ACCU-CHEK® Instant

Roche

SYSTEM EVALUATION

Accu-Chek Instant: System Evaluation

Contents

The Accu-Chek Instant system

Introduction

The Accu-Chek Instant system is a unique solution designed to meet the diverse needs of people with diabetes and their healthcare professionals. The system's features, such as the intuitive target range indicator and an exciting new test strip design with a wide sample application area, provide effortless solutions to help make blood glucose testing easier. The strip ejecter feature interface supports simple diabetes management, and *Bluetooth*® connectivity offers quick insights virtually anytime and anywhere.

The system provides excellent accuracy and precision. The Accu-Chek Instant test strips 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.[1,2] This document describes key features of the Accu-Chek Instant system and summarises study results for accuracy, precision, hematocrit, and interfering substances.

1. The International Organization for Standardization EN ISO 15197:2015. In vitro diagnostic test systems—Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.

2. Breitenbeck et al. Accuracy assessment of a blood glucose monitoring system for self-testing with three test strip lots following ISO 15197:2013/ISO 15179:2015. J Diabetes Sci Technol. 2017 11(4) 854-855.

Main Features

The Accu-Chek Instant system introduces our new blood glucose monitoring system, which includes innovations that simplify testing and contribute to successful diabetes management.

Target range indicator

The test result includes an arrow that shows if the test result falls above, within, or below the target range. The target range is represented by the green region of the target range indicator. If the test result falls above or below the target range, the arrow flashes next to the blue or red dot that best represents how far the test result is out of range.

Easy edge dosing

The test strip has a large dosing area compared to leading brands. The wide yellow application area is designed to enable dosing anywhere on the edge of the strip[1].

Fast test time

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

Proven accuracy

The Accu-Chek Instant system fulfils the *ISO 15197:2013/EN ISO 15197:2015* standard and delivers even tighter accuracy for reliable results, making it one of Roche's most accurate systems to-date.

Automatic coding

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

Intuitive design and user-friendly navigation

A simple two-button interface allows the user to see time and date as well as view 720 past test results.

Simple and Hygenic Strip Ejecter

The user-friendly strip ejecter allows for easy and hygenic test strip removal.

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 the mySugr app, for convenient visualisation and sharing with a healthcare professional or other caregiver.

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.

[1] Roche data on file

System Specifications

The tables below describe the specifications for the Accu-Chek Instant meter and 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	At least 720 blood glucose results and 30 control results are stored and viewable on the meter.
Automatic off	90 seconds after performing a test, 15 seconds after test strip is removed, 5 seconds from last test result screen
Power supply	Two 3-volt lithium batteries (coin cell type CR2032)
Display	LCD
Meter dimensions	77.1 mm length × 48.6 mm width × 15.3 mm height
Weight	Approx. 43 g (with batteries)
Construction	Hand-held
Protection class	III
Meter type	Suitable for continuous operation
Interfaces Continua CERTIFIED	USB: micro-B connector Continua Certified® to a Continua Certified manager

Strip Technology

Measurement Principle

When an Accu-Chek Instant test strip is inserted into the Accu-Chek Instant 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 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 hematocrit and temperature compensated-glucose result.

Dosing Area

The new Accu-Chek Instant test strip design has a large dosing area compared to leading brands, which allows a small blood sample to be applied anywhere on the wide yellow edge[2].

Accu-Chek Instant test strip

[2] Roche data on file

Performance Evaluation

Capillary Whole Blood Accuracy (Technician)

Study Design

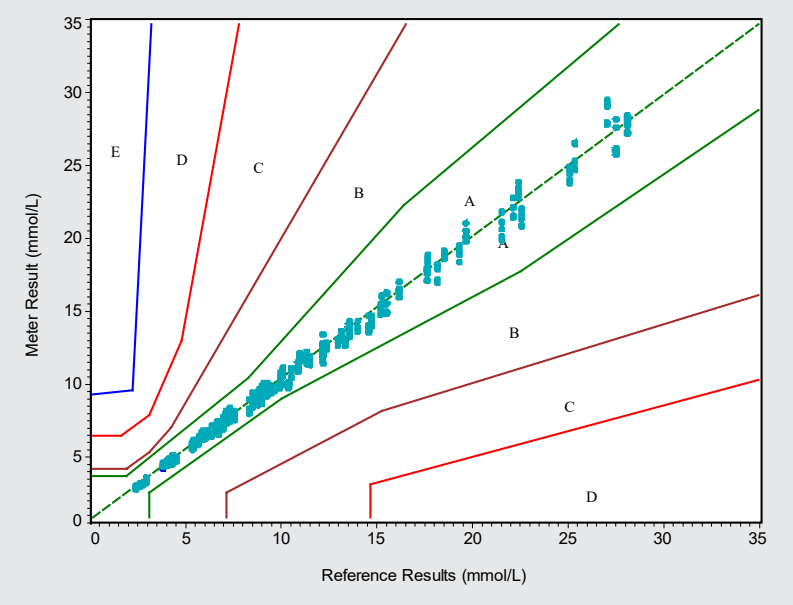
Technicians at one participating facility performed capillary finger sticks on patients. Two glucose test strips from three individual strip lots were dosed for each subject, for a total of 200 glucose meter results per lot. Meter results were compared to whole blood reference samples.

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.

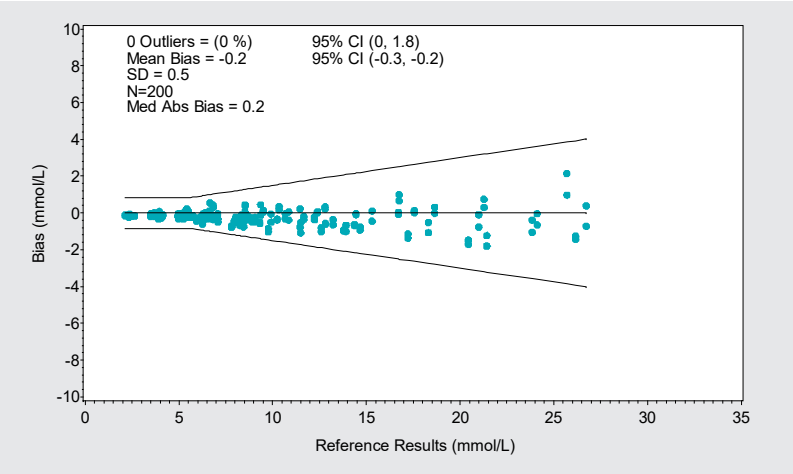
Results (Pooled Strip Lots)

Subjects	100
Glucose Range (Reference)	2.2 to 26.7 mmol/L
Hematocrit Range (Reference)	30 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)

Results (Strip Lot 1)



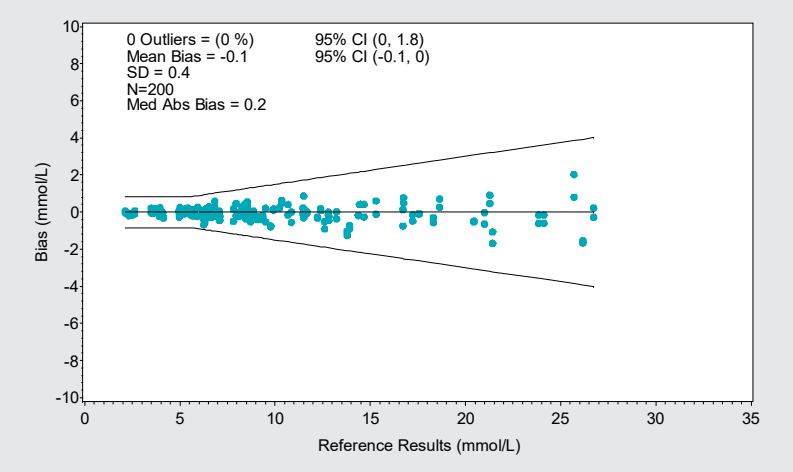
Results <5.6 mmol/L

Within ±0.28 mmol/L	Within ±0.56 mmol/L	Within ±0.83 mmol/L
94.4% (51/54)	100.0% (54/54)	100.0% (54/54)

Results ≥5.6 mmol/L

Within ±5%	Within ±10%	Within ±15%
70.5% (103/146)	99.3% (145/146)	100.0% (146/146)

Results (Strip Lot 2)



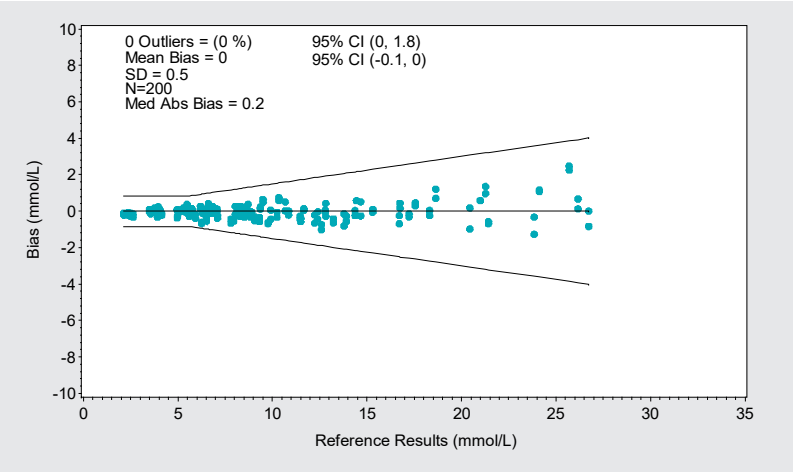
Results <5.6 mmol/L

Within ±0.28 mmol/L	Within ±0.56 mmol/L	Within ±0.83 mmol/L
98.1% (53/54)	100.0% (54/54)	100.0% (54/54)

Results ≥5.6 mmol/L

Within ±5%	Within ±10%	Within ±15%
82.2% (120/146)	99.3% (145/146)	100.0% (146/146)

Results (Strip Lot 3)



Results <5.6 mmol/L

Within ±0.28 mmol/L	Within ±0.56 mmol/L	Within ±0.83 mmol/L
90.7% (49/54)	100.0% (54/54)	100.0% (54/54)

Results ≥5.6 mmol/L

Within ±5%	Within ±10%	Within ±15%
80.8% (118/146)	99.3% (145/146)	100.0% (146/146)

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 Accu-Chek Instant 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

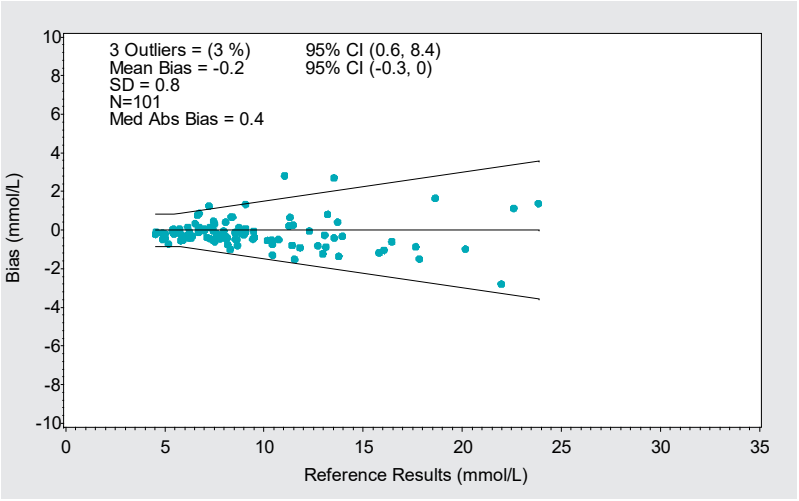
Patients at one facility were asked to read the labeling provided with the Accu-Chek Instant system, and to subsequently perform a finger stick and dose a test strip from one strip lot. The patients were given no instruction by a trained technician. The subjects' results were compared to whole blood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

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	101
Glucose Range (Reference)	4.5 to 23.9 mmol/L
Hematocrit Range (Reference)	29 to 55%



- At glucose concentrations <5.6 mmol/L, 100% of the test results were within ±0.83 mmol/L of the reference results.
- At glucose concentrations ≥5.6 mmol/L, 96.7% of the test results were within ±15% of the reference results.

Conclusion

97% of the data are within the bias requirements, 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.

Venous Whole Blood Accuracy

Study Design

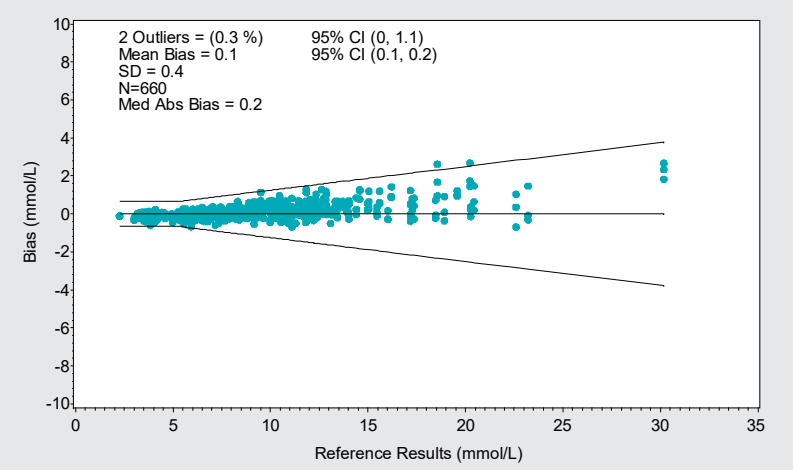
Technicians at one clinical site collected blood via venipuncture. Test strips from three independent lots were then dosed with the venous blood samples by the technicians. Two test strips were tested for each of three lots. Meter results were compared to whole blood reference samples.

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	220
Glucose Range (Reference)	2.3 to 30.2 mmol/L
Hematocrit 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	71.9% (41/57)	100.0% (57/57)	100.0% (57/57)
2	91.2% (52/57)	98.2% (56/57)	100.0% (57/57)
3	94.7% (54/57)	100.0% (57/57)	100.0% (57/57)

Results ≥5.6 mmol/L

Lot	Within ±5%	Within ±10%	Within ±12.5%
1	87.7% (143/163)	99.4% (162/163)	100.0% (163/163)
2	80.4% (131/163)	99.4% (162/163)	99.4% (162/163)
3	74.8% (122/163)	97.5% (159/163)	99.4% (162/163)

Results <4.2 mmol/L

Lot	Within ±0.28 mmol/L	Within ±0.56 mmol/L	Within ±0.83 mmol/L
1	69.2% (27/39)	100.0% (39/39)	100.0% (39/39)
2	87.2% (34/39)	97.4% (38/39)	100.0% (39/39)
3	92.3% (36/39)	100.0% (39/39)	100.0% (39/39)

Results ≥4.2 mmol/L

Lot	Within ±5%	Within ±10%	Within ±15%	Within ±20%
1	85.1% (154/181)	99.4% (180/181)	100.0% (181/181)	100.0% (181/181)
2	82.3% (149/181)	99.4% (180/181)	100.0% (181/181)	100.0% (181/181)
3	77.3% (140/181)	97.8% (177/181)	100.0% (181/181)	100.0% (181/181)

Conclusion

99.7% 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 Accu-Chek Instant system provides accurate results with venous blood samples.

Arterial Whole Blood Accuracy

Study Design

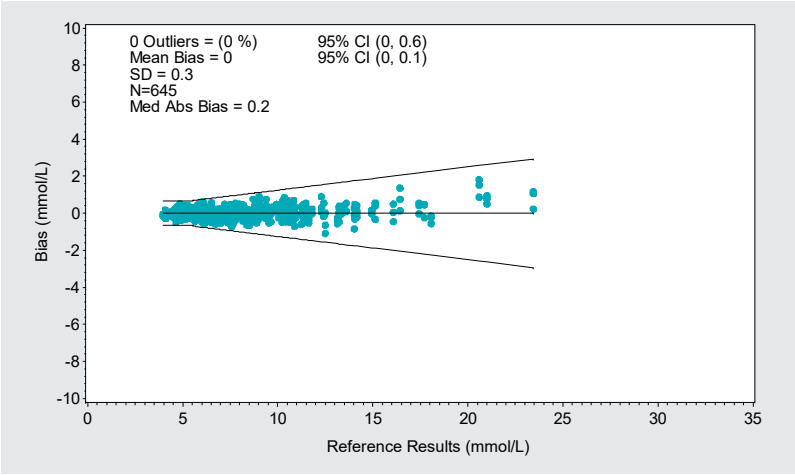
Technicians at one clinical site collected arterial blood using their standard operating procedure. Test strips from three independent lots were then dosed with the arterial blood samples by the technicians. Meter results were compared to whole blood reference samples.

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	215
Glucose Range (Reference)	4.0 to 23.5 mmol/L
Hematocrit Range (Reference)	21 to 57%



Results <5.6 mmol/L

Lot	Within ±0.28 mmol/L	Within ±0.56 mmol/L	Within ±0.67 mmol/L
1	83.7% (36/43)	100.0% (43/43)	100.0% (43/43)
2	79.1% (34/43)	100.0% (43/43)	100.0% (43/43)
3	83.7% (36/43)	100.0% (43/43)	100.0% (43/43)

Results ≥5.6 mmol/L

Lot	Within ±5%	Within ±10%	Within ±12.5%
1	84.9% (146/172)	100.0% (172/172)	100.0% (172/172)
2	87.8% (151/172)	99.4% (171/172)	100.0% (172/172)
3	87.2% (150/172)	99.4% (171/172)	100.0% (172/172)

Results <4.2 mmol/L

Lot	Within ±0.28 mmol/L	Within ±0.56 mmol/L	Within ±0.83 mmol/L
1	80.0% (4/5)	100.0% (5/5)	100.0% (5/5)
2	100.0% (5/5)	100.0% (5/5)	100.0% (5/5)
3	100.0% (5/5)	100.0% (5/5)	100.0% (5/5)

Results ≥4.2 mmol/L

Lot	Within ±5%	Within ±10%	Within ±15%	Within ±20%
1	83.8% (176/210)	99.5% (209/210)	100.0% (210/210)	100.0% (210/210)
2	84.3% (177/210)	99.5% (209/210)	100.0% (210/210)	100.0% (210/210)
3	85.7% (180/210)	99.0% (208/210)	100.0% (210/210)	100.0% (210/210)

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 Accu-Chek Instant system provides accurate results with arterial blood samples.

Neonatal Capillary Whole Blood Accuracy

Study Design

Studies were conducted to assess the accuracy of the Accu-Chek Instant 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.

Acceptance Criteria *(CLSI POCT12-A3)*:

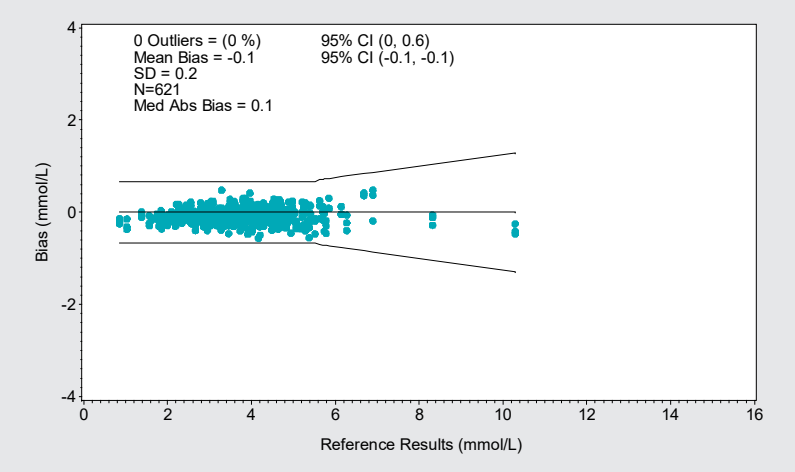
- ≥95% of the individual results shall fall within ±0.67 mmol/L of the reference results at glucose concentrations <5.6 mmol/L and within ±12.5% at glucose concentrations ≥5.6 mmol/L.
- ≥98% of the individual results shall fall within ±0.83 mmol/L of the reference results at glucose concentrations <4.2 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	207
Glucose Range (Reference)	0.9 to 10.3 mmol/L
Hematocrit Range (Reference)	28 to 65%



Results <5.6 mmol/L

Lot	Within ±5 mg/dL	Within ±10 mg/dL	Within ±12 mg/dL
1	77.9% (152/195)	99.5% (194/195)	100.0% (195/195)
2	92.3% (180/195)	100.0% (195/195)	100.0% (195/195)
3	91.8% (179/195)	100.0% (195/195)	100.0% (195/195)

Results ≥5.6 mmol/L

Lot	Within ±5%	Within ±10%	Within ±12.5%
1	66.7% (8/12)	100.0% (12/12)	100.0% (12/12)
2	83.3% (10/12)	100.0% (12/12)	100.0% (12/12)
3	66.7% (8/12)	100.0% (12/12)	100.0% (12/12)

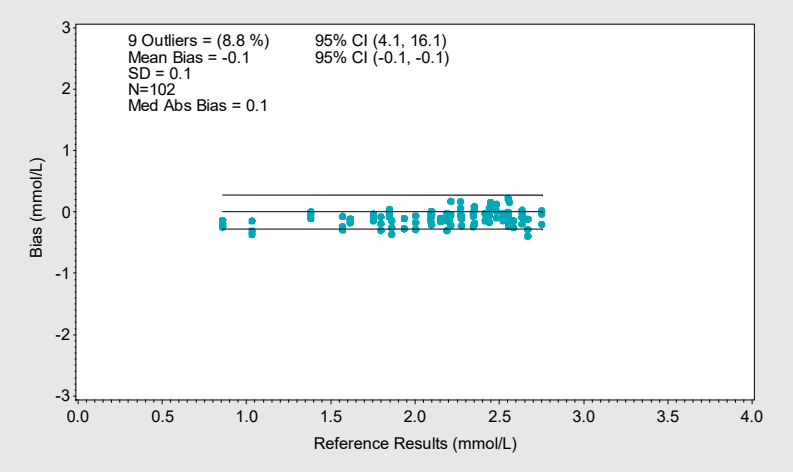
Results <4.2 mmol/L

Lot	Within ±0.28 mmol/L	Within ±0.56 mmol/L	Within ±0.83 mmol/L
1	85.2% (115/135)	100.0% (135/135)	100.0% (135/135)
2	92.6% (125/135)	100.0% (135/135)	100.0% (135/135)
3	91.9% (124/135)	100.0% (135/135)	100.0% (135/135)

Results ≥4.2 mmol/L

Lot	Within ±5%	Within ±10%	Within ±15%	Within ±20%
1	54.2% (39/72)	95.8% (69/72)	100.0% (72/72)	100.0% (72/72)
2	86.1% (62/72)	100.0% (72/72)	100.0% (72/72)	100.0% (72/72)
3	79.2% (57/72)	100.0% (72/72)	100.0% (72/72)	100.0% (72/72)

Results Below 2.8 mmol/L (Pooled Strip Lots)



Results <2.8 mmol/L

N	Mean Bias (mmol/L)
102	-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 Accu-Chek Instant 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 Accu-Chek Instant 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 SD or CV (based on glucose level) was calculated using results from all vials and strip lots.

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	2.6	0.1	--
Mid	6.6	0.2	2.9
High	16.6	0.3	2.0

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 2.9% for concentrations above 5.6 mmol/L. These data indicate that the Accu-Chek Instant system provides precise results with control solutions.

System Precision—Repeatability

Study Design

Repeatability of the Accu-Chek Instant 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.

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	4.7	0.1	--
3	7.6	0.2	2.2
4	12.0	0.3	2.5
5	19.6	0.5	2.4

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 2.5% for concentrations above 5.6 mmol/L. These data indicate that the Accu-Chek Instant system provides precise results with venous blood.

Impact of Hematocrit

Study Design

Three levels of glycolised venous blood were tested with various hematocrit levels to determine the impact of hematocrit on the performance of the Accu-Chek Instant system. Meter results were compared to a sample at nominal hematocrit (42%).

Target Glucose Levels:

- 2.2 mmol/L
- 6.7 mmol/L
- 19.4 mmol/L

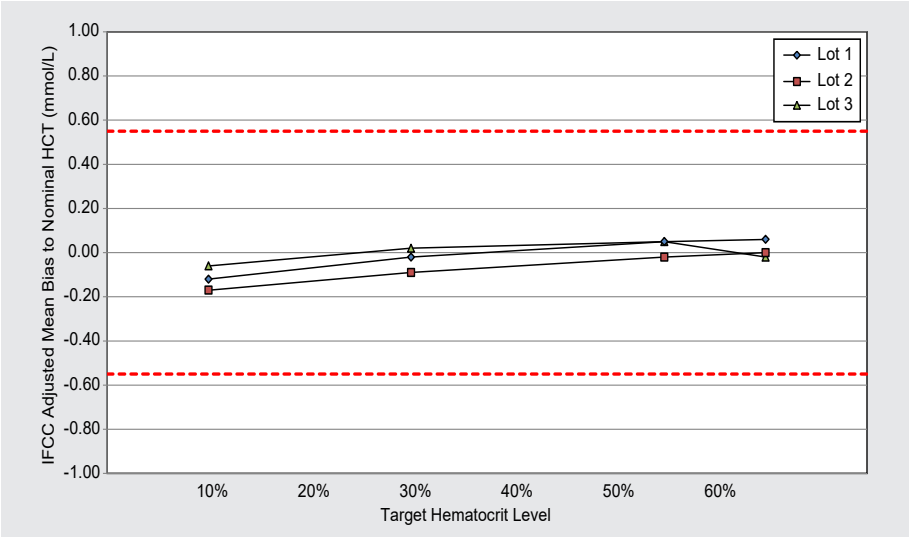
Hematocrit Levels:

- 10%
- 30%
- 55%
- 65%

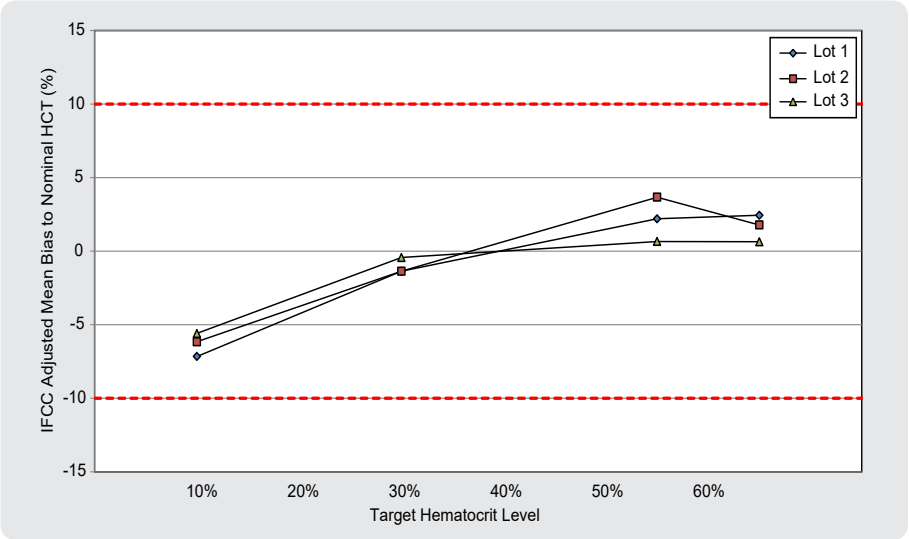
Acceptance Criteria *(ISO 15197:2013/EN ISO 15197:2015)*:

- 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 hematocrit sample (42%) mean bias (to reference glucose) at glucose concentrations ≥5.6 mmol/L.

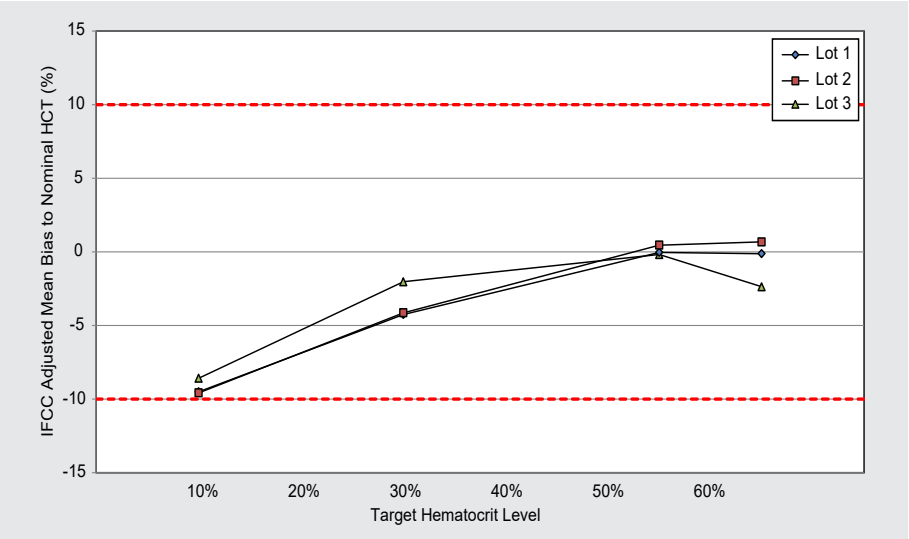
Results (2.2 mmol/L)



Results (6.7 mmol/L)



Results (19.4 mmol/L)



Conclusion

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

Impact of Potentially Interfering Substances

The Accu-Chek Instant system has been thoroughly evaluated with potential interfering substances. Substances were tested at concentrations described by the Clinical Lab Standard Institute in document *EP7-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).

  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).

  Acetone Upper Therapeutic Concentration: 1.70E–01

  1.70 / 10 = 0.17 mmol/L
- **00 Exponent:** Use the stated value with no adjustment.

  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

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
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	100 g/L	25 g/L
Heparin (Li)	80000 U/L	1100 U/L
Heparin (Na)	80000 U/L	1100 U/L
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 when tested with the Accu-Chek Instant system.

Substance	Accu-Chek Instant system Accuracy Threshold (mmol/L)
Ascorbic Acid[3]	> 0.28
Lipidemia (Triglycerides)[4]	> 20.30
Xylose[5]	> 0.67

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

[4] Lipemic samples (triglycerides) in excess of 20.30 mmol/L may produce elevated results.

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

Conclusion

The data presented demonstrate the capability of the Accu-Chek Instant meter and test strips and indicate that the system is compliant with the performance requirements of *ISO 15197:2013/ EN ISO 15197:2015*. With a less than 4-second test, minimal sample volume, and test strip ejecter intuitive target range indicator, the Accu-Chek Instant system is an easy-to-use tool for monitoring of 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.

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