ACCU-CHEK® Instant S

Roche

Accu-Chek® Instant S

System Evaluation

ACCU-CHEK®

Accu-Chek® Instant S System Evaluation

Contents

The Accu-Chek® Instant S System

Introduction

The Accu-Chek Instant S system is a 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 latest test strip design with a wide sample application area, provide effortless solutions to help make blood glucose testing easier. The easy-to-navigate meter interface supports simple diabetes management, and USB connectivity offers access to additional diabetes management support.

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. This document describes key features of the Accu-Chek Instant S system and summarises study results for accuracy, precision, haematocrit, and interfering substances.

Main Features

The Accu-Chek Instant S system introduces our latest 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 S system fulfills 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 single meter button makes it easy to access the last test result, as well as 7, 30, and 90 day averages.

Failsafes

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

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 S 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
Haematocrit	10 to 65%
Range altitude	Up to 3,094 meters (10,150 feet) above sea level
Sample types	Capillary, venous, arterial, neonatal
Test sites	Fingertip
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	At least 720 blood glucose results and 30 control results are stored and viewable with external software.
Automatic off	90 seconds after performing a test, 15 seconds after test strip is removed, 5 seconds from last test result screen
Power supply	One 3-volt lithium battery (coin cell type CR2032)
Display	LCD
Meter dimensions	77.1 mm length × 48.6 mm width × 15.3 mm height
Weight	Approximately 40 g (with battery)
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 S 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 haematocrit and temperature compensated-glucose result.

Dosing Area

The latest 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

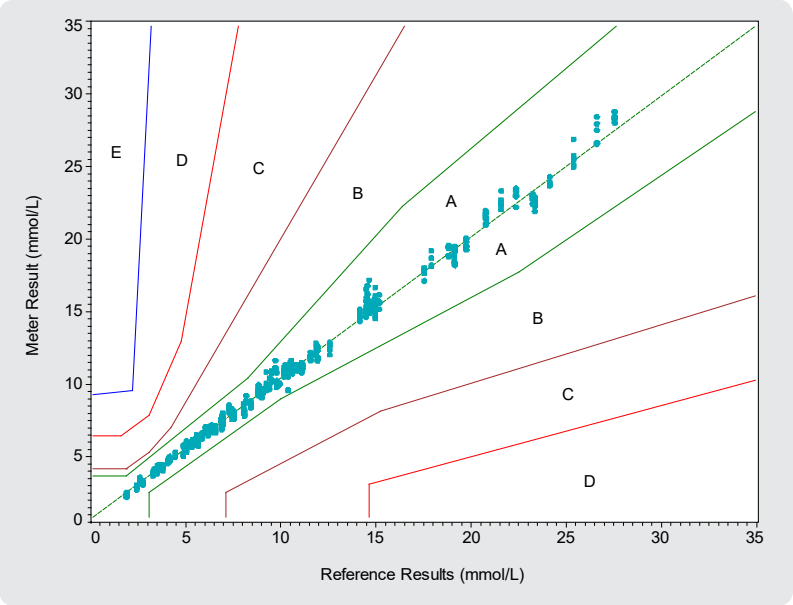
Technicians at one participating facility performed capillary finger sticks on patients. Two glucose test strips from three individual strip lots were dosed for each subject, for a total of 200 glucose meter results per lot. Meter results were compared to whole blood reference samples.

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.

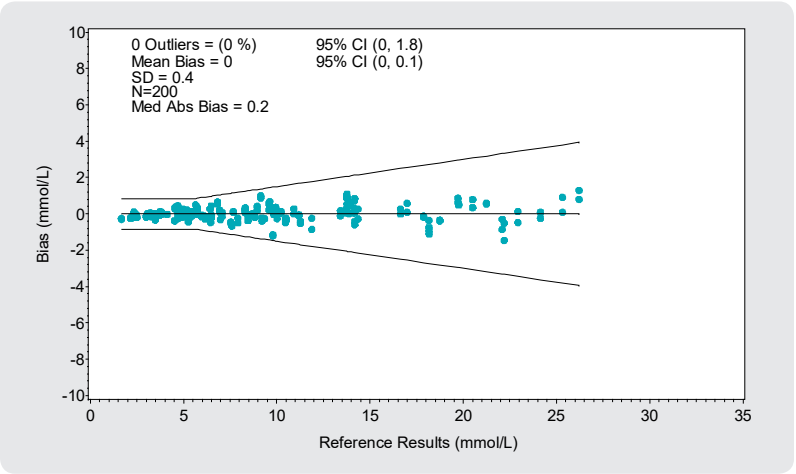
Results (Pooled Strip Lots)

Subjects	100
Glucose Range (Reference)	1.7 to 26.2 mmol/L
Haematocrit Range (Reference)	26 to 50%



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)



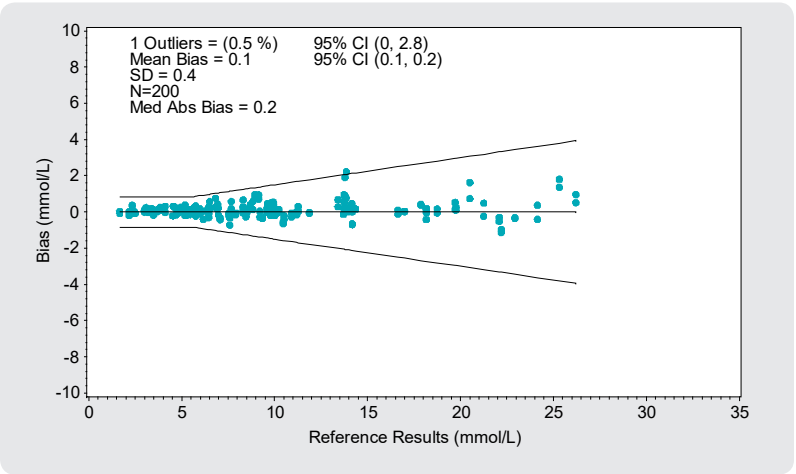
Results <5.6 mmol/L

Within ±0.28 mmol/L	Within ±0.56 mmol/L	Within ±0.83 mmol/L
85.0% (51/60)	100.0% (60/60)	100.0% (60/60)

Results ≥5.6 mmol/L

Within ±5%	Within ±10%	Within ±15%
81.4% (114/140)	97.9% (137/140)	100.0% (140/140)

Results (Strip Lot 2)



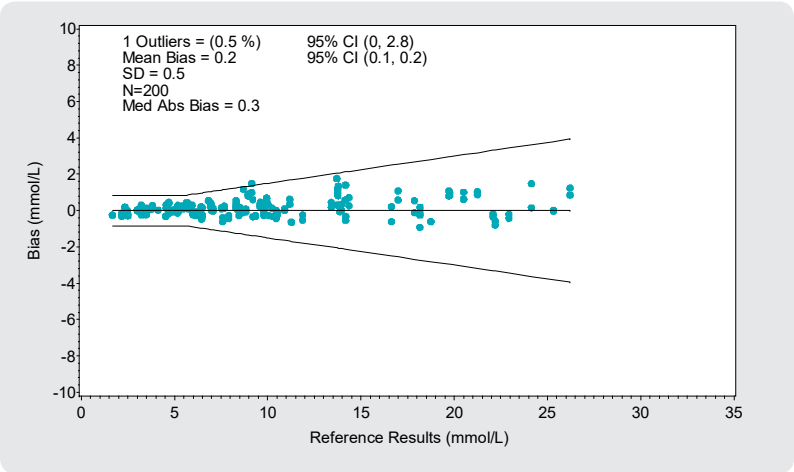
Results <5.6 mmol/L

Within ±0.28 mmol/L	Within ±0.56 mmol/L	Within ±0.83 mmol/L
88.3% (53/60)	100.0% (60/60)	100.0% (60/60)

Results ≥5.6 mmol/L

Within ±5%	Within ±10%	Within ±15%
78.6% (110/140)	96.4% (135/140)	99.3% (139/140)

Results (Strip Lot 3)



Results <5.6 mmol/L

Within ±0.28 mmol/L	Within ±0.56 mmol/L	Within ±0.83 mmol/L
85.0% (51/60)	100.0% (60/60)	100.0% (60/60)

Results ≥5.6 mmol/L

Within ±5%	Within ±10%	Within ±15%
72.1% (101/140)	96.4% (135/140)	99.3% (139/140)

Conclusion

99.7% 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 S 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

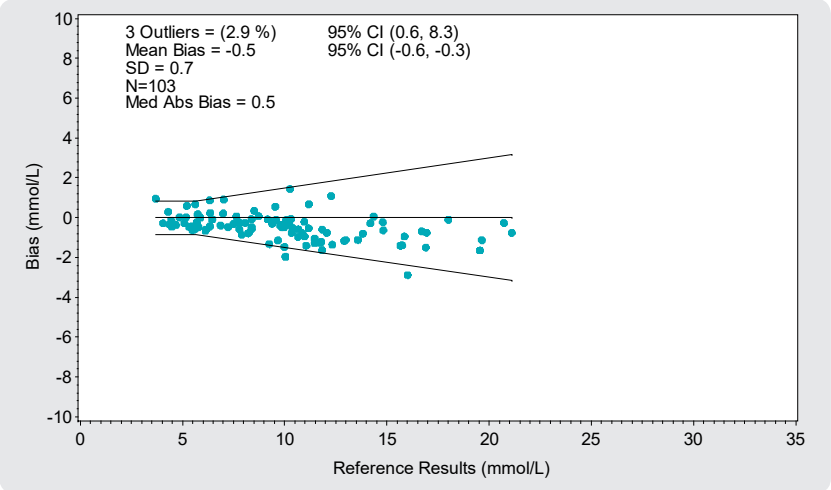
Patients at one facility were asked to read the labeling provided with the Accu-Chek Instant S system, and to subsequently perform a finger stick and dose a test strip from one strip lot. The patients were given no instruction by a trained technician. The subjects' results were compared to whole blood 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	103
Glucose Range (Reference)	3.7 to 21.1 mmol/L
Haematocrit Range (Reference)	31 to 56%



- At glucose concentrations <5.6 mmol/L, 92.9% of the test results were within ±0.83 mmol/L of the reference results.
- At glucose concentrations ≥5.6 mmol/L, 97.8% of the test results were within ±15% of the reference results.

Conclusion

97.1% 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

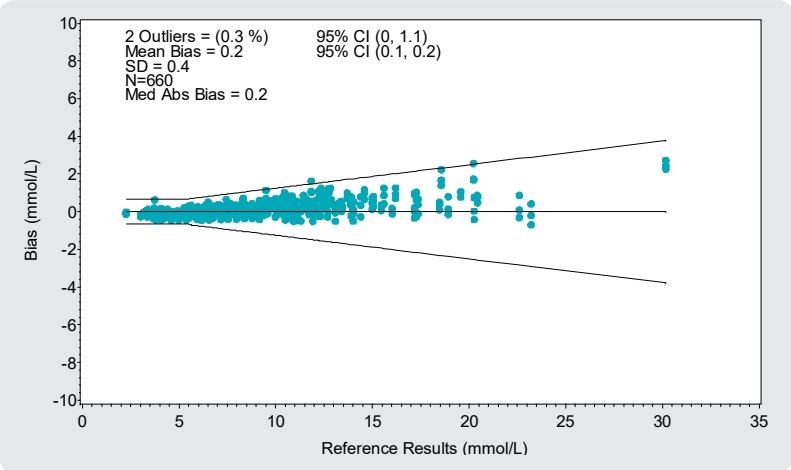
Technicians at one clinical site collected blood via venipuncture. Test strips from three independent lots were then dosed with the venous blood samples by the technicians. Two test strips were tested for each of three lots. Meter results were compared to whole blood reference samples.

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
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	80.7% (46/57)	100.0% (57/57)	100.0% (57/57)
2	100.0% (57/57)	100.0% (57/57)	100.0% (57/57)
3	89.5% (51/57)	98.2% (56/57)	100.0% (57/57)

Results ≥5.6 mmol/L

Lot	Within ±5%	Within ±10%	Within ±12.5%
1	91.4% (149/163)	100.0% (163/163)	100.0% (163/163)
2	82.8% (135/163)	98.8% (161/163)	98.8% (161/163)
3	73.6% (120/163)	98.2% (160/163)	100.0% (163/163)

Results <4.2 mmol/L

Lot	Within ±0.28 mmol/L	Within ±0.56 mmol/L	Within ±0.83 mmol/L
1	84.6% (33/39)	100.0% (39/39)	100.0% (39/39)
2	100.0% (39/39)	100.0% (39/39)	100.0% (39/39)
3	89.7% (35/39)	97.4% (38/39)	100.0% (39/39)

Results ≥4.2 mmol/L

Lot	Within ±5%	Within ±10%	Within ±15%	Within ±20%
1	89.5% (162/181)	100.0% (181/181)	100.0% (181/181)	100.0% (181/181)
2	84.5% (153/181)	98.9% (179/181)	100.0% (181/181)	100.0% (181/181)
3	75.1% (136/181)	98.3% (178/181)	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 S system provides accurate results with venous blood samples.

Arterial Whole Blood Accuracy

Study Design

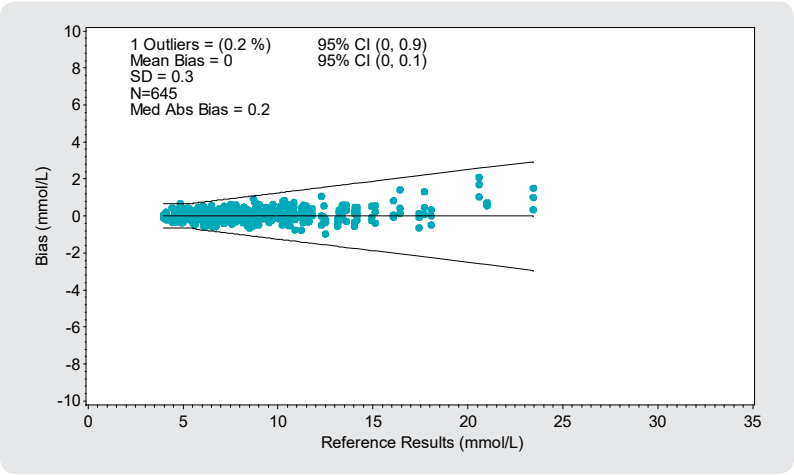
Technicians at one clinical site collected arterial blood using their standard operating procedure. Test strips from three independent lots were then dosed with the arterial blood samples by the technicians. Meter results were compared to whole blood reference samples.

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
Haematocrit 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	81.4% (35/43)	100.0% (43/43)	100.0% (43/43)
2	76.7% (33/43)	97.7% (42/43)	97.7% (42/43)
3	86.0% (37/43)	100.0% (43/43)	100.0% (43/43)

Results ≥5.6 mmol/L

Lot	Within ±5%	Within ±10%	Within ±12.5%
1	89.0% (153/172)	100.0% (172/172)	100.0% (172/172)
2	84.9% (146/172)	98.8% (170/172)	100.0% (172/172)
3	83.1% (143/172)	100.0% (172/172)	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	100.0% (5/5)	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	86.7% (182/210)	100.0% (210/210)	100.0% (210/210)	100.0% (210/210)
2	82.4% (173/210)	98.6% (207/210)	100.0% (210/210)	100.0% (210/210)
3	82.9% (174/210)	99.0% (208/210)	100.0% (210/210)	100.0% (210/210)

Conclusion

99.8% 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 S 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 S 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)*:

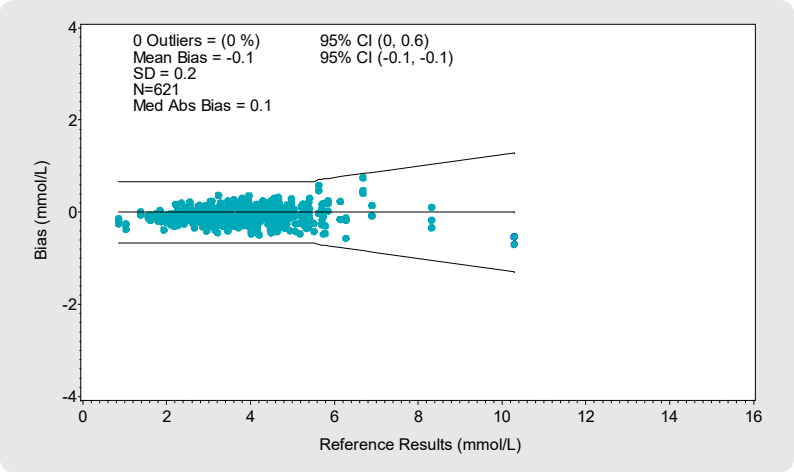
- ≥95% of the individual results shall fall within ±0.67 mmol/L of the reference results at glucose concentrations <5.6 mmol/L and within ±12.5% at glucose concentrations ≥5.6 mmol/L.
- ≥98% of the individual results shall fall within ±0.83 mmol/L of the reference results at glucose concentrations <4.2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



Results <5.6 mmol/L

Lot	Within ±0.28 mmol/L	Within ±0.56 mmol/L	Within ±0.67 mmol/L
1	80.0% (156/195)	100.0% (195/195)	100.0% (195/195)
2	95.9% (187/195)	100.0% (195/195)	100.0% (195/195)
3	91.3% (178/195)	100.0% (195/195)	100.0% (195/195)

Results ≥5.6 mmol/L

Lot	Within ±5%	Within ±10%	Within ±12.5%
1	58.3% (7/12)	100.0% (12/12)	100.0% (12/12)
2	66.7% (8/12)	91.7% (11/12)	100.0% (12/12)
3	66.7% (8/12)	91.7% (11/12)	100.0% (12/12)

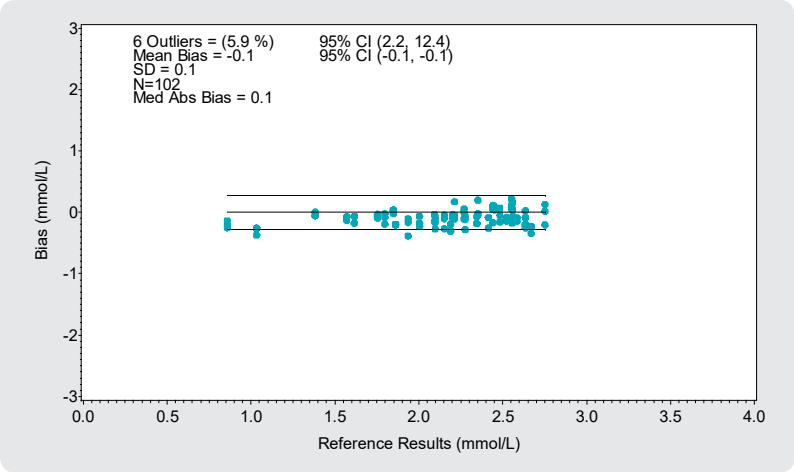
Results <4.2 mmol/L

Lot	Within ±0.28 mmol/L	Within ±0.56 mmol/L	Within ±0.83 mmol/L
1	85.9% (116/135)	100.0% (135/135)	100.0% (135/135)
2	98.5% (133/135)	100.0% (135/135)	100.0% (135/135)
3	90.4% (122/135)	100.0% (135/135)	100.0% (135/135)

Results ≥4.2 mmol/L

Lot	Within ±5%	Within ±10%	Within ±15%	Within ±20%
1	58.3% (42/72)	97.2% (70/72)	100.0% (72/72)	100.0% (72/72)
2	79.2% (57/72)	98.6% (71/72)	100.0% (72/72)	100.0% (72/72)
3	81.9% (59/72)	98.6% (71/72)	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 mmo/L show minimal mean bias. These data confirm that the Accu-Chek Instant S 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 S 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	2.5	0.1	--
Mid	6.5	0.2	3.0
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 3.0% for concentrations above 5.6 mmol/L. These data indicate that the Accu-Chek Instant S system provides precise results with control solutions.

System Precision—Repeatability

Study Design

Repeatability of the Accu-Chek Instant S 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	2.1	0.1	--
2	4.6	0.1	--
3	7.6	0.2	2.1
4	11.9	0.3	2.2
5	19.3	0.4	2.2

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 2.2% for concentrations above 5.6 mmol/L. These data indicate that the Accu-Chek Instant S system provides precise results with venous blood.

Impact of Haematocrit

Study Design

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

Target Glucose Levels:

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

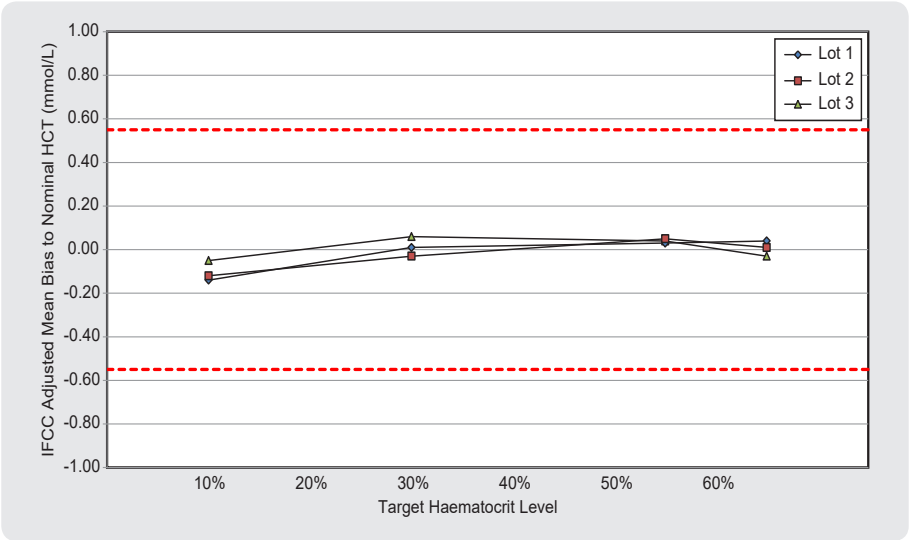
Haematocrit Levels:

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

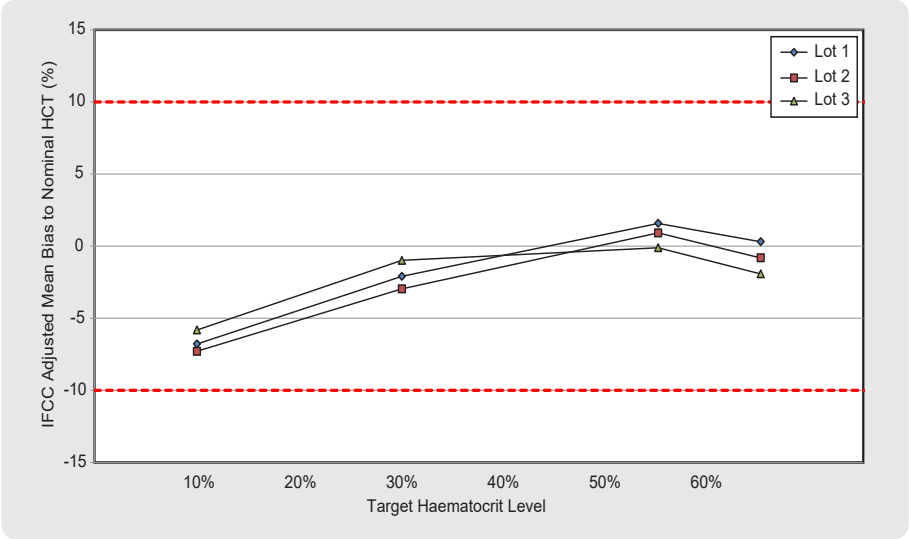
Acceptance Criteria *(ISO 15197:2013/EN ISO 15197:2015)*:

- Mean bias (to reference glucose) shall not exceed ±0.56 mmol/L to the nominal haematocrit 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.

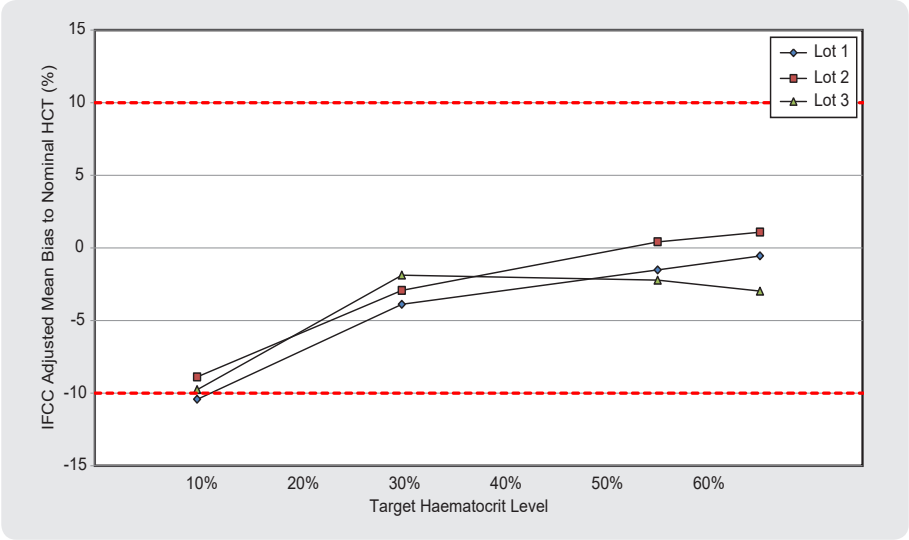
Results (2.2 mmol/L)



Results (6.7 mmol/L)



Results (19.4 mmol/L)



Conclusion

Data from all three lots confirm that the Accu-Chek Instant S 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 Accu-Chek Instant S 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/

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.

Substance	Highest Concentration Tested (mmol/L)	Upper Therapeutic Concentration (mmol/L)
Acarbose	0.93	0.000156
Acetaminophen	1.32	0.344
Acetazolamide	0.27	0.0856
Acetone	10.3	0.17
N-Acetyl-L-Cysteine	1.23	0.307
N-Acetylprocainamide	0.54	0.0361
Acetylsalicylic Acid	3.33	0.0555
Acyclovir	0.22	0.0977
Albumin	0.76	0.82
Albuterol	1.05	0.000063
Allopurinol	0.37	0.147
Aminocaproic Acid	3.05	1.53
Amiodarone	0.07	0.0217
Amitriptyline	0.04	0.000578
Amoxapine	0.003	0.000296
Amoxicillin	16.4	0.0493
Ampicillin	0.15	0.0716
Astemizole	0.02	0.000218
Atorvastatin	0.00179	0.000448
Atropine	0.03	0.000692
Benserazide	0.02	0.00505
Bile Acids	0.04	0.017
Bilirubin (conjugated)	1.03	0.00340
Bilirubin (unconjugated)	1.03	0.019
Buspirone	0.03	0.00000519

Substance	Highest Concentration Tested (mmol/L)	Upper Therapeutic Concentration (mmol/L)
Caffeine	0.52	0.185
Calcium Chloride	5.00	2.75
Captopril	0.02	0.00405
Carbamazepine	0.13	0.0635
Beta-Carotene	0.01	0.0037
Cefaclor	5.4	0.0632
Cefadroxil	0.28	0.0991
Ceftriaxone	1.8	1.01
Cephalexin	0.92	0.186
Cephalothin	5.06	1.91
Cetirizine	0.02	0.00373
Chenodeoxycholic Acid	0.08	0.0025
Chlorothiazide	0.0913	0.0304
Chlorpropamide	2.89	0.795
Cholesterol	13	7.75
Cholic Acid	0.06	0.0015
Cimetidine	0.4	0.0396
Citalopram	0.0185	0.00558
Citric Acid	1.56	0.16
Clindamycin	0.09	0.04
Clonidine	0.09	0.000028
Creatinine	2.65	0.13
Cyclophosphamide	1.44	0.701
L-Cysteine	0.41	0.116
L-Cystine	2.08	0.117
Desipramine	0.004	0.00255
Dexamethasone	0.0306	0.0113
Dextromethorphan	0.04	0.000019
Diclofenac	0.17	0.027
Dicumarol	0.18	0.175
Digoxin	0.01	0.000017
Diltiazem	0.44	0.000724
Diphenhydramine	0.03	0.00101
Dipyrone	0.33	undetermined
Disopyramide	0.15	0.0165
L-Dopa	0.1	0.0127
Dopamine	0.01	0.00135
Doxazosin	0.02	0.000224
Doxycycline	0.06	0.0135

Substance	Highest Concentration Tested (mmol/L)	Upper Therapeutic Concentration (mmol/L)
EDTA dipotassium	8.9	0.00113
EDTA disodium calcium	4.81	0.00113
Enalapril	0.16	0.000725
Ephedrine	0.06	0.00005
Equilin	0.56	0.0186
Erythromycin	0.82	0.0627
Estradiol	0.004	0.00000000918
Estrone	0.04	0.00000037
Ethanol	76	43.4
Ethosuximide	1.77	0.708
Ethyl Acetoacetate	1.54	0.15
Ethylene Glycol	0.81	0.0242
Famotidine	0.02	0.00241
Felodipine	0.13	0.000025
Fenofibrate	0.14	0.0416
Fenoprofen	0.83	0.268
Flecainide	0.02	0.00413
5-Fluorocytosine	2.32	0.527
Fluoxetine	0.39	0.00153
Flurbiprofen	0.2	0.0655
Fluticasone	0.00225	0.000000841
Fructose	13.88	0.33
Furosemide	0.18	0.016
Galactose	16.7	3.33
Galactose-1-Phosphate	0.12	0.007
Gamma Globulins	3000 mg/dL	1600 mg/dL
Gemfibrozil	0.6	0.184
Gentamicin	0.08	0.0222
Gentisic Acid	0.12	0.0324
Glimepiride	0.02	0.00112
Glipizide	0.18	0.00224
Glucosamine	25.1	0.13
Glutathione (reduced)	0.2	0.02
Glyburide	0.03	0.000486
Glycerol	1.09	0.196
Hemoglobin	10 g/L	2.5 g/L
Heparin (Li)	80000 U/L	1100 U/L
Heparin (Na)	80000 U/L	1100 U/L
Hydrochlorothiazide	0.02	0.00126

Substance	Highest Concentration Tested (mmol/L)	Upper Therapeutic Concentration (mmol/L)
Hydrocortisone	0.03	0.0006
DL-Beta-Hydroxybutyric Acid	9.61	0.27
Hydroxychloroquine Sulfate	0.12	0.00039
Ibandronic Acid	0.02	0.001
Ibuprofen	2.43	0.354
Indomethacin	0.14	0.0123
Insulin	20 U/dL	0.004 U/dL
Isoniazid	0.36	0.146
Kanamycin	0.186	0.0619
Lactic Acid	11.1	2.2
Lactitol	2.9	undetermined
Lactose	0.29	0.015
Lecithin	16	11.9
Lidocaine	0.1	0.0213
Lisinopril	0.02	0.000202
Loratadine	0.03	0.00009
Lovastatin	0.01	0.000173
Magnesium Sulfate	2.16	0.216
Maltitol	0.59	undetermined
Maltose	10.52	3.51
D-Mannitol	33	undetermined
D-Mannose	0.56	undetermined
Metaproterenol	0.09	0.00006
Metformin	3.88	0.031
Methimazole	0.02	0.00727
Methyl Dopa	0.07	0.0355
Methylhydroxyprogesterone	1.45	0.00000002
Metoclopramide	0.0149	0.0025
Metoprolol Tartrate	0.03	0.00187
Mexiletine	0.06	0.0139
Misoprostol	0.02	0.00000212
Nadolol	0.06	0.00011
Naproxen	4.35	0.521
Neostigmine Bromide	0.01	0.00115
Nicotine	0.12	0.00199
Nifedipine	1.16	0.000566
Nitrofurantoin	0.17	0.00298
Nordoxepin	0.19	0.000309
D-Norpropoxyphene	0.02	0.0081

Substance	Highest Concentration Tested (mmol/L)	Upper Therapeutic Concentration (mmol/L)
Nortriptyline	0.01	0.00143
Norverapamil	0.02	0.000455
Oleic Acid	1.24	0.039
Omeprazole	0.02	0.00811
Oxalic Acid	2.22	0.02
Palmitic Acid	5.85	0.2
D-Penicillamine	0.16	0.0442
Penicillin G	0.42	0.034
Phenelzine	0.04	0.000015
L-Phenylalanine	3.03	0.21
Phenytoin	0.40	0.0793
Pindolol	0.02	0.000326
Pioglitazone	0.14	0.00445
Piroxicam	0.09	0.029
Polysorbate 80	0.003	undetermined
Potassium Chloride	6.7	3.1
Prednisolone	0.0111	0.00111
Primidone	0.23	0.0871
Probenecid	2.11	0.522
Procainamide	0.43	0.068
Propranolol	0.04	0.00129
Pseudoephedrine	0.06	0.00666
Pyridinealdoxime Methiodide (PAM)	0.94	0.015
Pyridostigmine	0.0221	0.00188
Pyridoxine	0.18	undetermined
Pyruvic Acid	0.45	0.102
Quinine Sulfate	0.15	0.05
Ramipril	0.09	0.000125
Ranitidine	0.64	0.0111
Repaglinide	0.11	0.00088
Rifampicin	0.1	0.0194
Rosiglitazone	0.11	0.00182
Salicylic Acid	4.34	0.0689
Sodium Bicarbonate	40	0.0029
D-Sorbitol	3.85	0.0024
Stearic Acid	0.53	0.098
Streptomycin	0.21	0.148
Sucrose	14.61	0.0018
Terfenadine	0.53	0.00000954

Substance	Highest Concentration Tested (mmol/L)	Upper Therapeutic Concentration (mmol/L)
Tetracycline	0.23	0.018
Theophylline	1.39	0.111
Thioridazine	0.11	0.0105
L-Thyroxine	0.06	0.000184
Tobramycin	0.08	0.0235
Tolazamide	6.42	0.0482
Tolbutamide	3.7	0.677
Trazodone	0.05	0.0132
Triamterene	0.24	0.00077
Trimethoprim	0.21	0.0482
DL-Tyrosine	1.33	1.3
Urea	100	6.3
Uric Acid	1.4	0.48
Valproic Acid	3.01	0.735
Vancomycin	0.14	0.0276
Verapamil	0.02	0.00117
Vitamin B12	0.01	0.000000062
Vitamin E	0.46	0.046
Voluven	800 mg/dL	800 mg/dL
Warfarin	0.32	0.0811
Xylitol	13.2	0.0079

The following compounds were found to be interfering substances when tested with the Accu-Chek Instant S system.

Substance	Accu-Chek Instant S System Accuracy Threshold (mmol/L)
Ascorbic Acid[3]	> 0.28
Lipidemia (Triglycerides)[4]	> 20.34
Xylose[5]	> 0.67

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

[4] Lipemic samples (triglycerides) in excess of 20.34 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 S 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 intuitive target range indicator, the Accu-Chek Instant S 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.

www.accu-chek.com ▪ 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 button battery immediately call the 24-hour Poisons Information Centre on 13 11 26 for fast, expert advice.

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