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# Accutrend Glucose Control

**cobas**<sup>®</sup>

REF	CONTENT	SYSTEM
05213231 160	Glucose Control Low Level - 4 mL Glucose Control High Level - 4 mL	Accutrend Plus Accu-Chek <sup>®</sup> InstantPlus

**For use in the USA only**

This is a CLIA Waived test system. A Certificate of CLIA Waiver (or higher) is required to perform the test. Information on obtaining CLIA certificates can be found at [www.cms.hhs.gov/clia](http://www.cms.hhs.gov/clia). Facilities performing testing must have a CLIA Certificate of Waiver. 42 USC 263a(c)(2).

Laboratories with a certificate of waiver must follow the manufacturer's instructions for performing the test. 42 CFR 493.15(e)(1). Any modifications and/or failure to follow test system instructions, including those for limitations/intended use and performance of QC testing as a failure alert mechanism, results in use that is considered high complexity and subject to all applicable CLIA requirements. All applicable state and local laws must be met.

Any adverse reactions experienced with the use of this product, and/or quality problems should also be reported to the FDA's MedWatch Adverse Event Reporting program online (at [www.fda.gov/MedWatch/report.htm](http://www.fda.gov/MedWatch/report.htm)), by phone (1-800-FDA-1088), or by returning the postage-paid FDA form 3500 (which may be downloaded from [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm)) by mail to (MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787) or fax (1-800-FDA-1078).

**Intended use**

Accutrend Glucose Control solutions are for use with Accutrend Plus and Accu-Chek InstantPlus meters with Accutrend Glucose Test Strips [REF] 11447475 160. These solutions allow you to perform quality control checks to ensure that your system is working properly.

**What are glucose control solutions?**

Each glucose control solution contains a known amount of glucose. These solutions are used in exactly the same way as a drop of blood. If the control solution is within the acceptable range as printed on the container of glucose test strips, or on the value sheet enclosed, you know that your testing system is working properly and that you are performing the test correctly.

**Routine quality control testing should be done**

- If you leave the cap off the container of test strips.
- When you open a new container of test strips.
- Before using your meter for the first time.
- If you drop the meter.
- When your glucose test result does not agree with the way you feel.
- When you want to check the way you are performing your blood glucose test.
- When you want to check the performance of the meter and test strip.
- If you have repeated a test and the result is still higher or lower than expected.

**Reagents**

Each bottle of glucose control solution contains varied amounts of glucose plus buffers, preservatives and inert ingredients.

**Precautions and warnings**

**DO NOT TAKE INTERNALLY OR INJECT.** If swallowed, seek immediate medical attention.

For in vitro diagnostic use. Accutrend Glucose Control solutions are for in vitro (outside the body) diagnostic use only.

Exercise the normal precautions required for handling all laboratory reagents.

Disposal of all waste material should be in accordance with local guidelines. Safety data sheet available for professional user on request.

 All components of the pack can be discarded along with household waste or, if used in a laboratory or doctors office, according to relevant local guidelines.

**Reagent handling**

Be sure to write the date on the label when you open a new bottle of control solution. A bottle is good for 3 months after opening or until the "Use By" date printed on the label, whichever comes first.

**Storage and stability**

Always store glucose control solutions at 36-86 °F (2-30 °C).

Do not freeze.

**Materials provided**

This package provides one bottle each of Low Level and High Level Glucose control solutions.

**Materials required (but not provided)**

Accutrend Plus or Accu-Chek InstantPlus meter  
Accutrend Glucose Test Strips  
Code Strip (included in your box of glucose test strips)  
Accutrend Plus or Accu-Chek InstantPlus User's Manual

**Testing**

Testing a control solution is very much like testing whole blood from your finger. The test steps are the same, except that you use glucose control solution instead of blood. Refer to your User's Manual for complete testing instructions. Test the two levels of control solutions separately.

**Understanding quality control test results****When a control result is in the acceptable range**

- You can feel confident that your test strips and meter are working correctly and that you are performing the test correctly.

**When a control result is NOT in the acceptable range**

- You may not be doing the test correctly. Repeat the test, carefully following instructions.
- The test strip may be damaged by exposure to very high or low temperatures or by high humidity. Repeat the test using a new strip from a fresh container. Be sure that the meter is correctly coded for the new test strips.
- Check the expiration date on the container of strips. If your strips are out of date, throw the rest away. Use a new strip from a fresh container and repeat the test. Be sure that the meter is correctly coded for the new test strips.
- Check the expiration date on the control solution bottles. A bottle is good for three months after opening or until the "Use By" date printed on the label, whichever comes first.
- Be sure the control solution you are using is clear. Do not use a cloudy solution.
- Be sure the test strip is clean and free of contamination.
- The sample drop was too small.

If you have checked all of these factors and your results are still not within the appropriate range for the test strip you used, call 1-800-440-3638, for technical assistance.

**Additional control solutions**

Accutrend Glucose control solutions are available in 4 mL bottles and may be purchased from your medical supply distributor. Each package contains one bottle of each control level (low and high).

**Return policy**

If there is a problem with the Accutrend Glucose Control solutions, you may be asked to return them to Roche Diagnostics. Before returning, call Roche Diagnostics Technical Support at 1-800-440-3638. You will be mailed a return authorization label which must be placed on the shipping carton.

**Symbols**

	Contents of kit
	Analyzers/Instruments on which reagents can be used
	Consult instructions for use
	Use-by date
	Temperature limit
	Manufacturer



# Accutrend Glucose Control



REF	Catalogue number
LOT	Batch code
IVD	In vitro diagnostic medical device

**FOR US CUSTOMERS ONLY: LIMITED WARRANTY**

Roche Diagnostics warrants that this product will meet the specifications stated in the labeling when used in accordance with such labeling and will be free from defects in material and workmanship until the expiration date printed on the label. THIS LIMITED WARRANTY IS IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR PARTICULAR PURPOSE. IN NO EVENT SHALL ROCHE DIAGNOSTICS BE LIABLE FOR INCIDENTAL, INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES.

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