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Accutrend Cholesterol Control

cobas[®]

REF	CONTENT	SYSTEM
05219957 001	Low Level 1 x 2 mL High Level 1 x 2 mL	Accutrend Plus Accu-Chek [®] InstantPlus

English

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. 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), 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) by mail to (MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787) or fax (1-800-FDA-1078).

For use with Accutrend Plus and Accu-Chek InstantPlus meters with Accutrend Cholesterol Test Strips [REF] 05213312160 and Accu-Chek InstantPlus Cholesterol Test Strips [REF] 11418262160. A quick, simple way to help ensure accurate blood cholesterol testing.

What is cholesterol control?

Cholesterol control solutions allow you to perform quality control checks to ensure that your system is working properly. Each control solution contains a known amount of cholesterol. These solutions are used in exactly the same way as a drop of blood. If the control solution is within an acceptable range, you know that your meter and test strips are 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 you want to check the way you are performing your blood 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.

Materials provided

This package provides one bottle of each low level and high level cholesterol control solutions.

Handling

Be sure to write the date on the label when you open a new bottle of control solution. A bottle is good for 60 days after opening or until the "Use By" date printed on the label, whichever comes first.

Store cholesterol control solutions at 36° to 77° F (2 to 25° C). Do not freeze.

You will also need

Accutrend Plus or Accu-Chek InstantPlus meter
Accutrend or Accu-Chek InstantPlus Cholesterol Test Strips
Code Strip (included in your box of cholesterol 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 cholesterol 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.
- 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.
- Check the expiration date on the control solution bottles. A bottle is good for 60 days 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.

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.

Reagents

Each 2 mL bottle of cholesterol control contains:

Cholesterol (bovine)
Serum albumin (bovine)
Glucose
Preservatives

Performance characteristics

Several lot numbers of cholesterol test strips are used to determine the expected range for each level of cholesterol control. The ranges for a particular lot number are printed on an insert that comes in each box of cholesterol test strips and each box of control solutions. **Due to lot-specific value assignments, you may expect different means and ranges on other lots of this product. The means and ranges may be found on the enclosed addendum.**

Precautions and warnings

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

For in vitro diagnostic use. Accutrend Cholesterol Control solutions are for **in vitro** (outside the body) diagnostic use only. They are not to be taken internally or injected.

Storage and stability

Always store cholesterol control solutions at 36° to 77° F (2 to 25° C). Do not freeze.

Additional control solutions

Accutrend Cholesterol Control solutions are available in 2 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 Cholesterol Control solutions, you may be asked to return them to Roche Diagnostics. Before returning, call technical assistance 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



Accutrend Cholesterol Control




-  Temperature limit
-  Manufacturer
-  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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 US Customer Technical Support 1-800-440-3638

