ACCU-CHEK® Inform II Controls

ACCU-CHEK® Inform II Controls

ACCU-CHEK® Inform II

Controls

Cat. No. 05213509001
Control Level 1
Control Level 2

For performance checks on the Accu-Chek Inform II system with Accu-Chek Inform II test strips and Accu-Chek Performa system with Accu-Chek Performa test strips.

Testing control solutions with known glucose levels establishes that the operator and the system are performing acceptably. Control results must be within the defined acceptable ranges before valid patient testing is allowed.

Note: Write the discard date on the bottle label. The control solution is stable for 3 months after opening or until the **Expiration** date on the bottle label, whichever comes first.

The **Accu-Chek Inform II Control** pack contains two control solutions, one for the hypoglycemic range (control solution 1, gray cap) and one for the hyperglycemic range (control solution 2, white cap).

Note: The solution can stain fabric. Wash with soap and water.
DO NOT INGEST! Seek immediate medical attention if swallowed.

WARNING: Choking hazard. Small parts. Keep away from children under the age of 3 years.

Procedure • Test control solutions the same way a blood sample is tested. See the meter Operator's Manual for specific use instructions. Put the meter on a flat surface, such as a table. Remove the control bottle cap. Wipe the tip of the bottle with a lint-free wipe. Squeeze the bottle until a tiny drop forms at the tip. Touch the drop to the **front edge** of the yellow window of the test strip. The meter will indicate when sufficient control solution is in the test strip. Wipe the tip of the bottle with a lint-free wipe, then cap the bottle tightly. The result appears on the display. Remove and discard the used test strip per facility policy.

You can compare the result with the acceptable range printed on the test strip container label. If the result is within the acceptable range, correct functioning of the system is assured. If the result lies outside the range given or if an error message is displayed, repeat the test. If the same applies to the second result, contact Roche at 1-800-440-3638.

Note: Refer to the meter Operator's Manual for system operating conditions. Control solutions taken directly from the refrigerator must be allowed to adjust to room temperature (without opening the control solution bottle).

Sources of error • If the results obtained are outside the acceptable range:

1. Were the test strips or control solutions expired?
2. Was the tip of the control solution bottle wiped before and after use?
3. Were the test strip container and control solution bottle caps always closed tightly?
4. Was the test strip used immediately after removing it from the container?
5. Were the test strips and control solutions stored properly?
6. Were the testing steps followed?
7. Was the correct control solution level selected when the test was performed?
8. Did the code number on the meter display match the code number on the test strip container?

If the problem is not resolved, contact Roche at 1-800-440-3638.

Stability • The printed **Expiration** date is valid if the unopened control solutions are stored at 39–86 ºF (4–30 ºC). The control solution does not need to be kept in the refrigerator. Do not freeze.

Disposal • Dispose in domestic waste. Consult local ordinances as they may vary.

Testing Intervals

Follow your facility's policy for control testing intervals.

Control testing should be performed:

- The first time before using the meter for patient testing
- At intervals established by the facility
- When a new box of test strips is opened
- If the test strip container is left open
- If test strips were incorrectly stored
- If there is a question about a patient's glucose result
- To check the performance of the system
- If the meter was dropped

Your facility may require that control testing be successfully performed **after** any of the following occur and **before** patient testing resumes:

- Previous control test results were out of the acceptable range
- Control tests were not performed at the proper interval

Control results must be within the designated range on the test strip container label, or as defined by your facility, before being considered acceptable. Patients can be tested after controls have been acceptably performed at the proper testing interval.

Ingredients

- Glucose
- Buffer
- Biological Salt
- Preservative
- Non-reactive ingredients
- FD&C Blue #1

	Temperature limitation (store at)
	Manufacturer
GTIN	Global Trade Item Number

Distributed by:
Roche Diagnostics
9115 Hague Road
Indianapolis, IN 46256 USA
www.accu-chekinformii.com

Roche Diabetes Care GmbH
Sandhofer Strasse 116
68305 Mannheim, Germany

For Prescription Use Only

Made in U.S.A.
U.S. Pat.: http://www.roche-diagnostics.us/patents

07981503002-0820

Roche