ACCU-CHEK® Inform II

Test Strips and 1 Code Key

PROFESSIONAL USE

Cat. No. 05942861001

Important Information

The ACCU-CHEK Inform II test strips have been developed such that there is no interference with maltose.*

*Data on file

Intended use

The ACCU-CHEK Inform II test strips are for use with the ACCU-CHEK Inform II meter to quantitatively measure glucose (sugar) in venous whole blood, arterial whole blood, neonatal heelstick, or fresh capillary whole blood samples drawn from the fingertips as an aid in monitoring the effectiveness of glucose control. The system is not for use in diagnosis or screening of diabetes mellitus, nor for testing neonate cord blood samples.

The ACCU-CHEK Inform II blood glucose monitoring system is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use in professional healthcare settings. This system should only be used with single-use, auto-disabling lancing devices.

The multiple-patient use ACCU-CHEK Inform II blood glucose monitoring system will consist of:

- Meter: ACCU-CHEK Inform II meter
- Test Strip: ACCU-CHEK Inform II test strip
- Controls: ACCU-CHEK Inform II control solutions

The FDA, CDC, and CMS recommend that Point of Care blood testing devices, such as the ACCU-CHEK Inform II system, should be used only on one patient and not shared. If a meter is used for a single patient then cleaning and disinfecting the exterior surface of the meter is, at minimum, recommended daily. If meters must be used on more than one patient, then the meters must be properly cleaned and disinfected after every patient.[1] Follow the guidelines for cleaning and disinfecting provided in the ACCU-CHEK Inform II Operator's Manual.

For in vitro diagnostic use

Important Safety Information

- All parts of the glucose monitoring system should be considered potentially infectious and are capable of transmitting blood-borne pathogens between patients and healthcare professionals.[2]
- Follow your facility's infection control procedures when handling blood-contaminated items. Always adhere to the recognized procedures for handling objects that are potentially contaminated with human material. Follow the hygiene and safety policy of your laboratory or institution.
- Disinfect the meter after use on each patient. The ACCU-CHEK Inform II system may only be used for testing multiple patients when Standard Precautions and the ACCU-CHEK Inform II system disinfecting procedures are followed.
- Read and follow the ACCU-CHEK Inform II cleaning and disinfecting instructions found in the ACCU-CHEK Inform II Operator's Manual.
- Wash hands thoroughly with soap and water before and after testing each patient.
- Always wear a new pair of clean gloves for each patient.
- **Never** use fingerstick devices for more than one person. Use auto-disabling, **single-use** fingerstick devices for assisted monitoring of blood glucose.[1,3]

Test Strip Storage and Handling

- Use the test strips at temperatures between 61–95 °F (16–35 °C).
- Use the test strips between 10–80 % relative humidity. Humidity is the amount of dampness in the air.
- Store the test strips at temperatures between 39–86 °F (4–30 °C). Do not freeze.
- Store unused test strips in the original container with the cap closed. Do not remove test strips from the test strip container and put them into another container such as a plastic bag or pocket, etc.
- Close the container tightly immediately after removing a test strip to protect the test strips from humidity.
- Use the test strip immediately after removing it from the container.
- Discard test strips that are past the expiration date printed on the test strip container. If the expiration date is missing or illegible, do not use the test strips.

Sample Collection and Preparation

Prepare the selected blood collection site per facility policy.

Venous or arterial samples

The following criteria need to be met when performing a blood glucose test on venous or arterial samples.

- Caution should be taken to clear arterial lines before blood is drawn.
- To minimize the effect of glycolysis, blood glucose determination with venous or arterial blood must be performed within 30 minutes of sample collection.
- Avoid air bubbles with the use of pipettes.
- Fresh venous and arterial blood samples containing the anticoagulants EDTA, lithium heparin, or sodium heparin are acceptable. Iodoacetate or fluoride-containing anticoagulants are not recommended.
- Refrigerated samples should be brought to room temperature slowly prior to testing.

Neonate samples

As a matter of good clinical practice, caution is advised in the interpretation of neonate blood glucose values below 50 mg/dL. Please follow the recommendations for follow-up care that have been set by your institution for critical blood glucose values in neonates. Glucose values in neonates suspect for galactosemia should be confirmed by an alternate glucose methodology.

Getting Ready to Test

Refer to the ACCU-CHEK Inform II Operator's Manual.

Performing a Blood Glucose Test

Refer to the ACCU-CHEK Inform II Operator's Manual.

Understanding Test Results

The normal fasting glucose level for a non-diabetic adult is below 100 mg/dL.[4,5] Two hours after meals, the normal blood glucose level for a non-diabetic adult is less than 140 mg/dL.[4]

These test strips deliver results that correspond to the blood glucose concentrations in plasma as per the recommendation of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC).[6] Therefore, the meter displays blood glucose concentrations that refer to plasma although you always apply whole blood to the test strip.

Unusual test results

If "**LO**" is displayed on the meter, blood glucose may be below 10 mg/dL.

If "**HI**" is displayed on the meter, blood glucose may be over 600 mg/dL.

For detailed information on error codes, please refer to the ACCU-CHEK Inform II Operator's Manual.

If the blood glucose result does not reflect the patient's clinical symptoms, or seems unusually high or low, perform a control test. If the control test confirms that the system is working properly, repeat the blood glucose test. If the repeated blood glucose result still seems unusual, follow facility guidelines for further action.

Limitations

- The ACCU-CHEK Inform II test strips are for testing fresh capillary, venous, arterial, or neonatal whole blood. Cord blood samples cannot be used.
- Hematocrit should be between 10–65 %.
- Lipemic samples (triglycerides) in excess of 1800 mg/dL may produce elevated results.
- Blood concentrations of galactose >15 mg/dL will cause overestimation of blood glucose results.
- Intravenous administration of ascorbic acid which results in blood concentrations of ascorbic acid >3 mg/dL will cause overestimation of blood glucose results.
- If peripheral circulation is impaired, collection of capillary blood from the approved sample sites is not advised as the results might not be a true reflection of the physiological blood glucose level. This may apply in the following circumstances: severe dehydration as a result of diabetic ketoacidosis or due to hyperglycemic hyperosmolar non-ketotic syndrome, hypotension, shock, decompensated heart failure NYHA Class IV, or peripheral arterial occlusive disease.
- This system has been tested at altitudes up to 10,000 feet.
- The performance of this system has not been evaluated in the critically ill.

Performance Characteristics

The ACCU-CHEK Inform II system complies with the requirements of EN ISO 15197 (In vitro diagnostic test systems – Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus).

Calibration: The system is calibrated with venous blood containing various glucose concentrations. The reference values are obtained using a validated test method. This test method is referenced to the hexokinase method and is traceable to an NIST standard.

Sample size: 0.6 µL

Test time: 5 seconds

System measurement range: 10–600 mg/dL

Accuracy (method comparison)

Capillary blood study: In a study conducted with the ACCU-CHEK Inform II system at one physician site with capillary blood samples, the following results were obtained. Data across the entire reportable range meets the acceptance criteria of >95 % of individual values within ±15 mg/dL of the reference values at glucose concentrations <75 mg/dL and within ±20 % of the reference values at glucose concentrations ≥75 mg/dL.

Results for glucose concentrations less than 75 mg/dL

Within ±5 mg/dL 11/16 (68.8 %)	**Within ±10 mg/dL** 16/16 (100 %)
Within ±15 mg/dL 16/16 (100 %)	

Results for glucose concentrations greater than or equal to 75 mg/dL

Within ±5 % 57/84 (67.9 %)	**Within ±10 %** 74/84 (88.1 %)
Within ±15 % 83/84 (98.8 %)	**Within ±20 %** 84/84 (100 %)

N = 100
y = 1.012x - 2.7
r = 0.993
range = 21–547 mg/dL
HCT range = 29–50 %

Venous blood study: In studies conducted with the ACCU-CHEK Inform II system at hospital and clinical sites with venous blood samples, the following results were obtained:

Results for glucose concentrations less than 75 mg/dL

Within ±5 mg/dL 67/77 (87.0 %)	**Within ±10 mg/dL** 76/77 (98.7 %)
Within ±15 mg/dL 76/77 (98.7 %)	

Results for glucose concentrations greater than or equal to 75 mg/dL

Within ±5 % 277/373 (74.3 %)	**Within ±10 %** 357/373 (95.7 %)
Within ±15 % 371/373 (99.5 %)	**Within ±20 %** 372/373 (99.7 %)

N = 450
y = 1.009x - 1.9
r = 0.995
range = 19–546 mg/dL
HCT range = 20–63 %

Arterial blood study: In a study conducted with the ACCU-CHEK Inform II system at a hospital with arterial blood samples, the following results were obtained:

Results for glucose concentrations less than 75 mg/dL

Within ±5 mg/dL 4/4 (100 %)	**Within ±10 mg/dL** 4/4 (100 %)
Within ±15 mg/dL 4/4 (100 %)	

Results for glucose concentrations greater than or equal to 75 mg/dL

Within ±5 % 147/210 (70.0 %)	**Within ±10 %** 201/210 (95.7 %)
Within ±15 % 210/210 (100 %)	**Within ±20 %** 210/210 (100 %)

N = 214
y = 1.038x - 3.5
r = 0.990
range = 58–322 mg/dL
HCT range = 19–54 %

Neonatal blood study: In a study conducted with the ACCU-CHEK Inform II system at a hospital with neonatal blood samples, the following results were obtained:

Results for glucose concentrations less than 75 mg/dL

Within ±5 mg/dL 83/105 (79.0 %)	**Within ±10 mg/dL** 99/105 (94.3 %)
Within ±15 mg/dL 105/105 (100 %)	

Results for glucose concentrations greater than or equal to 75 mg/dL

Within ±5 % 52/86 (60.5 %)	**Within ±10 %** 76/86 (88.4 %)
Within ±15 % 84/86 (97.7 %)	**Within ±20 %** 85/86 (98.8 %)

N = 191
y = 1.011x + 1.5
r = 0.976
range = 18–153 mg/dL
HCT range = 23–58 %
HCT mean = 40 %

These studies show that the ACCU-CHEK Inform II system compares well with a plasma laboratory method.

Precision

Precision studies using control solutions (day-to-day precision) and blood (within-lot precision) are shown below:

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

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

Maltose Testing

The performance of the system with venous blood samples spiked with varying concentrations of maltose was tested and is shown below.

Target Glucose (mg/dL)	Maltose Concentration (mg/dL)	Mean Bias (mg/dL)
60	300	7.8
60	360	8.1
60	500	10.7

Test principle

The enzyme on the test strip, mutant variant of quinoprotein glucose dehydrogenase (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 the blood glucose result. The sample and environmental conditions are also evaluated using a small AC signal.

Reagent composition†

Nitrosoaniline Mediator	6.72 %
Quinoprotein glucose dehydrogenase‡	15.27 %
Pyrroloquinoline quinone	0.14 %
Buffer	34.66 %
Stabilizer	0.54 %
Non-reactive ingredients	42.66 %

†Minimum at time of manufacture
‡From *A. calcoaceticus*, recombinant in *E. coli*, detailed description in patent application WO 2007/118647 (as "mutant 31" in table 4)

References

1. *FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication*, Update November 29, 2010. http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm. Accessed March 20, 2012.
2. *Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007*. http://www.cdc.gov/hicpac/2007IP/2007isolationPrecautions.html. Accessed March 20, 2012.
3. *CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens,* (2010). http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html. Accessed March 20, 2012.
4. American Diabetes Association: Classification and Diagnosis of Diabetes. Sec. 2. Standards of Medical Care in Diabetes-2016. Diabetes Care, 39, (Suppl. 1), S13-S22, 2016.
5. *Tietz Fundamentals of Clinical Chemistry, 6th Edition*, Edited by Burtis CA and Ashwood ED, W. B. Saunders Co., Philadelphia, PA, 2008, p. 849.
6. D'Orazio et al.: Approved IFCC Recommendation on Reporting Results for Blood Glucose (Abbreviated); *Clinical Chemistry* 51:9 1573-1576 (2005).

Limited Warranty

Roche warrants that your ACCU-CHEK Inform II test strips will be free from defects in materials and workmanship until the product expiration date printed on the label if the test strips are used and stored in the manner described in this package insert and in your ACCU-CHEK blood glucose meter Operator's Manual. If, prior to the expiration date of the test strips, there is a defect in materials or workmanship, Roche will replace the test strips free of charge. Your sole and exclusive remedy with respect to the test strips shall be replacement. Any warranty claim should be directed to the ACCU-CHEK Customer Care Service Center at 1-800-440-3638.

THE ABOVE WARRANTY IS EXCLUSIVE OF ALL OTHER WARRANTIES, AND ROCHE MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION THE IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT SHALL ROCHE BE LIABLE TO THE PURCHASER OR ANY OTHER PERSON FOR ANY INCIDENTAL, CONSEQUENTIAL, INDIRECT, SPECIAL OR PUNITIVE DAMAGES ARISING FROM OR IN ANY WAY CONNECTED WITH THE PURCHASE OR USE OF THE TEST STRIPS. NO WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, IF ANY IS IMPLIED FOR THE SALE OF THE TEST STRIPS, SHALL EXTEND FOR A LONGER DURATION THAN THE EXPIRATION DATE OF THE TEST STRIPS.

Some states do not allow limitations on how long an implied warranty will last or the exclusion of incidental or consequential damages, so the above limitation and exclusion may not apply to you. This warranty gives you specific legal rights, which vary from state to state.

Explanation of Symbols

	Temperature limitation (store at)
GTIN	Global Trade Item Number

Problems or Questions?

Professionals: 1-800-440-3638
Call the ACCU-CHEK Customer Care Service Center 24 hours a day, 365 days a year.

www.accu-chek.com

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For Prescription Use Only

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Roche Diabetes Care, Inc.
9115 Hague Road
Indianapolis, IN 46256

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9115 Hague Road
Indianapolis, IN 46256

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