipuncture. Test strips from three independent lots were then dosed with the venous blood samples by the technicians. Two test strips were tested for each of three lots. Meter results were compared to whole blood reference samples. [9]

Acceptance Criteria *(CLSI POCT12-A3)*:

- ≥95% of the individual results shall fall within ±0.67 mmol/L of the reference results at glucose concentrations <5.6 mmol/L and within ±12.5% at glucose concentrations ≥5.6 mmol/L.
- ≥98% of the individual results shall fall within ±0.83 mmol/L of the reference results at glucose concentrations <4.2 mmol/L and within ±20% at glucose concentrations ≥4.2 mmol/L.

Results (pooled strip lots)

Subjects	222
Glucose Range (Reference)	0.8 to 31.4 mmol/L
Haematocrit Range (Reference)	31 to 53%



Results <5.6 mmol/L

Lot	Within ±0.28 mmol/L	Within ±0.56 mmol/L	Within ±0.67 mmol/L
1	96.1% (73/76)	100.0% (76/76)	100.0% (76/76)
2	97.4% (74/76)	100.0% (76/76)	100.0% (76/76)
3	97.4% (74/76)	100.0% (76/76)	100.0% (76/76)

Results ≥5.6 mmol/L

Lot	Within ±5%	Within ±10%	Within ±12.5%
1	92.9% (342/368)	99.7% (367/368)	100.0% (368/368)
2	91.6% (337/368)	100.0% (368/368)	100.0% (368/368)
3	96.7% (356/368)	99.7% (367/368)	99.7% (367/368)

[9] **Testing performed with Accu-Chek Guide meters. Roche data on file showing equivalency of Accu-Chek Guide Me meter to Accu-Chek Guide meter.**

Results <4.2 mmol/L

Lot	Within ±0.28 mmol/L	Within ±0.56 mmol/L	Within ±0.83 mmol/L
1	100.0% (36/36)	100.0% (36/36)	100.0% (36/36)
2	100.0% (36/36)	100.0% (36/36)	100.0% (36/36)
3	97.2% (35/36)	100.0% (36/36)	100.0% (36/36)

Results ≥4.2 mmol/L

Lot	Within ±5%	Within ±10%	Within ±15%	Within ±20%
1	92.9% (379/408)	99.8% (407/408)	100.0% (408/408)	100.0% (408/408)
2	91.2% (372/408)	100.0% (408/408)	100.0% (408/408)	100.0% (408/408)
3	96.3% (393/408)	99.8% (407/408)	100.0% (408/408)	100.0% (408/408)

Conclusion

99.9% of the data for all lots combined are within the first bias requirement and 100% are within the second bias requirement, clearly exceeding the acceptance criteria. These data confirm that the system provides accurate results with venous blood samples.

Arterial whole blood accuracy

Study design

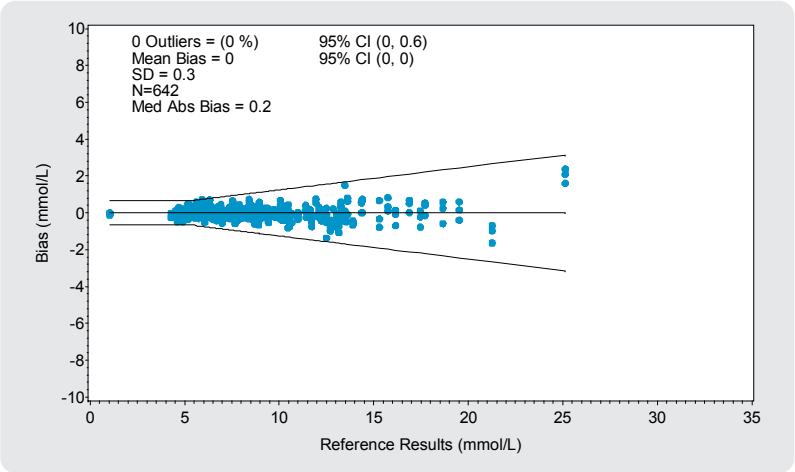
Technicians at one clinical site collected arterial blood using their standard operating procedure. Test strips from three independent lots were then dosed with the arterial blood samples by the technicians. Meter results were compared to whole blood reference samples. [10]

Acceptance Criteria *(CLSI POCT12-A3)*:

- ≥95% of the individual results shall fall within ±0.67 mmol/L of the reference results at glucose concentrations <5.6 mmol/L and within ±12.5% at glucose concentrations ≥5.6 mmol/L.
- ≥98% of the individual results shall fall within ±0.83 mmol/L of the reference results at glucose concentrations <4.2 mmol/L and within ±20% at glucose concentrations ≥4.2mmol/L.

Results (pooled strip lots)

Subjects	214
Glucose Range (Reference)	1.0 to 25.1 mmol/L
Haematocrit Range (Reference)	18 to 59%



Results <5.6 mmol/L

Lot	Within ±0.28 mmol/L	Within ±0.56 mmol/L	Within ±0.67 mmol/L
1	88.9% (32/36)	100.0% (36/36)	100.0% (36/36)
2	88.9% (32/36)	100.0% (36/36)	100.0% (36/36)
3	86.1% (31/36)	100.0% (36/36)	100.0% (36/36)

Results ≥5.6 mmol/L

Lot	Within ±5%	Within ±10%	Within ±12.5%
1	90.4% (161/178)	99.4% (177/178)	100.0% (178/178)
2	89.3% (159/178)	98.3% (175/178)	100.0% (178/178)
3	87.6% (156/178)	98.9% (176/178)	100.0% (178/178)

[10] **Testing performed with Accu-Chek Guide meters. Roche data on file showing equivalency of Accu-Chek Guide Me meter to Accu-Chek Guide meter.**

Results <4.2 mmol/L

Lot	Within ±0.28 mmol/L	Within ±0.56 mmol/L	Within ±0.83 mmol/L
1	100.0% (1/1)	100.0% (1/1)	100.0% (1/1)
2	100.0% (1/1)	100.0% (1/1)	100.0% (1/1)
3	100.0% (1/1)	100.0% (1/1)	100.0% (1/1)

Results ≥4.2 mmol/L

Lot	Within ±5%	Within ±10%	Within ±15%	Within ±20%
1	89.7% (191/213)	99.5% (212/213)	100.0% (213/213)	100.0% (213/213)
2	88.7% (189/213)	98.6% (210/213)	100.0% (213/213)	100.0% (213/213)
3	86.9% (185/213)	98.6% (210/213)	100.0% (213/213)	100.0% (213/213)

Conclusion

100% of the data for all lots combined are within both sets of bias requirements, clearly exceeding the acceptance criteria. These data confirm that the system provides accurate results with arterial blood samples.

Neonatal capillary whole blood accuracy

Study design

Studies were conducted to assess the accuracy of the system with neonatal capillary blood samples. Technicians at one participating facility performed capillary heel sticks on newborns (less than 30 days old) and dosed test strips from three independent strip lots. Meter results were compared to whole blood reference samples. [11]

Acceptance Criteria *(CLSI POCT12-A3)*:

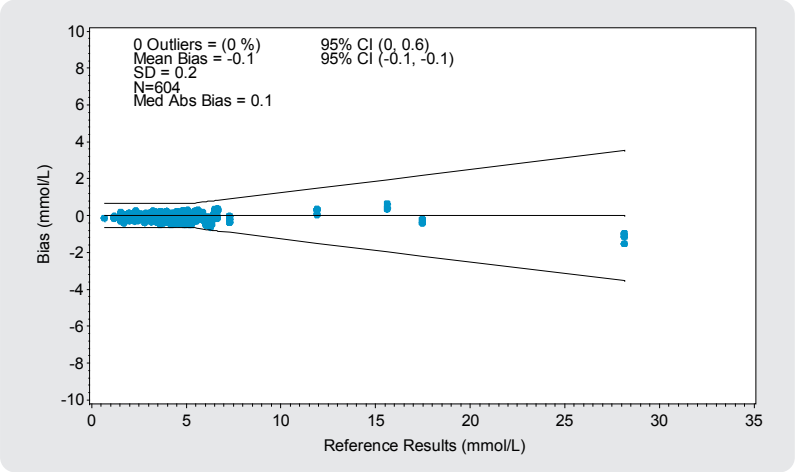
- ≥95% of the individual results shall fall within ±0.67 mmol/L of the reference results at glucose concentrations <5.6 mmol/L and within ±12.5% at glucose concentrations ≥5.6 mmol/L.
- ≥98% of the individual results shall fall within ±0.83 mmol/L of the reference results at glucose concentrations <4.2 mmol/L and within ±20% at glucose concentrations ≥4.2 mmol/L.

Additional Criteria:

- The mean bias shall not be significantly higher than 0.28 mmol/L nor significantly lower than -0.28 mmol/L for all results <2.8 mmol/L.

All results (pooled strip lots)

Subjects	201 (Lot 1 & Lot 2), 202 (Lot 3)
Glucose Range (Reference)	0.7 to 28.2 mmol/L
Haematocrit Range (Reference)	19 to 62%



Results <5.6 mmol/L

Lot	Within ±0.28 mmol/L	Within ±0.56 mmol/L	Within ±0.67 mmol/L
1	92.8% (167/180)	100.0% (180/180)	100.0% (180/180)
2	90.0% (162/180)	100.0% (180/180)	100.0% (180/180)
3	82.3% (149/181)	100.0% (181/181)	100.0% (181/181)

Results ≥5.6 mmol/L

Lot	Within ±5%	Within ±10%	Within ±12.5%
1	90.5% (19/21)	100.0% (21/21)	100.0% (21/21)
2	81.0% (17/21)	100.0% (21/21)	100.0% (21/21)
3	81.0% (17/21)	100.0% (21/21)	100.0% (21/21)

[11] **Testing performed with Accu-Chek Guide meters. Roche data on file showing equivalency of Accu-Chek Guide Me meter to Accu-Chek Guide meter.**

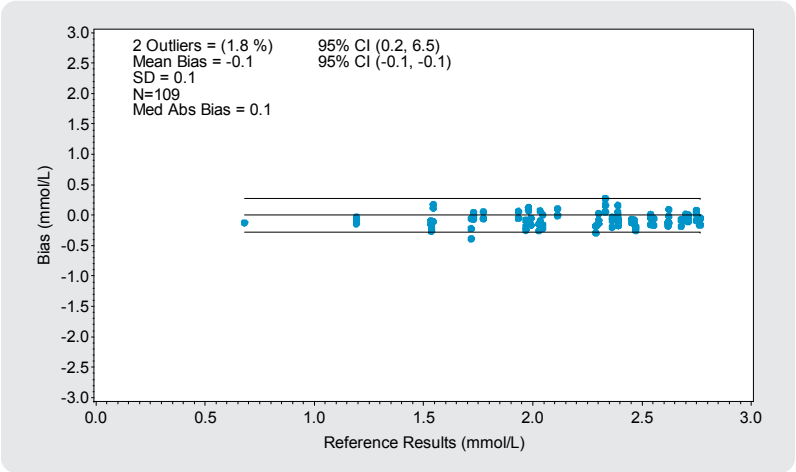
Results <4.2 mmol/L

Lot	Within ±0.28 mmol/L	Within ±0.56 mmol/L	Within ±0.83 mmol/L
1	97.4% (111/114)	100.0% (114/114)	100.0% (114/114)
2	95.6% (109/114)	100.0% (114/114)	100.0% (114/114)
3	90.4% (104/115)	100.0% (115/115)	100.0% (115/115)

Results ≥4.2 mmol/L

Lot	Within ±5%	Within ±10%	Within ±15%	Within ±20%
1	79.3% (69/87)	100.0% (87/87)	100.0% (87/87)	100.0% (87/87)
2	75.9% (66/87)	100.0% (87/87)	100.0% (87/87)	100.0% (87/87)
3	63.2% (55/87)	98.9% (86/87)	100.0% (87/87)	100.0% (87/87)

Results below 2.8 mmol/L (pooled strip lots)



Results <2.8 mmol/L

N	Mean Bias (mmol/L)
109	-0.1

Conclusion

100% of the data for all lots combined are within both sets of bias requirements, clearly exceeding the acceptance criteria. In addition, results under 2.8 mmol/L show minimal mean bias. These data confirm that the system provides accurate results with neonatal blood samples, including samples with very low glucose levels (less than 2.8 mmol/L).

System precision—intermediate precision

Study design

Intermediate precision of the system was assessed using aqueous control solutions. Ten vials of test strips from each of three lots were allocated per target glucose level. Ten replicates per vial were collected, and the overall standard deviation (SD) or coefficient of variation (CV) (based on glucose level) was calculated using results from all vials and strip lots.[12]

Control Solutions:

- **Low:** 1.7 to 3.3 mmol/L
- **Mid:** 5.5 to 7.4 mmol/L
- **High:** 14.0 to 19.0 mmol/L

Acceptance Criteria:

- Standard deviation (SD) shall be ≤0.17 mmol/L at glucose concentrations <5.6 mmol/L.
- Coefficient of variation (CV) shall be ≤3.0% at glucose concentrations ≥5.6 mmol/L.

Results (pooled strip lots)

Level	Mean	SD	CV
Low	2.5	0.1	—
Mid	6.5	—	2.4
High	16.5	—	2.3

Conclusion

All acceptance criteria are clearly met. In fact, with all strip lots pooled, the SD value is 0.1 mmol/L for glucose concentrations less than 5.6 mmol/L, and CV values are at or below 2.4% for concentrations above 5.6 mmol/L. These data indicate that the system provides precise results with control solutions.

[12] **Testing performed with Accu-Chek Guide meters. Roche data on file showing equivalency of Accu-Chek Guide Me meter to Accu-Chek Guide meter.**

System precision—repeatability

Study design

Repeatability of the system was assessed using venous blood samples. Ten vials of test strips from each of three lots were allocated per target glucose level. Ten replicates per vial were collected, and the overall SD or CV (based on glucose level) was calculated using results from all vials and strip lots.[13]

Venous Blood Samples:

- **Level 1:** 1.7 to 2.8 mmol/L
- **Level 2:** 2.8 to 6.1 mmol/L
- **Level 3:** 6.2 to 8.3 mmol/L
- **Level 4:** 8.4 to 13.9 mmol/L
- **Level 5:** 13.9 to 22.2 mmol/L

Acceptance Criteria:

- Standard deviation (SD) shall be ≤0.22 mmol/L at glucose concentrations <5.6 mmol/L.
- Coefficient of variation (CV) shall be ≤4.0% at glucose concentrations ≥5.6 mmol/L.

Results (pooled strip lots)

Level	Mean	SD	CV
1	2.3	0.1	—
2	4.5	0.1	—
3	7.3	—	2.1
4	11.5	—	2.6
5	18.3	—	2.6

Conclusion

All acceptance criteria are clearly met. In fact, with all strip lots pooled, the SD values are at or below 0.1 mmol/L for glucose concentrations less than 5.6 mmol/L, and CV values are at or below 2.6% for concentrations above 5.6 mmol/L. These data indicate that the system provides precise results with venous blood.

[13] **Testing performed with Accu-Chek Guide meters. Roche data on file showing equivalency of Accu-Chek Guide Me meter to Accu-Chek Guide meter.**

Impact of hematocrit

Study design

Five levels of glycolised venous blood were tested with various hematocrit levels to determine the impact of haematocrit on the performance of the system. Meter results were compared to a sample at nominal hematocrit (42%).[14]

Target Glucose Levels:

- 2.2 mmol/L
- 4.4 mmol/L
- 7.0 mmol/L
- 11.1 mmol/L
- 18.0 mmol/L

Haematocrit Levels:

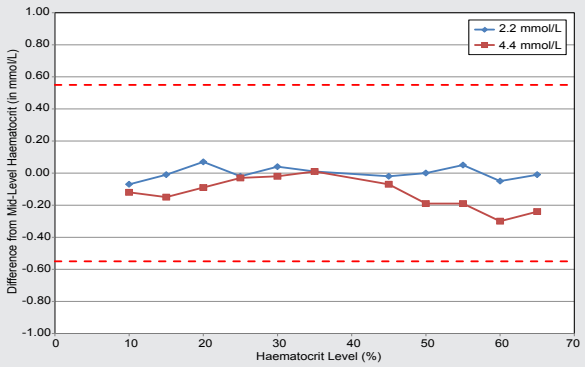
- 10%, 15%, 20%, 25%, 30%, 35%
- 45%, 50%, 55%, 60%, 65%

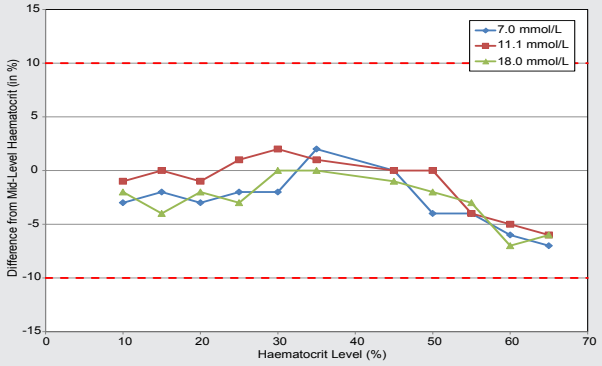
Acceptance Criteria *(ISO 15197:2013/EN ISO 15197:2015)*:

- Mean bias (to reference glucose) shall not exceed ±0.56 mmol/L to the nominal hematocrit sample (42%) mean bias (to reference glucose) at glucose concentrations <5.6 mmol/L.
- Mean bias (to reference glucose) shall not exceed ±10% to the nominal haematocrit sample (42%) mean bias (to reference glucose) at glucose concentrations ≥5.6 mmol/L.

Results

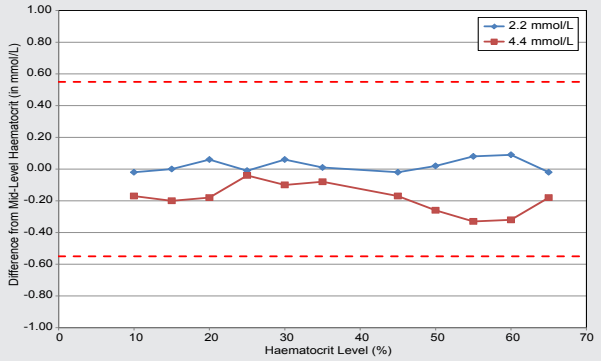
Strip lot 1

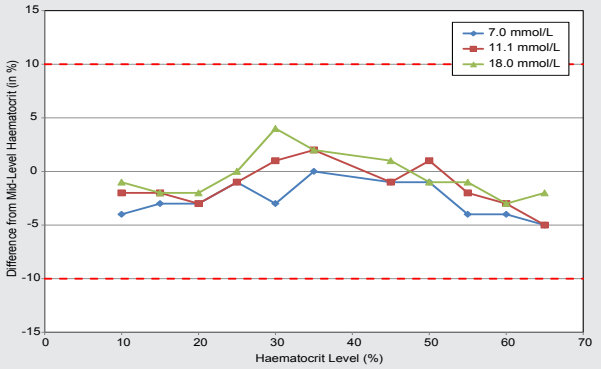




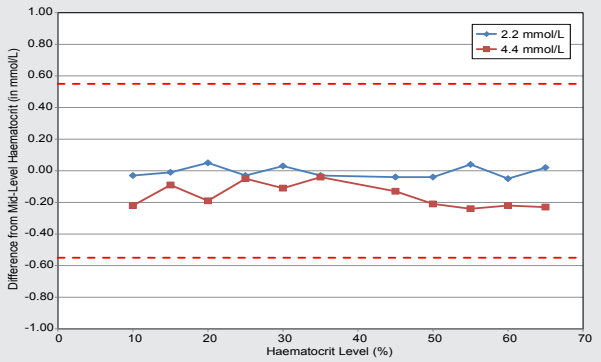
[14] **Testing performed with Accu-Chek Guide meters. Roche data on file showing equivalency of Accu-Chek Guide Me meter to Accu-Chek Guide meter.**

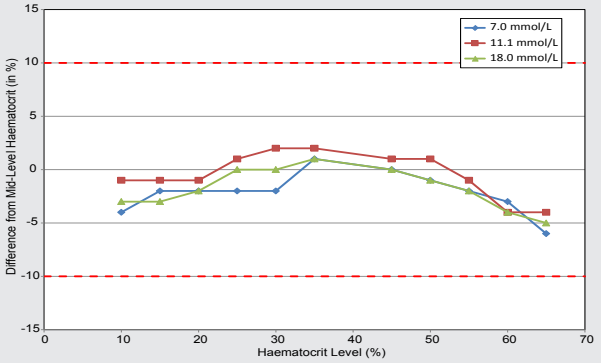
Strip lot 2





Strip lot 3





Conclusion

Data from all three lots confirm that the system supports a claimed haematocrit range of 10% to 65% and meets *ISO 15197:2013/EN ISO 15197:2015* requirements.

Impact of potentially interfering substances

The system has been thoroughly evaluated with potential interfering substances.[15] Substances were tested at concentrations described by the Clinical Lab Standard Institute in document *EP07-A2 — Interference Testing in Clinical Chemistry; Approved Guideline*, when available. Testing was conducted according to the *ISO 15197:2013/EN ISO 15197:2015* standard. Many of the endogenous and exogenous compounds were evaluated at concentrations three or more times therapeutic plasma concentrations. Each medication and metabolite was evaluated at the following target glucose levels to ensure accuracy:

- 2.8 to 5.6 mmol/L
- 13.9 to 19.4 mmol/L

Test results indicate that the system provides accurate results in the presence of the substances tested, generally well beyond the therapeutic or physiologic range. See the table below for a list of the substances evaluated, along with the concentration tested and the upper therapeutic concentration. All concentrations are in terms of mmol/L unless noted otherwise.

Note: Concentrations below are shown in exponential notation, in order to display values in a uniform manner across the wide range of concentrations. To convert these values:

- **Positive Exponent:** Move the decimal point to the right by the number of places specified by the exponent (number after E).

  For example, Acetone Highest Concentration Tested: 1.03E+01 = 1.03 x 10 = 10.3 mmol/L
- **Negative Exponent:** Move the decimal point to the left by the number of places specified by the exponent (number after E).

  For example, Acetone Upper Therapeutic Concentration: 1.70E–01 = 1.70 / 10 = 0.17 mmol/L
- **00 Exponent:** Use the stated value with no adjustment.

  For example, Acetaminophen Highest Concentration Tested: 1.32E+00 = 1.32 mmol/L

Substance	Highest Concentration Tested (mmol/L)	Upper Therapeutic Concentration (mmol/L)
Acarbose	9.30E-01	1.56E-04
Acetaminophen	1.32E+00	3.44E-01
Acetazolamide	2.70E-01	8.56E-02
Acetone	1.03E+01	1.70E-01
N-Acetyl-L-Cysteine	1.23E+00	3.07E-01
N-Acetylprocainamide	5.40E-01	3.61E-02
Acetylsalicylic Acid	3.33E+00	5.55E-02
Acyclovir	2.20E-01	9.77E-02
Albumin	7.60E-01	8.20E-01
Albuterol	1.05E+00	6.30E-05

[15] **Testing performed with Accu-Chek Guide meters. Roche data on file showing equivalency of Accu-Chek Guide Me meter to Accu-Chek Guide meter.**

Substance	Highest Concentration Tested (mmol/L)	Upper Therapeutic Concentration (mmol/L)
Allopurinol	3.70E-01	1.47E-01
Aminocaproic Acid	3.05E+00	1.53E+00
Amiodarone	7.00E-02	2.17E-02
Amitriptyline	4.00E-02	5.78E-04
Amoxapine	3.00E-03	2.96E-04
Amoxicillin	1.64E+01	4.93E-02
Ampicillin	1.50E-01	7.16E-02
Astemizole	2.00E-02	2.18E-04
Atorvastatin	1.79E-03	4.48E-04
Atropine	3.00E-02	6.92E-04
Benserazide	2.00E-02	5.05E-03
Bile Acids	4.00E-02	1.70E-02
Bilirubin (conjugated)	1.03E+00	3.40E-03
Bilirubin (unconjugated)	1.03E+00	1.90E-02
Bromide	3.80E+01	3.80E+01
Buspirone	3.00E-02	5.19E-06
Caffeine	5.20E-01	1.85E-01
Calcium Chloride	5.00E+00	2.75E+00
Captopril	2.00E-02	4.05E-03
Carbamazepine	1.30E-01	6.35E-02
Beta-Carotene	1.00E-02	3.70E-03
Cefaclor	5.40E+00	6.32E-02
Cefadroxil	2.80E-01	9.91E-02
Ceftriaxone	1.80E+00	1.01E+00
Cephalexin	9.20E-01	1.86E-01
Cephalothin	5.06E+00	1.91E+00
Cetirizine	2.00E-02	3.73E-03
Chenodeoxycholic Acid	8.00E-02	2.50E-03
Chlorothiazide	9.13E-02	3.04E-02
Chlorpropamide	2.89E+00	7.95E-01
Cholesterol	1.30E+01	7.75E+00
Cholic Acid	6.00E-02	1.50E-03
Cimetidine	4.00E-01	3.96E-02
Citalopram	1.85E-02	5.58E-03
Citric Acid	1.56E+00	1.60E-01
Clindamycin	9.00E-02	4.00E-02
Clonidine	9.00E-02	2.80E-05
Creatinine	2.65E+00	1.30E-01
Cyclophosphamide	1.44E+00	7.01E-01
L-Cysteine	4.10E-01	1.16E-01

Substance	Highest Concentration Tested (mmol/L)	Upper Therapeutic Concentration (mmol/L)
L-Cystine	2.08E+00	1.17E-01
Desipramine	4.00E-03	2.55E-03
Dexamethasone	3.06E-02	1.13E-02
Dextromethorphan	4.00E-02	1.90E-05
Diclofenac	1.70E-01	2.70E-02
Dicumarol	1.80E-01	1.75E-01
Digoxin	1.00E-02	1.70E-05
Diltiazem	4.40E-01	7.24E-04
Diphenhydramine	3.00E-02	1.01E-03
Dipyrone	3.30E-01	undetermined
Disopyramide	1.50E-01	1.65E-02
L-Dopa	1.00E-01	1.27E-02
Dopamine	1.00E-02	1.35E-03
Doxazosin	2.00E-02	2.24E-04
Doxycycline	6.00E-02	1.35E-02
EDTA dipotassium	8.90E+00	1.13E-03
EDTA disodium calcium	4.81E+00	1.13E-03
Enalapril	1.60E-01	7.25E-04
Ephedrine	6.00E-02	5.00E-05
Equilin	5.60E-01	1.86E-02
Erythromycin	8.20E-01	6.27E-02
Estradiol	4.00E-03	9.18E-09
Estrone	4.00E-02	3.70E-07
Ethanol	7.60E+01	4.34E+01
Ethosuximide	1.77E+00	7.08E-01
Ethyl Acetoacetate	1.54E+00	1.50E-01
Ethylene Glycol	8.10E-01	2.42E-02
Famotidine	2.00E-02	2.41E-03
Felodipine	1.30E-01	2.50E-05
Fenofibrate	1.40E-01	4.16E-02
Fenoprofen	8.30E-01	2.68E-01
Flecainide	2.00E-02	4.13E-03
5-Fluorocytosine	2.32E+00	5.27E-01
Fluoxetine	3.90E-01	1.53E-03
Flurbiprofen	2.00E-01	6.55E-02
Fluticasone	2.25E-03	8.41E-07
Fructose	1.39E+01	3.30E-01
Furosemide	1.80E-01	1.60E-02
Galactose	1.67E+01	3.33E+00

Substance	Highest Concentration Tested (mmol/L)	Upper Therapeutic Concentration (mmol/L)
Galactose-1-Phosphate	1.20E-01	7.00E-03
Gamma Globulins	3000 mg/dL	1600 mg/dL
Gemfibrozil	6.00E-01	1.84E-01
Gentamicin	8.00E-02	2.22E-02
Gentisic Acid	1.20E-01	3.24E-02
Glimepiride	2.00E-02	1.12E-03
Glipizide	1.80E-01	2.24E-03
Glucosamine	2.51E+01	1.30E-01
Glutathione (reduced)	2.00E-01	2.00E-02
Glyburide	3.00E-02	4.86E-04
Glycerol	1.09E+00	1.96E-01
Hemoglobin	10 g/L	2.5 g/L
Heparin (Li)	8000 U/dL	110 U/dL
Heparin (Na)	8000 U/dL	110 U/dL
Hydrochlorothiazide	2.00E-02	1.26E-03
Hydrocortisone	3.00E-02	6.00E-04
DL-Beta-Hydroxybutyric Acid	9.61E+00	2.70E-01
Hydroxychloroquine Sulfate	1.20E-01	3.90E-04
Ibandronic Acid	2.00E-02	1.00E-03
Ibuprofen	2.43E+00	3.54E-01
Indomethacin	1.40E-01	1.23E-02
Insulin	20 U/dL	0.004 U/dL
Isoniazid	3.60E-01	1.46E-01
Kanamycin	1.86E-01	6.19E-02
Lactic Acid	1.11E+01	2.20E+00
Lactitol	2.90E+00	undetermined
Lactose	2.90E-01	1.50E-02
Lecithin	1.60E+01	1.19E+01
Lidocaine	1.00E-01	2.13E-02
Lisinopril	2.00E-02	2.02E-04
Loratadine	3.00E-02	9.00E-05
Lovastatin	1.00E-02	1.73E-04
Magnesium Sulfate	2.16E+00	2.16E-01
Maltitol	5.90E-01	undetermined
Maltose	1.52E+00	3.51E+00
D-Mannitol	3.30E+01	undetermined
D-Mannose	5.60E-01	undetermined
Metaproterenol	9.00E-02	6.00E-05
Metformin	3.88E+00	3.10E-02

Substance	Highest Concentration Tested (mmol/L)	Upper Therapeutic Concentration (mmol/L)
Methimazole	2.00E-02	7.27E-03
Methyl Dopa	7.00E-02	3.55E-02
Methylhydroxyprogesterone	1.45E+00	2.00E-08
Metoclopramide	1.49E-02	2.50E-03
Metoprolol Tartrate	3.00E-02	1.87E-03
Mexiletine	6.00E-02	1.39E-02
Misoprostol	2.00E-02	2.12E-06
Nadolol	6.00E-02	1.10E-04
Naproxen	4.35E+00	5.21E-01
Neostigmine Bromide	1.00E-02	1.15E-03
Nicotine	1.20E-01	1.99E-03
Nifedipine	1.16E+00	5.66E-04
Nitrofurantoin	1.70E-01	2.98E-03
Nordoxepin	1.90E-01	3.09E-04
D-Norpropoxyphene	2.00E-02	8.10E-03
Nortriptyline	1.00E-02	1.43E-03
Norverapamil	2.00E-02	4.55E-04
Oleic Acid	1.24E+00	3.90E-02
Omeprazole	2.00E-02	8.11E-03
Oxalic Acid	2.22E+00	2.00E-02
Palmitic Acid	5.85E+00	2.00E-01
D-Penicillamine	1.60E-01	4.42E-02
Penicillin G	4.20E-01	3.40E-02
Phenelzine	4.00E-02	1.50E-05
L-Phenylalanine	3.03E+00	2.10E-01
Phenytoin	4.00E-01	7.93E-02
Pindolol	2.00E-02	3.26E-04
Pioglitazone	1.40E-01	4.45E-03
Piroxicam	9.00E-02	2.90E-02
Polysorbate 80	3.00E-03	undetermined
Potassium Chloride	6.70E+00	3.10E+00
Prednisolone	1.11E-02	1.11E-03
Primidone	2.30E-01	8.71E-02
Probenecid	2.11E+00	5.22E-01
Procainamide	4.30E-01	6.80E-02
Propranolol	4.00E-02	1.29E-03
Pseudoephedrine	6.00E-02	6.66E-03
Pyridinealdoxime Methiodide (PAM)	9.40E-01	1.50E-02
Pyridostigmine	2.21E-02	1.88E-03

Substance	Highest Concentration Tested (mmol/L)	Upper Therapeutic Concentration (mmol/L)
Pyridoxine	1.80E-01	undetermined
Pyruvic Acid	4.50E-01	1.02E-01
Quinine Sulfate	1.50E-01	5.00E-02
Ramipril	9.00E-02	1.25E-04
Ranitidine	6.40E-01	1.11E-02
Repaglinide	1.10E-01	8.80E-04
Rifampicin	1.00E-01	1.94E-02
Rosiglitazone	1.10E-01	1.82E-03
Salicylic Acid	4.34E+00	6.89E-02
Sodium Bicarbonate	4.00E+01	2.90E-03
D-Sorbitol	3.85E+00	2.40E-03
Stearic Acid	5.30E-01	9.80E-02
Streptomycin	2.10E-01	1.48E-01
Sucrose	1.46E+01	1.80E-03
Terfenadine	5.30E-01	9.54E-06
Tetracycline	2.30E-01	1.80E-02
Theophylline	1.39E+00	1.11E-01
Thioridazine	1.10E-01	1.05E-02
L-Thyroxine	6.00E-02	1.84E-04
Tobramycin	8.00E-02	2.35E-02
Tolazamide	6.42E+00	4.82E-02
Tolbutamide	3.70E+00	6.77E-01
Trazodone	5.00E-02	1.32E-02
Triamterene	2.40E-01	7.70E-04
Trimethoprim	2.10E-01	4.82E-02
DL-Tyrosine	1.33E+00	1.30E+00
Urea	1.00E+02	6.30E+00
Uric Acid	1.40E+00	4.80E-01
Valproic Acid	3.01E+00	7.35E-01
Vancomycin	1.40E-01	2.76E-02
Verapamil	2.00E-02	1.17E-03
Vitamin B12	1.00E-02	6.20E-08
Vitamin E	4.60E-01	4.60E-02
Voluven	800 mg/dL	800 mg/dL
Warfarin	3.20E-01	8.11E-02
Xylitol	1.32E+01	7.90E-03

The following compounds were found to be interfering substances.

Substance	Accu-Chek Guide Me system Accuracy Threshold (mmol/L)
Ascorbic Acid [16]	> 0.28
Lipidemia (Triglycerides) [17]	> 20.34
Xylose [18]	> 0.67

[16] The system should not be used during intravenous administration of ascorbic acid.

[17] Lipemic samples (triglycerides) in excess of 20.34 mmol/L may produce elevated results.

[18] The system should not be used during xylose absorption test.

Conclusion

The data presented and the data on file demonstrate the capability of the Accu-Chek Guide Me meter and Accu-Chek Guide test strips and indicate that the system is compliant with the performance requirements of *ISO 15197:2013/EN ISO 15197:2015*.[19] With a test time of less than 4 seconds, minimal sample volume, and spill-resistant strip vial, the Accu-Chek Guide Me system is an easy-to-use tool for monitoring blood glucose levels. Along with these features, the system's accurate and reliable test results make it a best-in-class blood glucose monitoring system.

[19] **Roche data on file.**

www.accu-chek.com.au I Accu-Chek Enquiry Line 1800 251 816

WARNING - KEEP BATTERIES OUT OF REACH OF CHILDREN.
If you suspect your child has swallowed or inserted a battery, immediately call the 24-hour Poisons Information Centre on 13 11 26 for fast, expert advice.

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ABN 69 602 140 278. Date of preparation: February 2021. AU-802.