

Evaluation Report: ACCU-CHEK® Inform II Test Strips

New ACCU-CHEK® Inform II test strips provide accurate and reliable blood glucose measurements.

Introduction

The ACCU-CHEK Inform II system provides healthcare professionals with an accurate, reliable, and easy-to-use blood glucose system to aid in monitoring the effectiveness of glucose control. The ACCU-CHEK Inform II meter and test strips provide a reliable, 5-second test with underdose detection, compensation for potentially interfering substances, an expanded hematocrit range, and a sample volume of 0.6 µL. In addition, the system performs over 150 individual quality checks with every test, enabling it to compensate for factors such as temperature, strip degradation, and hematocrit that can cause errors or inaccurate results in other systems.

Several studies were conducted to assess the accuracy of the ACCU-CHEK Inform II test strip using capillary, venous, arterial, and neonate blood compared to a plasma-like reference. Precision studies were conducted using aqueous control solutions and spiked whole blood samples, and interference studies were conducted with over 190 potentially interfering substances. Test results demonstrate that the ACCU-CHEK Inform II system provides accurate and reliable blood glucose measurements under varied conditions, and eliminates maltose as a limitation.

ACCU-CHEK Inform II System Specifications

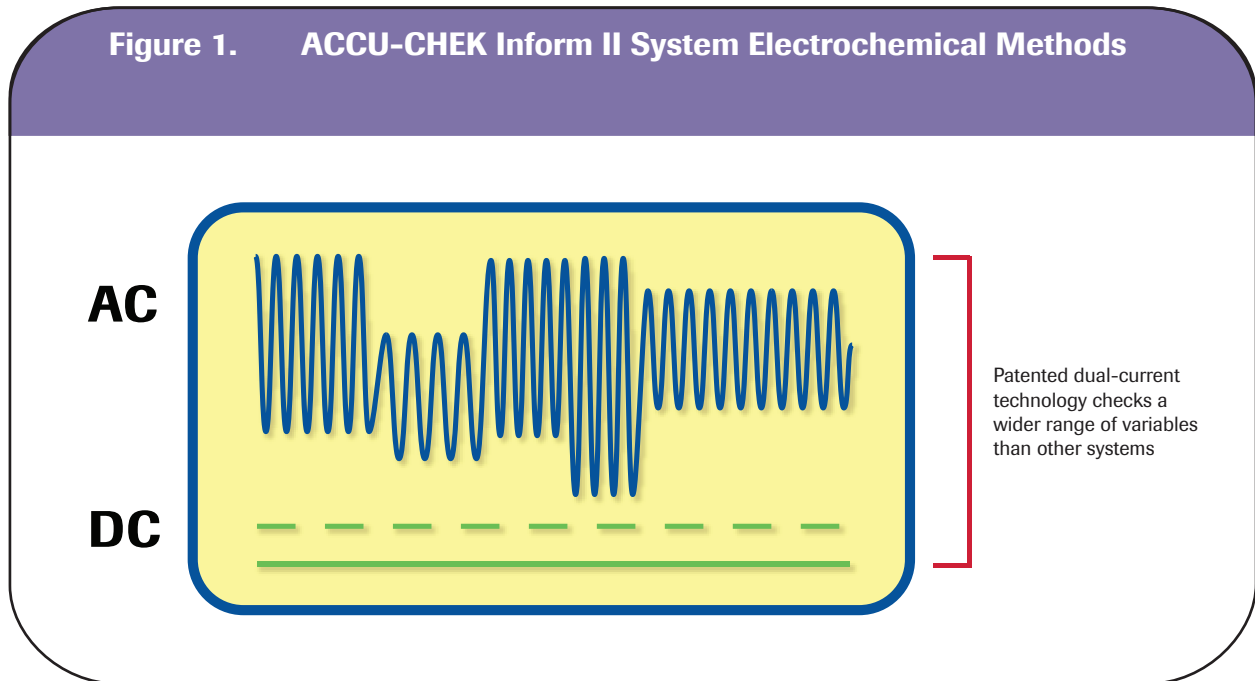
The table below indicates the specifications for the ACCU-CHEK Inform II meter and test strips.

Table 1. System Specifications

Category	ACCU-CHEK Inform II System Specification
Measurement principle	Mutant variant of quinoprotein glucose dehydrogenase (Mut. Q-GDH), electrochemical
Range of measurement	10 to 600 mg/dL
Measuring time	5 seconds
Operating temperature	61°F to 95°F
Operating humidity	10 to 80%
Sample volume	0.6 µL
Hematocrit range	10 to 65%
Altitude	Up to 10,000 feet above sea level
Sample types	Capillary, venous, arterial, neonatal
Support and safety functions	<ul style="list-style-type: none">• Automatic recognition and identification of control solutions• Lot expiration detection• Real-time clock for date and time• Configurable system lock-outs• Underdose detection• System integrity checks for test strip degradation• Result memory integrity checks• Error messages that clearly communicate a description of the error condition and possible resolution
Calibration	Lot-specific calibration information included with each vial of test strips

ACCU-CHEK Inform II Meter System Technology

The ACCU-CHEK Inform II system uses patented AC electrochemical methods, as well as basic DC electrochemical methods (see Figure 1).



DC current generated by the reaction on the test strip provides the basic blood glucose measurement, while a small AC signal provides the various compensations required for a fast, low-volume, highly accurate test.

Benefits of the AC and DC Electrochemical Methodology

AC impedance enables the ACCU-CHEK Inform II meter to gather and analyze significantly more information than other conventional DC systems. Significant benefits of the AC and DC electrochemical methods include:

- **Accurate and efficient temperature estimation.** Instead of relying on a conventional thermistor inside the meter, the ACCU-CHEK Inform II meter measures the temperature at the reaction zone on the test strip. AC impedance allows the meter to more accurately and efficiently compensate for temperature influences at the sample application site.
- **Compensation for hematocrit effects.** The ACCU-CHEK Inform II meter is able to compensate for hematocrit influences using AC impedance. This results in accurate performance across a broad hematocrit range (10 to 65%).
- **Underdose detection.** AC impedance is used to detect the application of a blood sample or control solution on one set of electrodes on the test strip. The system detects an adequate sample volume on another set of electrodes. This prevents the user from underdosing a test strip and obtaining a potentially inaccurate result.

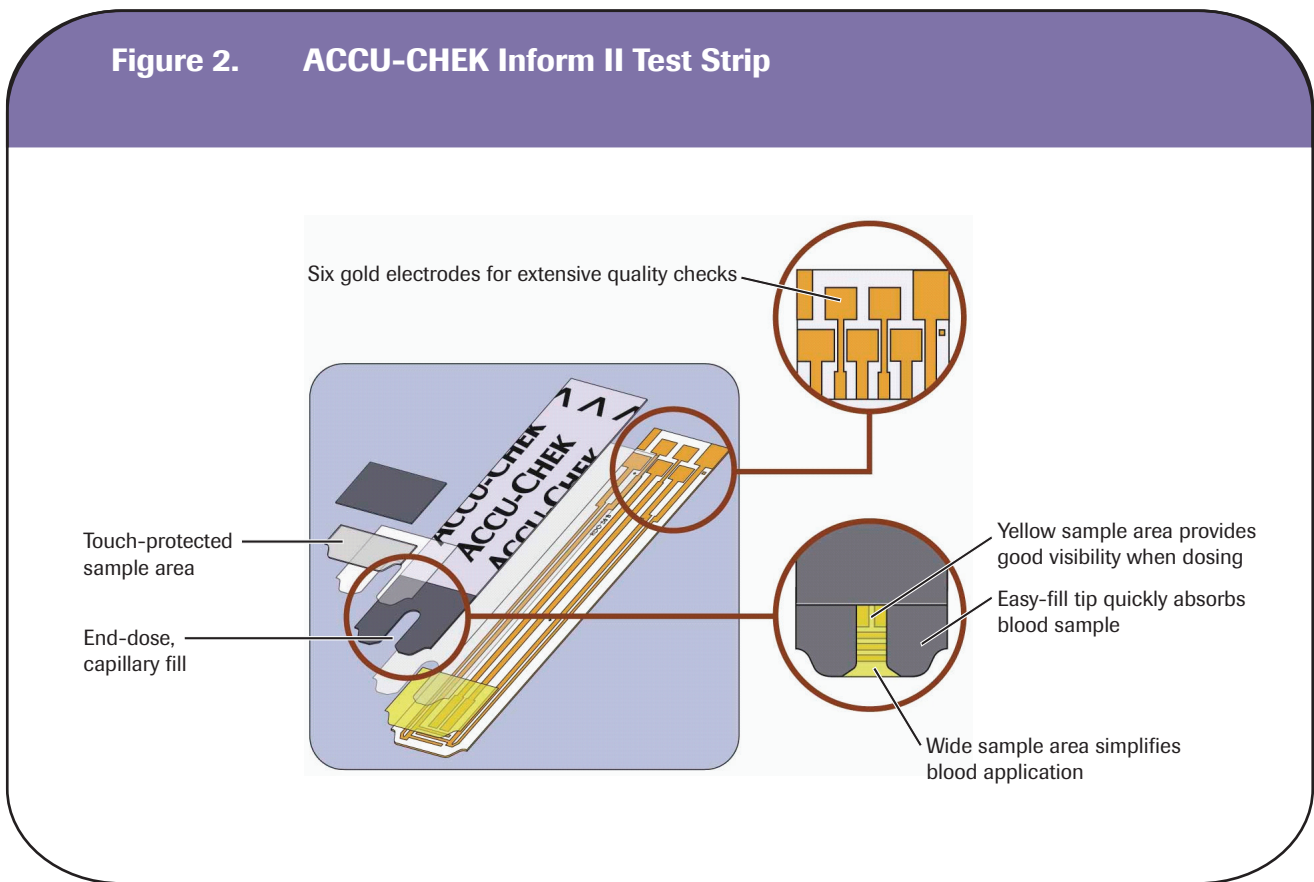
- **Automatic recognition of ACCU-CHEK Inform II control solutions.** By using AC impedance, the system can automatically distinguish quality control solutions from blood.
- **Electrical connection integrity.** The system can compensate for resistance of the strip up to a predefined threshold, which helps ensure an accurate result. If the strip is damaged or abused, the strip resistance will be above the threshold and the meter will not allow the strip to be used for a test.
- **Quality checks.** The ACCU-CHEK Inform II meter conducts extensive quality checks with every test, including test strip, meter, data, and dosing checks.

Meter Support and Safety Functions

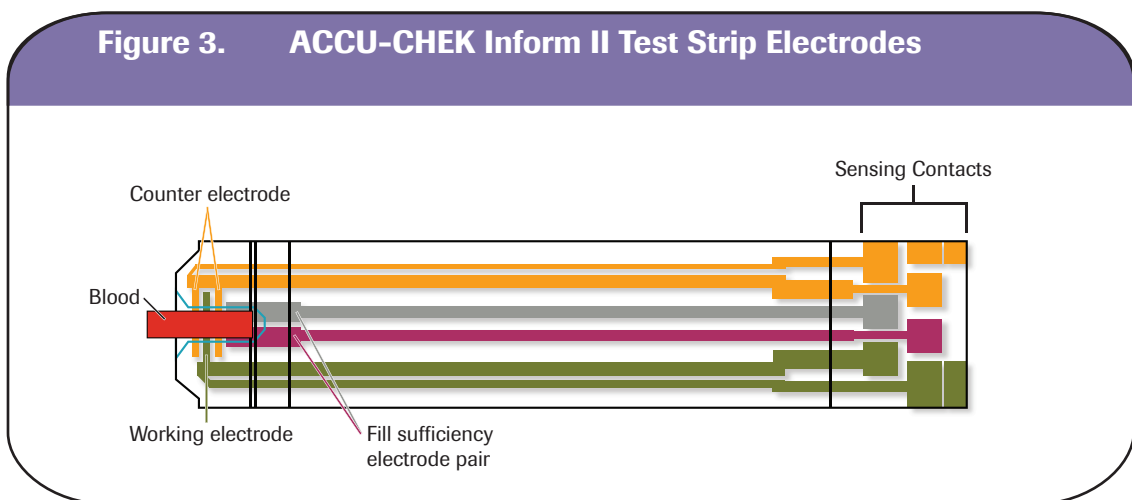
- **Lot expiration detection.** As a safety enhancement, the ACCU-CHEK Inform II meter utilizes information on the code chip to determine the expiration date of the lot. This feature helps prevent the user from using expired test strips. It also eliminates the need for the user to write the expiration date on the strip vial, as required by other systems.
- **Real-time clock for time and date.** A real-time clock is housed in the meter to help preserve time and date information in the event that the main battery is no longer available. This feature ensures that the meter can still determine the lot expiration date and provide accurate time stamps on results, even if the battery is removed or replaced.

ACCU-CHEK Inform II Test Strip

Strip Architecture and Functionality



The ACCU-CHEK Inform II test strip contains six gold electrodes (see Figure 2) that allow the system, along with its patented technology, to perform extensive quality checks. The two principle measurement electrodes, the counter electrode and working electrode, conduct integrity checks prior to measuring the glucose concentration. The remaining electrodes compensate for variations in strip resistance, as well as detect whether an adequate sample volume has been applied to the test strip (see Figure 3).



The following quality checks ensure that the user obtains an accurate result:

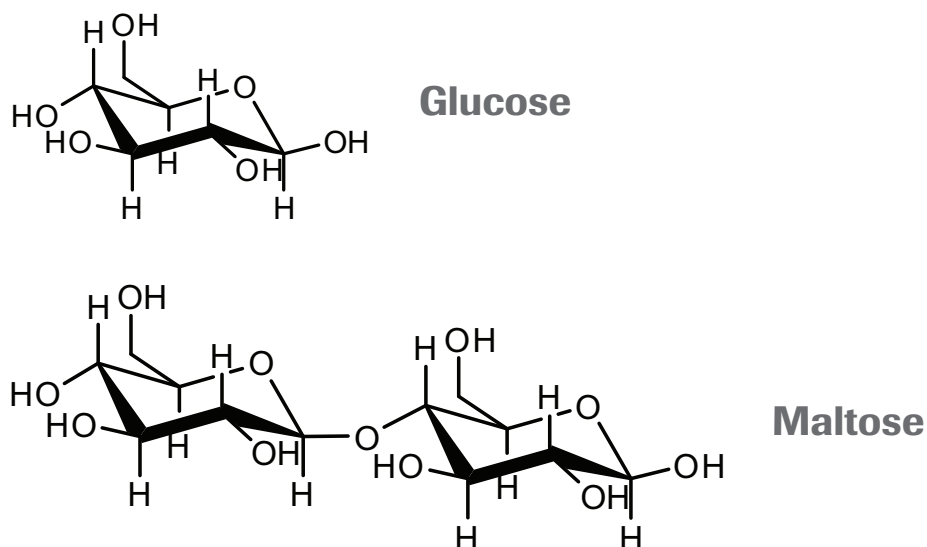
- **Sample checks**
 - Verify whether the correct amount of blood is applied to the test strip (fill detection)
 - Detect and identify the sample as blood or a control solution
 - Determine whether hematocrit will affect the result and make corrections as necessary
- **System checks**
 - Detect humidity exposure
 - Detect variations in temperature
- **Strip checks**
 - Evaluate the test strips and reagent for potential damage or abuse, including:
 - ◆ exposure to high humidity
 - ◆ scratches on the strip electrodes

Strip Reaction Principle

The enzyme on the ACCU-CHEK Inform II test strip, Mut. Q-GDH from *Acinetobacter calcoaceticus*, recombinant in *E. coli*, converts the glucose in the blood sample to gluconolactone. This reaction creates a harmless DC electrical current that the meter interprets for blood glucose. The sample and environmental conditions are also evaluated using a small AC signal.

The new Mut. Q-GDH enzyme was developed to eliminate maltose as a limitation, while maintaining the accuracy, precision, and test strip stability of the classic PQQ enzyme system. Molecular cloning techniques were used to modify the GDH-PQQ enzyme to create the Mut. Q-GDH enzyme, which has improved molecule size discrimination. While the molecular structures of glucose and maltose are similar, the mutant enzyme can distinguish the difference in size between the two molecules (see Figure 4), thereby eliminating the maltose interference limitation.

Figure 4. Glucose and Maltose Molecular Structure



Accuracy Studies Using the ACCU-CHEK Inform II System

Accuracy with Capillary Whole Blood, Performed by Patients

Patients at two participating facilities were asked to read the labeling provided with the ACCU-CHEK Inform II system, and to subsequently perform a finger stick and dose a test strip from one of four independent strip lots. The patients were given no instruction by a trained technician. The patient results were compared to whole blood reference samples, which were analyzed on a Roche/Hitachi 917 analyzer using glucose hexokinase methodology and mathematically converted to IFCC plasma-like reference values. Data from 184 patients were used in the analysis. The glucose reference values ranged from 43 to 579 mg/dL, and the hematocrit range tested was 23 to 57%.

In Figure 5, the data for all four strip lots are presented in a bias plot and assessed per the following acceptance criteria:

- 95% of the individual glucose results shall fall within ± 15 mg/dL of the reference results at glucose concentrations less than 75 mg/dL and within $\pm 20\%$ at glucose concentrations greater than or equal to 75 mg/dL.

In addition, to evaluate performance at an even higher level of accuracy, data were also assessed per the following tighter acceptance criteria:

- 95% of the individual glucose results shall fall within ± 12 mg/dL of the reference results at glucose concentrations less than 100 mg/dL and within $\pm 12.5\%$ at glucose concentrations greater than or equal to 100 mg/dL.

Figure 5. Accuracy with Capillary Whole Blood, Performed by Patients

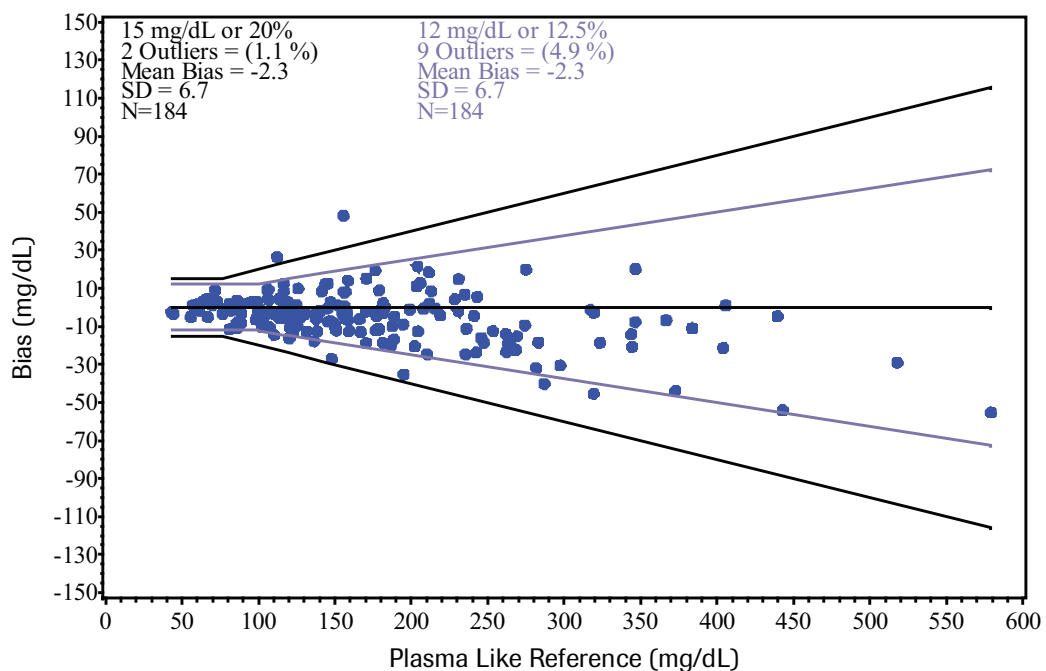


Table 2 presents a summary of results from the study. As seen in Figure 5 and Table 2, 98.9% of the data were within these bias requirements and the acceptance criteria were clearly met. These data demonstrate that the untrained user can obtain accurate results with capillary blood.

Table 2. Accuracy with Capillary Whole Blood, Performed by Patients

	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL	
Results <75 mg/dL	12/13 (92.3%)	13/13 (100%)	13/13 (100%)	
	Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
Results ≥ 75 mg/dL	86/171 (50.3 %)	145/171 (84.8 %)	167/171 (97.7 %)	169/171 (98.8 %)

	Within ± 12 mg/dL
Results <100 mg/dL	31/31 (100%)
	Within $\pm 12.5\%$
Results ≥ 100 mg/dL	144/153 (94.1%)

Accuracy with Capillary Whole Blood, Performed by Technician

A study was conducted to assess the accuracy of the ACCU-CHEK Inform II system with capillary blood samples. Technicians at a participating facility performed capillary finger sticks on 100 patients. One test strip from three individual strip lots was dosed for each patient, for a total of 300 glucose meter results. Results were compared to whole blood reference samples, which were analyzed on a Roche/Hitachi 917 analyzer using glucose hexokinase methodology and mathematically converted to IFCC plasma-like reference values. The glucose reference values ranged from 21 to 547 mg/dL, and the hematocrit range tested was 29 to 50%.

In Figure 6, the data for all three strip lots are presented in a bias plot and assessed per the following acceptance criteria:

- 95% of the individual glucose results shall fall within ± 15 mg/dL of the reference results at glucose concentrations less than 75 mg/dL and within $\pm 20\%$ at glucose concentrations greater than or equal to 75 mg/dL.

In addition, to evaluate performance at an even higher level of accuracy, data were also assessed per the following tighter acceptance criteria:

- 95% of the individual glucose results shall fall within ± 12 mg/dL of the reference results at glucose concentrations less than 100 mg/dL and within $\pm 12.5\%$ at glucose concentrations greater than or equal to 100 mg/dL.

Figure 6. Accuracy with Capillary Whole Blood, Performed by Technician

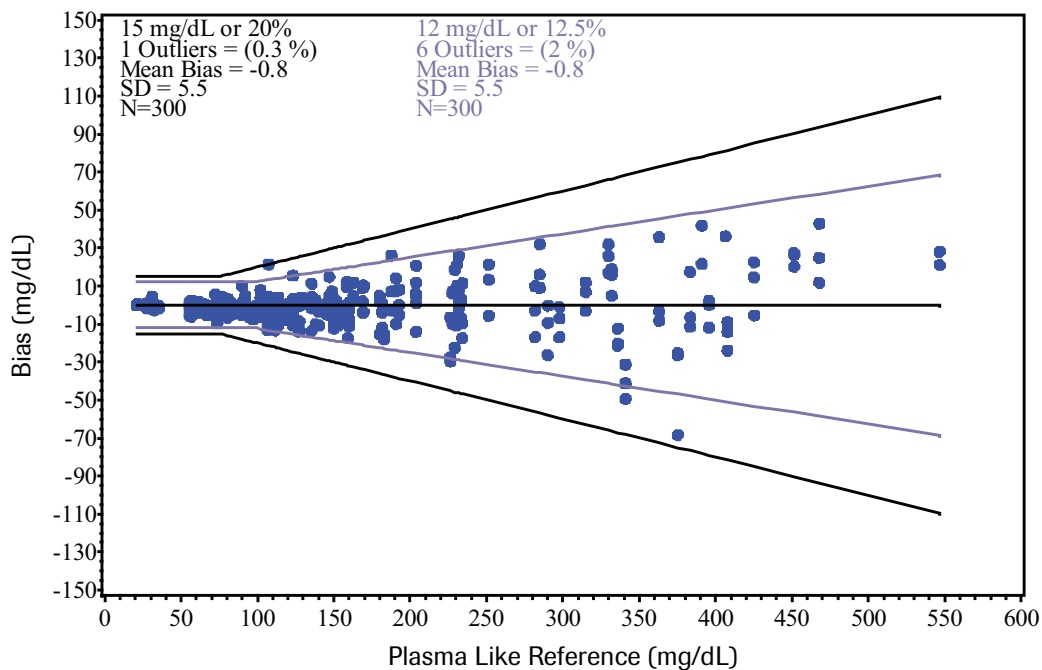


Table 3 presents a summary of results from the study. As seen in Figure 6 and Table 3, 99.7% of the data were within these bias requirements and the acceptance criteria were clearly met. These data demonstrate the excellent accuracy of the ACCU-CHEK Inform II system with capillary blood samples.

Table 3. Accuracy with Capillary Whole Blood, Performed by Technician

	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL	
Results <75 mg/dL	39/48 (81.3%)	48/48 (100%)	48/48 (100%)	
	Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
Results ≥ 75 mg/dL	149/252 (59.1%)	228/252 (90.5%)	250/252 (99.2%)	251/252 (99.6%)

	Within ± 12 mg/dL
Results <100 mg/dL	87/87 (100%)
	Within $\pm 12.5\%$
Results ≥ 100 mg/dL	207/213 (97.2%)

Accuracy with Venous Whole Blood

Technicians at five clinical sites collected blood via venipuncture. Test strips from three independent lots were then dosed with the venous blood samples by the technicians. These results were compared to whole blood reference samples, which were analyzed on a Roche/Hitachi 917 analyzer using glucose hexokinase methodology and mathematically converted to IFCC plasma-like reference values.

450 samples were included in the analysis. The glucose reference values ranged from 19 to 546 mg/dL, and the hematocrit range tested was 20 to 63%.

In Figure 7, the data for all three strip lots are presented in a bias plot and assessed per the following acceptance criteria:

- 95% of the individual glucose results shall fall within ± 15 mg/dL of the reference results at glucose concentrations less than 75 mg/dL and within $\pm 20\%$ at glucose concentrations greater than or equal to 75 mg/dL.

In addition, to evaluate performance at an even higher level of accuracy, data were also assessed per the following tighter acceptance criteria:

- 95% of the individual glucose results shall fall within ± 12 mg/dL of the reference results at glucose concentrations less than 100 mg/dL and within $\pm 12.5\%$ at glucose concentrations greater than or equal to 100 mg/dL.

Figure 7. Accuracy with Venous Whole Blood

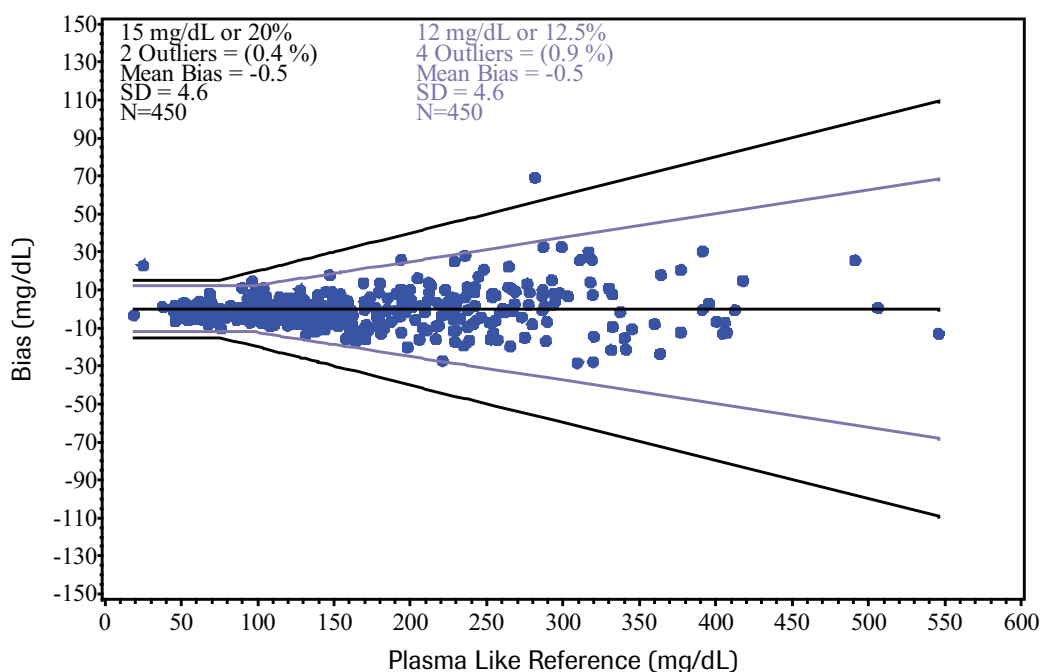


Table 4 presents a summary of results from the study. As seen in Figure 7 and Table 4, 99.6% of the data were within these bias requirements and the acceptance criteria were clearly met. These data confirm that the ACCU-CHEK Inform II system provides accurate results with venous blood samples.

Table 4. Accuracy with Venous Whole Blood

	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL	
Results <75 mg/dL	67/77 (87.0%)	76/77 (98.7%)	76/77 (98.7%)	
	Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
Results ≥ 75 mg/dL	277/373 (74.3%)	357/373 (95.7%)	371/373 (99.5%)	372/373 (99.7%)

	Within ± 12 mg/dL
Results <100 mg/dL	111/113 (98.2%)
	Within $\pm 12.5\%$
Results ≥ 100 mg/dL	335/337 (99.4%)

Accuracy with Neonatal Capillary Whole Blood

Studies were conducted to assess the accuracy of the ACCU-CHEK Inform II system with neonatal capillary blood samples. Technicians at a participating facility performed capillary heelsticks on newborns (less than 30 days old) and dosed test strips from three independent strip lots. These results were compared to whole blood reference samples, which were analyzed on a Roche/Hitachi 917 analyzer using glucose hexokinase methodology and mathematically converted to IFCC plasma-like reference values. Data from 191 patients were used in the analysis, and patient samples were tested with one test strip from each of the three lots. The glucose reference values ranged from 18 to 153 mg/dL and the hematocrit range tested was 23 to 58%.

In Figure 8, the data for all three strip lots are presented in a bias plot and assessed per the following acceptance criteria:

- 95% of the individual glucose results shall fall within ± 15 mg/dL of the reference results at glucose concentrations less than 75 mg/dL and within $\pm 20\%$ at glucose concentrations greater than or equal to 75 mg/dL.

In addition, to evaluate performance at an even higher level of accuracy, data were also assessed per the following tighter acceptance criteria:

- 95% of the individual glucose results shall fall within ± 12 mg/dL of the reference results at glucose concentrations less than 100 mg/dL and within $\pm 12.5\%$ at glucose concentrations greater than or equal to 100 mg/dL.

Figure 8. Accuracy with Neonatal Capillary Whole Blood

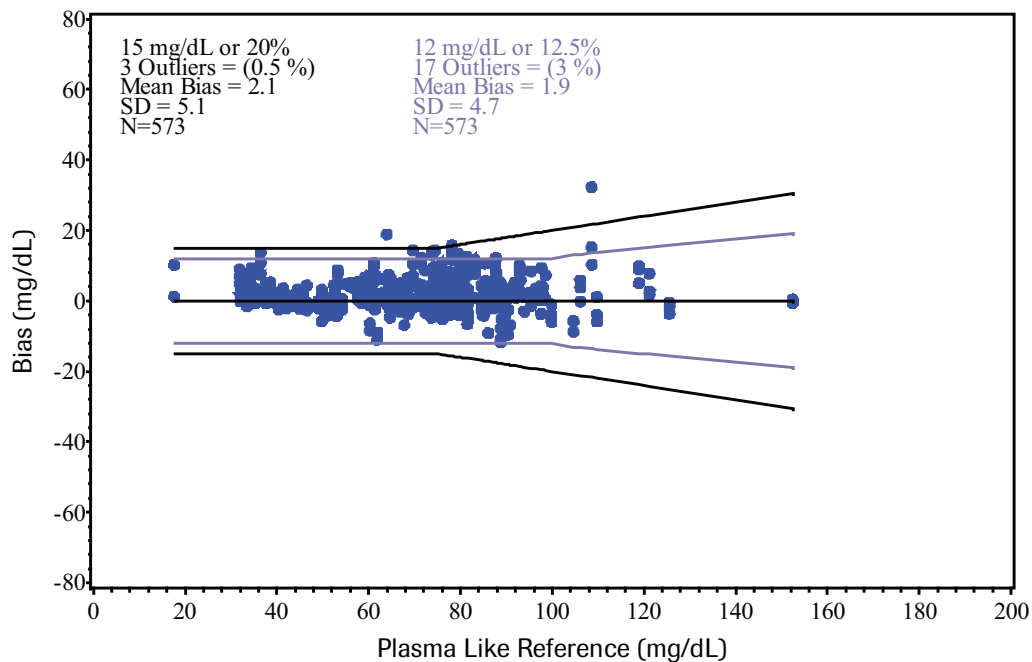


Table 5 presents a summary of results from the study. As seen in Figure 8 and Table 5, 99.5% of the data were within these bias requirements and the acceptance criteria were clearly met. These data indicate that the ACCU-CHEK Inform II system provides accurate results with neonatal whole blood samples.

Table 5. Accuracy with Neonatal Capillary Whole Blood

	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL	
Results <75 mg/dL	253/315 (80.3%)	299/315 (94.9%)	314/315 (99.7%)	
	Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
Results ≥ 75 mg/dL	161/258 (62.4%)	225/258 (87.2%)	252/258 (97.7%)	256/258 (99.2%)

	Within ± 12 mg/dL
Results <100 mg/dL	534/549 (97.3%)
	Within $\pm 12.5\%$
Results ≥ 100 mg/dL	22/24 (91.7%)

To further demonstrate accuracy with capillary neonate blood at very low glucose concentrations, Figure 9 shows results for glucose concentrations less than or equal to 50 mg/dL for all three strip lots using capillary heelstick blood samples from 45 neonates. Table 6 presents a summary of the results. As shown, 100% of the data were within the bias requirements and the acceptance criteria were clearly met, indicating the excellent accuracy of the ACCU-CHEK Inform II system with neonatal whole blood samples at glucose levels less than or equal to 50 mg/dL.

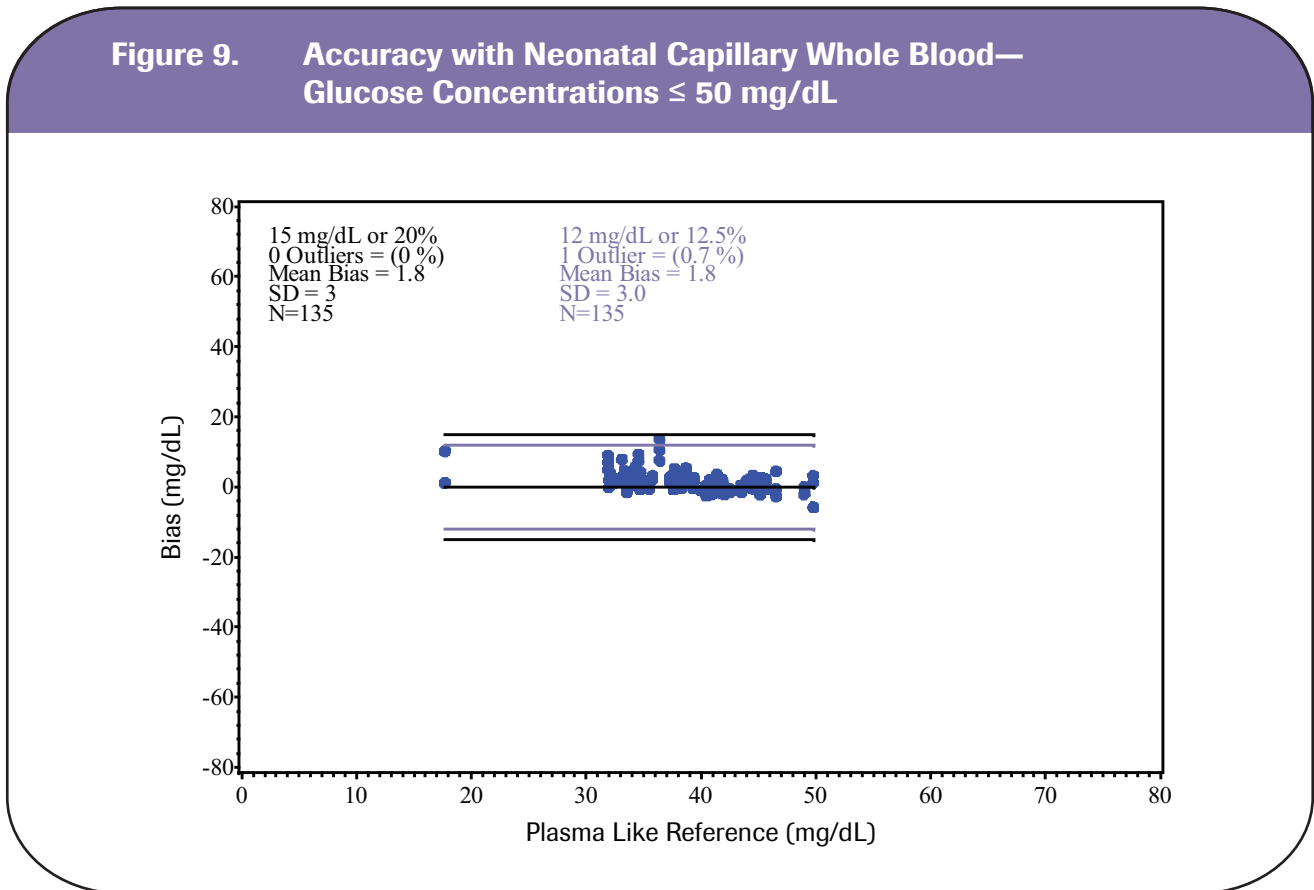


Table 6. Accuracy with Neonatal Capillary Whole Blood—Glucose Concentrations \leq 50 mg/dL

	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Results <75 mg/dL	118/135 (87.4%)	131/135 (97.0%)	135/135 (100%)

	Within ± 12 mg/dL
Results <100 mg/dL	134/135 (99.3%)

Accuracy with Arterial Whole Blood

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. These results were compared to whole blood reference samples, which were analyzed on a Roche/Hitachi 917 analyzer using glucose hexokinase methodology and mathematically converted to IFCC plasma-like reference values.

Data from 214 patients were used in the analysis, and patient samples were tested with one test strip from each of the three lots. The glucose reference values ranged from 58 to 322 mg/dL and the hematocrit range tested was 19 to 54%. The glucose range represents the samples collected at the clinical site, which did not exceed 322 mg/dL due to the site's glycemic control program.

In Figure 10, the data for all three strip lots are presented in a bias plot and assessed per the following acceptance criteria:

- 95% of the individual glucose results shall fall within ± 15 mg/dL of the reference results at glucose concentrations less than 75 mg/dL and within $\pm 20\%$ at glucose concentrations greater than or equal to 75 mg/dL.

In addition, to evaluate performance at an even higher level of accuracy, data were also assessed per the following tighter acceptance criteria:

- 95% of the individual glucose results shall fall within ± 12 mg/dL of the reference results at glucose concentrations less than 100 mg/dL and within $\pm 12.5\%$ at glucose concentrations greater than or equal to 100 mg/dL.

Figure 10. Accuracy with Arterial Whole Blood

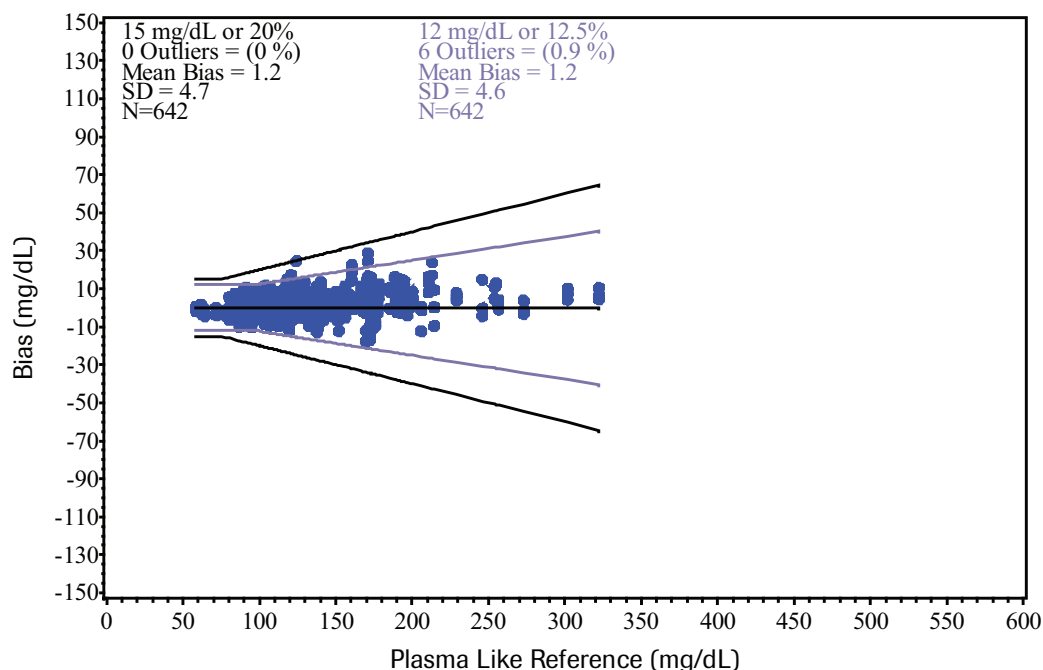


Table 7 presents a summary of results from the study. As seen in Figure 10 and Table 7, 100% of the data were within these bias requirements and the acceptance criteria were clearly met. As shown, the ACCU-CHEK Inform II system provides accurate results with arterial samples.

Table 7. Accuracy with Arterial Whole Blood

	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL	
Results <75 mg/dL	12/12 (100%)	12/12 (100%)	12/12 (100%)	
	Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
Results ≥ 75 mg/dL	447/630 (71.0%)	609/630 (96.7%)	628/630 (99.7%)	630/630 (100%)

	Within ± 12 mg/dL
Results <100 mg/dL	126/126 (100%)
	Within $\pm 12.5\%$
Results ≥ 100 mg/dL	510/516 (98.8%)

Accuracy with Hospital Samples (Venous and Arterial Whole Blood)

A study was conducted to assess the accuracy of the ACCU-CHEK Inform II system with blood samples from patients at one external hospital. Technicians dosed test strips from one representative test strip lot with venous and arterial whole blood samples. These results were compared to whole blood reference samples, which were analyzed on a cobas 6000 analyzer using glucose hexokinase methodology and mathematically converted to IFCC plasma like reference values. 1933 native samples were included in the analysis. The glucose reference values ranged from 12 to 468 mg/dL and the hematocrit range tested was 18% to 55%.

In Figure 11, the data are presented in a bias plot and assessed per the following acceptance criteria:

- 95% of the individual glucose results shall fall within ± 15 mg/dL of the reference results at glucose concentrations less than 75 mg/dL and within $\pm 20\%$ at glucose concentrations greater than or equal to 75 mg/dL.

In addition, to evaluate performance at an even higher level of accuracy, data were also assessed per the following tighter acceptance criteria:

- 95% of the individual glucose results shall fall within ± 12 mg/dL of the reference results at glucose concentrations less than 100 mg/dL and within $\pm 12.5\%$ at glucose concentrations greater than or equal to 100 mg/dL.

Figure 11. Accuracy with Hospital Samples (Venous and Arterial Whole Blood)

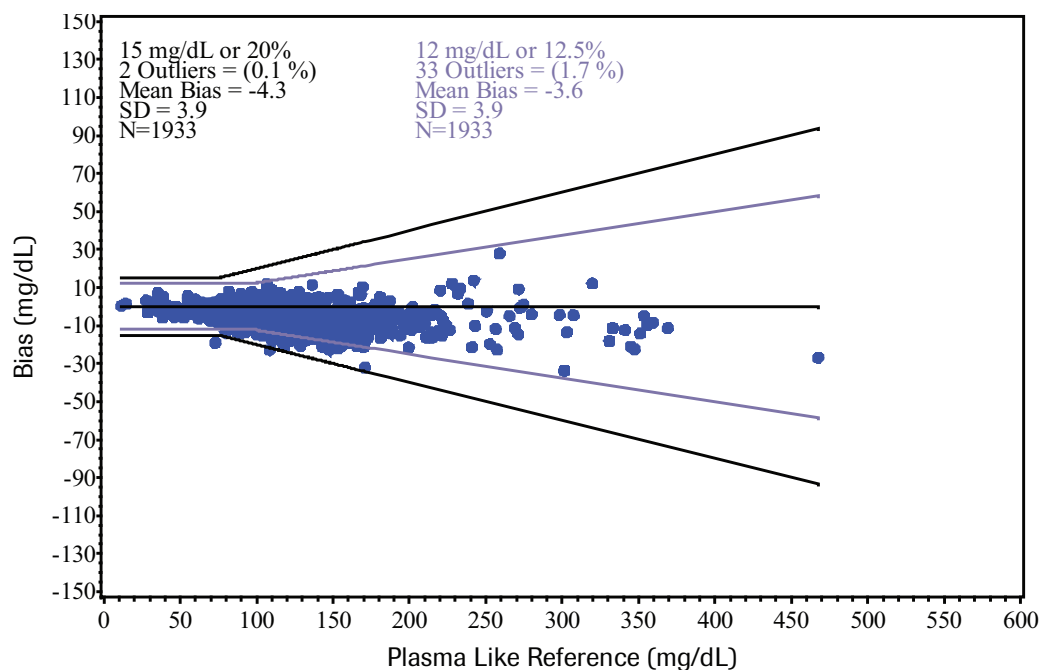


Table 8 presents a summary of results from the study. As seen in Figure 11 and Table 8, 99.9% of the data were within these bias requirements and the acceptance criteria were clearly met. These data demonstrate the excellent accuracy of the ACCU-CHEK Inform II system with samples from hospitalized patients.

Table 8. Accuracy with Hospital Samples (Venous and Arterial Whole Blood)

	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL	
Results <75 mg/dL	117/135 (86.7 %)	134/135 (99.3 %)	134/135 (99.3%)	
	Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
Results ≥ 75 mg/dL	967/1798 (53.8%)	1671/1798 (92.9%)	1787/1798 (99.4%)	1797/1798 (99.9%)

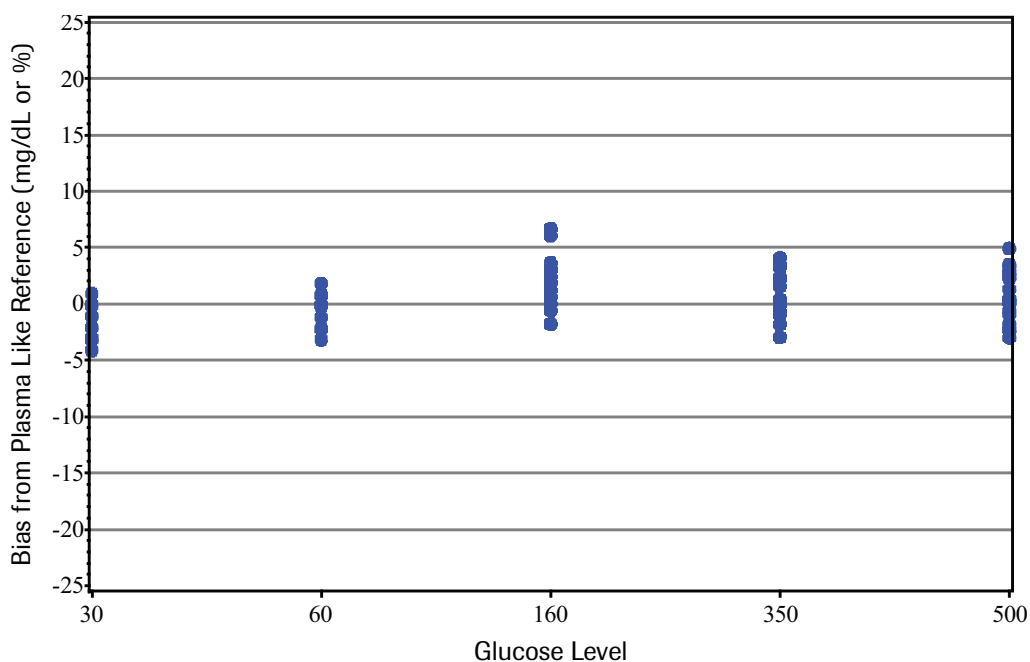
	Within ± 12 mg/dL
Results <100 mg/dL	615/621 (99.0%)
	Within $\pm 12.5\%$
Results ≥ 100 mg/dL	1285/1312 (97.9%)

Accuracy at Elevated Altitude

Testing occurred at one clinical facility located 10,150 feet above sea level. Glycolized venous blood was spiked to target glucose concentrations spanning the entirety of the glucose measuring range (35, 60, 160, 350, and 500 mg/dL), and tested with test strips from two independent strip lots. These results were compared to whole blood reference samples, which were analyzed on a Roche/Hitachi 917 analyzer using glucose hexokinase methodology and mathematically converted to IFCC plasma-like reference values. A total of 100 results were used for the analysis. The measured hematocrit of the pooled venous blood was 39%.

Figure 12 shows the individual result bias to the reference for each glucose level tested. As seen in Figure 12, 100% of the individual glucose results were within ± 10 mg/dL of the reference results (at 35 and 60 mg/dL) or within $\pm 10\%$ of the reference results (at 160, 350 and 500 mg/dL). These data indicate that the ACCU-CHEK Inform II system provides accurate results at elevated altitude.

Figure 12. Accuracy at Elevated Altitude



Cleaning and Disinfection Robustness

A study was conducted to evaluate lifetime robustness against cleaning and disinfection procedures of the ACCU-CHEK Inform II system. Six ACCU-CHEK Inform II meters were subjected to 12,045 cleaning and disinfection cycles with disinfecting wipes to simulate a lifetime of three years: three meters were tested with Clorox® Germicidal Wipes and three meters were tested with Super Sani-Cloth® wipes. Each cleaning and disinfection cycle included two steps:

- The meter is wiped to clean the housing using a disinfecting wipe, then wiped dry with a tissue.
- The meter is wiped three times horizontally and three times vertically using a fresh disinfecting wipe, and after waiting for the required contact time, wiped dry with a tissue.

Venous blood accuracy testing was performed after 12,045 cleaning and disinfection cycles. Glycolized venous blood was spiked to target glucose concentrations spanning the entirety of the glucose measuring range. This blood was then tested on meters that had undergone 12,045 cleaning and disinfection cycles, and a total of 225 test strip measurements were collected with strips from one representative test strip lot. Results were compared to whole blood reference samples, which were analyzed on a Roche/Hitachi 917 analyzer using glucose hexokinase methodology and mathematically converted to IFCC plasma-like reference values.

Table 9 indicates the results of venous blood accuracy testing after 12,045 cleaning and disinfection cycles. Data were assessed per the following acceptance criteria:

- 95% of the individual glucose results shall fall within ± 15 mg/dL of the reference results at glucose concentrations less than 75 mg/dL and within $\pm 20\%$ at glucose concentrations greater than or equal to 75 mg/dL.

As seen in Table 9, 100% of results gathered after cleaning and disinfection cycles simulating three years lifetime were well within the acceptance criteria. In addition, results from functional and aesthetic tests indicated the meter functionality was not impacted by the cleaning and disinfection procedure. These results confirm the robustness of the ACCU-CHEK Inform II meter against cleaning and disinfecting for three years lifetime using Clorox Germicidal Wipes and Super Sani-Cloth wipes.

Table 9. Cleaning and Disinfection Robustness – Venous Blood Accuracy at 3 Years Lifetime

	Target Glucose	n	Within ± 5 mg/dL or 5%	Within ± 10 mg/dL or 10%	Within ± 15 mg/dL or 15%
Clorox Germicidal Wipes	Results <75 mg/dL	45	45/45 (100%)	45/45 (100%)	45/45 (100%)
	Results ≥ 75 mg/dL	180	155/180 (86.1%)	180/180 (100%)	180/180 (100%)
	Total	225	200/225 (88.9%)	225/225 (100%)	225/225 (100%)
Super Sani-Cloth	Results <75 mg/dL	45	45/45 (100%)	45/45 (100%)	45/45 (100%)
	Results ≥ 75 mg/dL	180	144/180 (80.0%)	176/180 (97.8%)	180/180 (100%)
	Total	225	189/225 (84.0%)	221/225 (98.2%)	225/225 (100%)

ACCU-CHEK Inform II System Precision

The precision of the ACCU-CHEK Inform II system was assessed using both aqueous control solutions and venous blood samples. For both control solutions and blood samples, ten vials of test strips from each of three lots were allocated per sample type and level, for a total of 30 vials per glucose level. Ten replicates per vial were collected and the overall SD or CV was calculated (based on glucose level).

The following control levels were used in the precision studies:

- **Low:** 30 to 60 mg/dL
- **Mid:** 100 to 136 mg/dL
- **High:** 261 to 353 mg/dL

The following spiked venous blood levels were used in the precision studies:

- **1:** 30 to 50 mg/dL
- **2:** 50 to 110 mg/dL
- **3:** 110 to 150 mg/dL
- **4:** 150 to 250 mg/dL
- **5:** 250 to 400 mg/dL

Table 10 and Table 11 show the results of the precision testing with controls and blood, respectively, for a representative test strip lot. Acceptable performance is defined as:

- At glucose concentrations less than or equal to 75 mg/dL, a standard deviation (SD) of less than or equal to 5 mg/dL
- At glucose concentrations greater than 75 mg/dL, a coefficient of variance (CV) less than or equal to 5%.

Results show that all precision estimates for control and spiked venous blood are below the 5 mg/dL or 5% threshold. In fact, all SD values for control solutions and venous blood at glucose levels 75 mg/dL and below are at or below 2.7 mg/dL, while all CV values for control solutions and venous blood at glucose levels over 75 mg/dL are at or below 3.4%. These data indicate that the ACCU-CHEK Inform II system provides precise results with both control solutions and whole blood.

Table 10. System Precision (Day-to-Day)—Control Solutions

	Low	Mid	High
N	100	100	100
Mean (mg/dL)	44.6	117.6	305.6
SD (mg/dL)	1.2	2.2	4.6
CV (%)	2.6	1.9	1.5

Table 11. System Precision (Within-Run)—Blood

	1	2	3	4	5
N	100	100	100	100	100
Mean (mg/dL)	36.1	76.9	123.4	191.8	316.6
SD (mg/dL)	1.2	2.7	4.2	5.8	9.5
CV (%)	3.3	3.5	3.4	3.0	3.0

Impact of Hematocrit

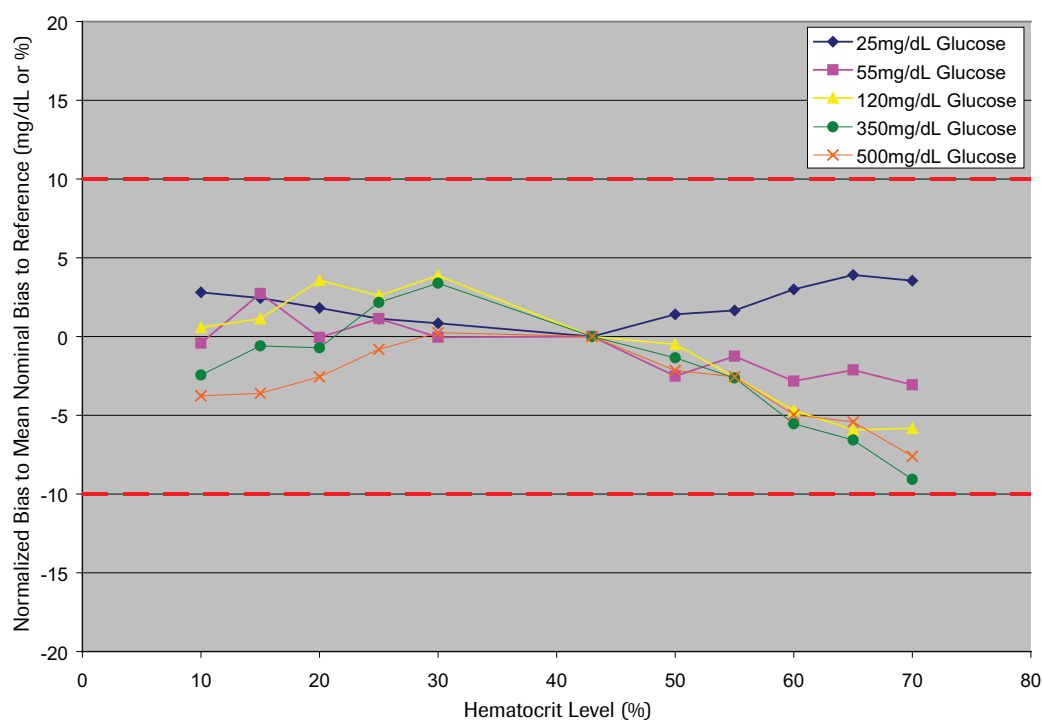
Five levels of glycolized venous blood with the target glucose level at 25, 55, 120, 350, and 500 mg/dL were tested with hematocrit levels adjusted to 10, 15, 20, 25, 30, 50, 55, 60, 65, and 70% to determine the impact of hematocrit on the performance of the ACCU-CHEK Inform II system. These results were compared to a sample at nominal hematocrit (43%).

Three ACCU-CHEK Inform II strip lots were tested and all lots met the following acceptance criteria:

- For glucose concentrations less than or equal to 75 mg/dL, a mean bias of less than or equal to 10 mg/dL
- For glucose concentrations greater than 75 mg/dL, a mean bias less than or equal to 10%.

The results for one representative lot are shown in Figure 13. Data from all three lots confirm that the ACCU-CHEK Inform II system supports a claimed hematocrit range of 10 to 65%.

Figure 13. Impact of Hematocrit



Impact of Potentially Interfering Substances

The ACCU-CHEK Inform II system has been thoroughly evaluated with potential interfering substances. Substances were tested at concentrations described by the Clinical Lab Standard Institute in documents *EP07: Interference Testing in Clinical Chemistry, 3rd edition* and *EP37: Supplemental Tables for Interference Testing in Clinical Chemistry, 1st edition*. Testing was conducted according to the ISO 15197:2013/EN ISO 15197:2015 standard and the FDA's *Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use Draft Guidance, issued November 30, 2018*. Many of the endogenous and exogenous compounds were evaluated at concentrations three or more times the therapeutic plasma concentrations. Each medication and metabolite was evaluated at three target glucose levels to ensure accuracy.

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 mg/dL 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, Acarbose Highest Concentration Tested: $6.00E+01 = 6.00 \times 10 = 60$ mg/dL

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

For example, Acarbose Upper Therapeutic Concentration: $1.00E-02 = 1.00 / 100 = 0.01$ mg/dL

- **00 Exponent:** Use the stated value with no adjustment.

For example, Acetaminophen Upper Therapeutic Concentration: $5.20E+00 = 5.20$ mg/dL

Table 12. Potential Interfering Substances List—Concentrations Tested

Substance	Highest Concentration Tested (mg/dL)	Upper Therapeutic Concentration (mg/dL)
Acarbose	6.00E+01	1.00E-02
Acetaminophen	2.00E+01	5.20E+00
Acetazolamide	6.00E+00	1.90E+00
Acetone	1.00E+02	2.00E+00
N-Acetylcysteine	5.00E+00	5.00E+00
Acetylprocainamide	1.50E+01	1.00E+00
Acetylsalicylic Acid	6.00E+01	1.00E+00
Acyclovir	6.60E+00	2.20E+00
Albumin	5.00E+03	5.20E+03
Albuterol	2.50E+01	1.50E-03
Allopurinol	6.00E+00	2.00E+00

Substance	Highest Concentration Tested (mg/dL)	Upper Therapeutic Concentration (mg/dL)
Aminocaproic Acid	8.00E-02	3.00E-01
Amiodarone HCl	5.00E+00	1.40E+00
Amitriptyline	1.00E+00	1.60E-02
Amoxapine	1.00E-01	9.30E-03
Amoxicillin	6.00E+02	1.80E+00
Ampicillin	7.50E+00	2.50E+00
Ascorbic Acid	3.00E+00	1.75E+00
Astemizole	1.00E+00	1.00E-02
Atorvastatin	5.00E-01	2.50E-02
Atropine	1.00E+00	2.00E-02
Azithromycin	1.20E+00	3.70E-01
Beta-carotene	6.00E-01	8.30E-02
Bevacizumab	6.40E+01	undetermined
Bile	1.50E+00	7.00E-01
Bilirubin (Conjugated)	5.00E+01	2.00E-01
Bilirubin (Unconjugated)	4.00E+01	2.00E+00
Biotin	4.00E-01	1.17E-01
Bupirone	1.00E+00	2.00E-04
Caffeine	1.00E+01	3.60E+00
Calcium (Chloride)	2.00E+01	3.00E-01
Calcium Gluconate	3.10E+01	undetermined
Captopril	5.00E-01	8.80E-02
Carbamazepine	4.50E+00	1.50E+00
Cefaclor	3.50E+01	2.90E+00
Cefadroxil	1.05E+01	3.60E+00
Cefazolin	1.20E+02	undetermined
Ceftriaxone	8.40E+01	2.80E+00
Cephalexin	3.20E+01	4.20E+00
Cephalothin	2.00E+02	6.00E+01
Cetirizine Dihydrochloride	1.00E+00	1.45E-01
Chenodeoxycholic Acid	3.00E+00	6.30E-02
Chlorothiazide	2.70E+00	9.00E-01
Chlorpropamide	8.00E+01	2.20E+01
Cholesterol	5.00E+02	2.00E+02

Substance	Highest Concentration Tested (mg/dL)	Upper Therapeutic Concentration (mg/dL)
Cholic Acid	2.40E+00	3.70E-01
Cimetidine	1.00E+01	1.00E+00
Citric Acid	3.00E+01	3.00E+00
Clindamycin HCl	5.10E+00	1.70E+00
Clonidine	2.00E+00	6.50E-04
Clopidogrel	7.20E+00	undetermined
Creatinine	3.00E+01	1.18E+00
Cyclophosphamide	3.75E+01	1.83E+01
Cyclosporine	5.00E-01	6.00E-02
Cysteine (L-)	5.00E+00	1.40E+00
Cystine (L-)	5.00E+01	1.50E+00
Desipramine	1.00E-01	6.80E-02
Dexamethasone	1.20E+00	4.00E-01
Diclofenac	5.00E+00	8.00E-01
Dicumarol	2.00E+01	5.90E+00
Digoxin	1.00E+00	1.30E-03
Diltiazem	2.00E+01	3.00E-02
Diphenhydramine HCl	1.00E+00	2.58E-02
Dipyrrone	1.10E+01	1.10E+00
Disopyramide	5.00E+00	5.60E-01
Docusate Sodium	2.49E+01	undetermined
DOPA (L-)	2.00E+00	2.50E-01
Dopamine	9.00E-02	2.07E-02
Doxazosinmesylate	1.00E+00	1.01E-02
Doxorubicin HCl	3.00E-02	undetermined
Doxycyclinehyclate	3.00E+00	6.00E-01
EDTA (K2)	3.60E+02	3.30E-01
Enalapril	8.00E+00	2.73E-02
Ephedrine	1.00E+00	1.00E-03
Equilin	1.50E+01	5.00E-01
Erythromycin	6.00E+01	4.60E+00
Estradiol	1.00E-01	2.50E-07
Estrone	1.00E+00	1.00E-05
Ethanol	6.00E+02	2.00E+02

Substance	Highest Concentration Tested (mg/dL)	Upper Therapeutic Concentration (mg/dL)
Ethinyl Estradiol	3.00E-04	undetermined
Ethosuximide	2.50E+01	1.00E+01
Ethyl Acetoacetate	5.10E+01	1.00E+00
Ethylene Glycol	5.00E+00	1.82E+01
Famotidine	6.00E-01	8.12E-02
Felodipine	5.00E+00	9.60E-04
Fenofibrate	5.00E+00	1.50E+00
Fenoprofen	2.00E+01	6.50E+00
Fentanyl	1.50E-02	1.00E-02
Flecainide	1.00E+00	1.71E-01
Fluconazole	1.00E+01	8.50E-01
5-Fluorocytosine	3.00E+01	6.80E+00
Fluoxetine	1.20E+01	4.73E-02
Flurbiprofen	5.00E+00	1.60E+00
Fructose	5.00E+02	6.00E+00
Furosemide	6.00E+00	5.30E-01
Galactose	1.50E+01	5.00E+00
Galactose-1-phosphate	5.00E+02	3.00E-01
Gamma Globulin	3.00E+03	1.60E+03
Gemfibrozil	1.50E+01	4.60E+00
Gentamicin	1.20E+01	1.00E+00
Gentisic Acid	1.80E+00	5.00E-01
Glimepiride	1.00E+00	5.47E-02
Glipizide	8.00E+00	1.00E-01
Glucosamine	4.50E+02	2.32E+00
Glutathione	6.14E+00	7.92E+01
Glycerol	5.00E+02	1.72E+00
Hemoglobin	1.00E+03	3.00E+00
Heparin (Li)	8000 U/dL	110 U/dL
Heparin (Na)	8000 U/dL	110 U/dL
Hydralazine	1.44E+00	4.80E-01
Hydrochlorothiazide	2.00E+00	3.76E-02
Hydrocortisone	2.00E+01	2.30E-02
Hydroxybutyric Acid	1.67E+02	2.81E+00

Substance	Highest Concentration Tested (mg/dL)	Upper Therapeutic Concentration (mg/dL)
Hydroxychloroquine Sulfate	4.00E+00	1.30E-02
Ibandronic Acid	5.00E-01	3.00E-02
Ibuprofen	5.00E+01	7.30E+00
Indomethacin	5.00E+00	4.40E-01
Insulin - Humulin N	20 U/dL	6-37 mU/L
Insulin - Humulin R	20 U/dL	6-37 mU/L
Iohexol	6.00E+01	undetermined
Isomalt	1.00E+01	undetermined
Isoniazid	5.00E+00	2.00E+00
Kanamycin	6.00E+00	3.00E+00
Ketoprofen	6.00E+00	undetermined
Ketorolac	2.10E+00	undetermined
Lactic acid	1.00E+02	1.20E+01
Lactitol Monohydrate	1.00E+01	undetermined
Lactose	1.00E+01	5.00E-01
Lansoprazole	2.00E+01	undetermined
Lecithins	5.00E+02	3.66E+02
Levofloxacin	3.60E+00	1.20E+00
Lidocaine	1.50E+00	5.00E-01
Lipidemia (Triglycerides)	1.80E+03	1.50E+02
Lisinopril	1.00E+00	8.20E-03
Loratadine	1.00E+00	2.90E-03
Magnesium (Sulfate)	2.60E+01	2.40E+00
Maltitol	1.00E+01	undetermined
Maltose	3.60E+02	1.20E+02
Mannitol	1.20E+03	6.00E+02
Mannose	1.00E+01	undetermined
Medroxyprogesterone	1.00E-02	2.00E-04
Metaproterenol	1.81E+00	1.30E-03
Metformin	5.00E+01	4.00E-01
Methadone	5.00E-01	1.06E-01
Methotrexate Hydrate	9.10E+01	4.55E+01
Methyl Dopa	1.50E+00	7.50E-01
Methylhydroxyprogesterone	5.00E+01	7.00E-04

Substance	Highest Concentration Tested (mg/dL)	Upper Therapeutic Concentration (mg/dL)
Methylprednisolone Sodium	8.00E-01	2.61E-01
Metoclopramide	5.00E-01	7.50E-02
Mevinolin (Lovastatin)	4.00E-01	7.00E-03
Metoprolol	1.80E+00	5.00E-02
Mexiletine HCl	1.00E+00	2.50E-01
Midazolam	5.00E-01	1.25E-01
Misoprostol	8.00E-01	8.10E-05
Morphine	8.00E-01	2.60E-01
Mycophenolate Mofetil	1.50E+00	undetermined
Mycophenolic Acid	1.50E+01	1.40E+00
Nadolol	2.00E+00	3.40E-03
Naproxen	1.00E+02	1.20E+01
Neostigmine Bromide	2.00E-01	3.50E-02
Neostigminemethylsulfate	2.00E-01	3.50E-02
Nicotine	2.00E+00	3.23E-02
Nifedipine	4.00E+01	1.96E-02
Nitrofurantoin	4.00E+00	7.10E-02
Nordoxepin	5.00E+00	8.20E-03
Normethylverapamil HCl	1.00E+00	2.00E-02
D-Norpropoxyphene Maleate	1.00E+00	2.64E-01
Nortipityline	3.00E-01	3.75E-02
Oleic Acid	3.50E+01	1.10E+00
Omeprazole	5.20E-01	2.80E-01
Oxalic Acid	2.00E+01	2.40E-01
Oxycodone	5.00E-02	1.08E-02
Palmitic Acid	1.50E+02	5.10E+00
PAM (Pralidoxime Methiodide)	2.50E+01	4.00E-01
Pancuronium Bromide	4.00E-01	undetermined
Pantoprazole	3.00E+00	1.00E+00
Papaverine	6.00E-01	undetermined
Penicillamine Hydrochloride	2.40E+00	6.60E-01
Penicillin	7.20E+01	1.20E+00
Phenelzine Sulfate	5.00E-01	2.00E-04
Phenylalanine (L-)	5.00E+01	3.40E+00

Substance	Highest Concentration Tested (mg/dL)	Upper Therapeutic Concentration (mg/dL)
Phenytoin	1.50E+01	2.00E+00
Pindolol	5.00E-01	8.10E-03
Pioglitazone	5.00E+00	1.59E-01
Piroxicam	1.00E+01	9.60E-01
Potassium Chloride	5.00E+01	3.83E+01
Prednisone	5.00E-01	3.30E-03
Primidone	5.00E+00	1.90E+00
Probenecid	6.00E+01	1.49E+01
Procainamide	1.00E+01	1.60E+00
Propofol	4.80E+00	1.60E+00
Propranolol	1.00E+00	3.35E-02
Pseudoephedrine	1.00E+00	1.10E-01
Pyridoxine	3.00E+00	undetermined
Pyruvic Acid	4.00E+00	9.00E-01
Quetiapine	5.00E-01	9.20E-02
Quinine Sulfate	4.80E+00	1.60E+00
Ramipril	3.58E+00	5.20E-03
Ranitidine	2.00E+01	3.50E-01
Repaglinide	5.00E+00	4.00E-02
Rifampicin	8.00E+00	1.60E+00
Rocuronium	1.80E+00	6.00E-01
Rosiglitazone	5.00E+00	6.52E-02
Salicylic Acid	6.00E+01	9.52E-01
Sirolimus (Rapamycin)	4.50E-03	undetermined
Sodium	115 – 175 mmol/L	136 – 145 mmol/L
Sodium Bicarbonate	3.36E+02	2.40E-02
Sodium Nitroprusside Dihydrate	5.00E-02	undetermined
Sorbitol (D-)	5.00E+02	4.40E-02
Stearic Acid	1.50E+01	2.80E+00
Streptomycin	1.50E+01	8.60E+00
Sucrose	5.00E+02	6.00E-02
Sulfamethoxazole	1.50E+00	undetermined
Tazobactam	7.20E+00	1.02E+00
Terfenadine	2.50E+01	4.50E-04

Substance	Highest Concentration Tested (mg/dL)	Upper Therapeutic Concentration (mg/dL)
Tetracycline	3.00E+01	8.00E-01
Theophylline	2.50E+01	2.00E+00
Thioridazine	4.00E+00	3.90E-01
L-Thyroxine Sodium	5.00E+00	1.43E-02
Tobramycin	3.60E+00	1.10E+00
Tolazamide	2.00E+02	1.50E+00
Tolbutamide	1.00E+02	1.83E+01
Trazodone	2.00E+00	4.90E-01
Triamterene	6.00E+00	1.95E-02
Trimethoprim	6.00E+00	1.40E+00
Tyrosine (L-)	2.40E+01	2.40E+01
Urea	6.00E+02	2.00E+01
Uric Acid	2.35E+01	7.20E+00
Valproic Acid	5.00E+01	1.06E+01
Vancomycin	2.00E+01	4.00E+00
Venlafaxine	5.00E-01	2.32E-02
Verapamil	1.00E+00	5.32E-02
Vitamin B12	1.00E+00	6.78E-05
Vitamin E	2.00E+01	2.00E+00
Voluven	8.00E+02	8.00E+02
Warfarin	1.00E+01	2.50E+00
Xylitol	2.00E+02	1.20E-01
Xylose	5.00E+02	3.00E+01
Zenapax (Daclizumab)	1.00E+01	1.00E+00

The following compounds, when tested with the ACCU-CHEK Inform II system, were found to be interfering substances.

Table 13. Interfering Substances

Substance	ACCU-CHEK Inform II System Accuracy Threshold (mg/dL)
Lipidemia (Triglycerides) ¹	> 1800
Galactose ²	> 15
Ascorbic Acid ³	> 3
N-Acetylcysteine ⁴	> 5

¹ Lipemic samples (triglycerides) in excess of 1800 mg/dL may produce elevated results.

² Blood concentrations of galactose greater than 15 mg/dL will cause overestimation of blood glucose results. Glucose values in neonates suspect for galactosemia should be confirmed by an alternate glucose methodology.

³ Intravenous administration of ascorbic acid that results in blood concentrations of ascorbic acid greater than 3 mg/dL will cause overestimation of blood glucose results.

⁴ Intravenous administration of N-acetylcysteine which results in blood concentrations greater than 5 mg/dL will cause overestimation of blood glucose results. Do not use during intravenous infusion of N-acetylcysteine.

Conclusion

The data presented in this document demonstrate the capability of the ACCU-CHEK Inform II meter and test strips. With new Mut. Q-GDH enzyme and the compensations provided by AC impedance, the system is optimized to meet today's performance needs by offering a 5-second test time, expanded hematocrit and environmental ranges, and minimal sample volume of 0.6 μ L. With every test, the system performs extensive quality checks to ensure accurate and reliable results. The system also eliminates the maltose limitation, which makes it suitable for use by patients receiving therapy with solutions containing or producing maltose.



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