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Accutrend Cholesterol

cobas[®]

REF	CONTENT	SYSTEM
05213312 160	25 test strips 1 code strip	Accutrend Plus Accu-Chek [®] 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. 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).

Intended use

Accutrend Cholesterol test strips are for the quantitative determination of total cholesterol in capillary whole blood. For use by health care professionals and for home use by people with diabetes for cholesterol screening.

For use with Accutrend Plus and Accu-Chek InstantPlus meters. Before using these test strips read this Method Sheet and the User's Manual carefully.

For in vitro diagnostic use**Patient information****Introduction**

Cholesterol is a substance which is naturally produced by the liver and is found in many foods. When the blood cholesterol level in the body reaches a certain point, it can build up in the arteries. This may lead to an increased risk of heart disease or stroke.

The Accutrend Cholesterol test is an easy-to-use test for home use that lets you measure the level of total cholesterol in your blood in minutes. Total cholesterol testing helps detect those persons that may be at risk for coronary heart disease.

The Accutrend Cholesterol test strip, used as directed with an Accutrend Plus or Accu-Chek InstantPlus meter, will accurately measure your total cholesterol level. The strip changes color as it reacts to total cholesterol in a drop of blood and the meter measures this color change. Your total blood cholesterol is then displayed on the display screen.

Product updates

This section of your method sheet may contain new information that has not yet been included in the Accutrend Plus or Accu-Chek InstantPlus User's Manuals. Refer to this section each time you get a new container of test strips for the latest revisions or updates.

Reagent handling

- Tightly re-cap the container immediately after removing a test strip. Exposure to light and moisture may discolor the test strips which may lead to an incorrect result.
- Do not cut or alter the test strips in any way. This will lead to an incorrect test result or an error code.

Storage and stability

- Store strips at 36-86 °F (2-30 °C). Do not freeze.

Tips for getting a good drop of blood

Accutrend Plus and Accu-Chek InstantPlus meters and strips **require a hanging drop of blood**. If you are new to self testing, or have had trouble getting enough blood in the past, you may want to review the following steps before you proceed with testing.

- Wash hands in warm, soapy water; rinse and dry completely. Warming the fingers can help increase blood flow. If you use an alcohol wipe to clean your finger, make sure the finger is completely dry before continuing.
- Let your arm hang down at your side briefly to allow blood to flow to fingertips.
- Grasp finger near area to be pricked and squeeze for three seconds.
- Keeping hand down, prick side of fingertip, and squeeze gently until you get a hanging drop of blood. For lancing the finger Roche Diagnostics recommends Accu-Chek Softclix, Accu-Chek Safe-T-Pro and Accu-Chek Safe-T-Pro Plus devices.

When testing cholesterol, wipe away the first drop of blood with a cotton ball or tissue. Apply the second drop of blood to the test strip. Be careful not to squeeze finger too hard.

What does my result mean?

The National Cholesterol Education Program recommends that repeated measurements of cholesterol be done to find out your baseline (beginning) value. At least 2 or 3 tests should be performed over a period of several weeks. The average of these values will determine your baseline cholesterol level. See your physician for more information on your baseline value.¹ The total cholesterol results and suggested actions below are for adults 20 years and older.¹

Always consult your physician before making any changes in your medication or diet based on your total blood cholesterol result.

Desirable total blood cholesterol

If your test result is below 200 mg/dL, your total cholesterol level is "desirable." Record your result and discuss with your physician how often you should retest your total cholesterol. Your level may change over time, especially if you change your eating or exercise habits.

If your result is between 190 and 199 mg/dL, your cholesterol level is close to the next risk group. ALL individuals with total blood cholesterol between 190 and 199 mg/dL, as reported by Accutrend Cholesterol test strips and the Accutrend Plus or the Accu-Chek InstantPlus meters, should talk to their doctor and confirm their blood cholesterol level in a clinical laboratory.

Borderline-high total blood cholesterol

If your test result is 200 to 239 mg/dL, your total cholesterol level is "borderline-high," which means you are at increased risk for developing coronary heart disease, compared to those with lower levels. You may not need intensive medical attention, but you should consult with your physician.

High total blood cholesterol

If your test result is 240 mg/dL or above, you are in the "high risk" category for developing heart disease.

One test is not enough to confirm high blood cholesterol. At least 2 or 3 tests should be performed over a period of several weeks. The average of these values will determine your total blood cholesterol level. **You should see your physician for more information or a complete medical check-up.**

Total cholesterol is affected by your diet and by your body's metabolism. However, your cholesterol level is only one factor related to heart disease. There are other factors like high blood pressure, smoking, diabetes, obesity, and inactivity (lack of exercise) that are called "risk factors" because they can also lead to heart disease.²

If you have any questions about your total blood cholesterol result or the risk factors, consult with your physician.

Unusual test results

If your total blood cholesterol value seems unusually high or low there may be a problem with your test procedure, test strip or meter.

The following can cause unusually high or low results:

- Test strip was not stored in container with cap tightly sealed.
- Test strip was used after expiration date.
- Test strip was stored in extreme temperatures.



Accutrend Cholesterol



- Proper maintenance and handling procedures for the Accutrend Plus or Accu-Chek InstantPlus meter have not been followed.
- The blood drop was too small.

Return policy

If you have a problem with your Accutrend Cholesterol test strips, you may be asked to return them, with the code strip, to Roche Diagnostics. Before returning, you must call Technical Support at 1-800-440-3638. You will be mailed a return authorization label which must be put on your shipping carton. Cartons received without this label will be returned to you at your expense.

Limitations of procedure

The limitations of the Accutrend Cholesterol test strips are listed on the Health care professionals information section of this Method Sheet. **Read the limitations carefully** and consult your health care professional if you have any questions.

Additional supplies

Additional Accutrend Cholesterol test strips, as well as Accutrend Cholesterol Control solutions, may be purchased directly from your medical supply distributor or retail pharmacy.

Health care professional information

The following sections of this Method Sheet contain information specific to health care professionals. If you are a person with diabetes who uses this product, read the Patient information section of this Method Sheet first. If you have questions about the Health care professional information listed in this section, ask your health care professional.

Health care professionals

Read the Patient information and the Health care professional information sections of this Method Sheet.

Test principle

The lipoprotein complexes are dissolved by the detergent DONS so that the cholesterol esterase can split the cholesterol ester into cholesterol and the corresponding fatty acid. Cholesterol is oxidized by cholesterol oxidase to give 4-cholesten-3-one + H₂O₂. The hydrogen peroxide reacts with a reduced indicator (TMB) by means of peroxidase to produce a blue color.^{3,4,5,6}

Reagent composition

See the outside of the test strip box for reagent composition.

Precautions and warnings

For in vitro diagnostic use.
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.

Reagent handling

Refer to the Patient information section of this Method Sheet.

Storage and stability

Refer to the Patient information section of this Method Sheet.

Limitations of procedure

Accutrend Cholesterol test strips give dependable test results if the following limitations are understood:

- System measurement range is 150-300 mg/dL.
- Only fresh capillary blood is recommended for accuracy determinations. Do not use venous or arterial blood.
- Recent illness, pregnancy, birth control pills and other conditions may change your total cholesterol level. If you are concerned or have any questions, talk with your doctor.
- Hematocrit values between 30-55 % do not significantly affect test results.
- This system has not been proven for use with neonates.
- In vitro bilirubin (unconjugated) up to 10 mg/dL, uric acid up to 9.0 mg/dL and triglycerides up to 400 mg/dL showed no interference.

- In situations of decreased peripheral blood flow, fingerstick blood testing may not be appropriate as it may not reflect the true physiological state. Examples would include but are not limited to: severe dehydration caused by diabetic ketoacidosis or the hyperglycemic hyperosmolar nonketotic state, hypotension, shock or peripheral vascular disease.^{7,8,9}
- Hemolyzed samples are not acceptable for testing.
- The following substances when present in pathologic concentrations may alter total cholesterol results: ascorbic acid, dopamine, methyl dopa, gentisic acid and acetaminophen.
- Excessive squeezing and milking of the puncture site may produce erroneous results.
- This system should not be used by hemophiliacs or by persons on thrombolytic therapy or blood thinning medication (anticoagulants).
- This system should be used at < 85 % relative humidity.
- Use **only** before the specified expiration date of each lot.
- Cholesterol determinations must be performed between 64-95 °F (18-35 °C).

Performance characteristics

The data shown represents typical performance results for the Accu-Chek InstantPlus and Accutrend Plus meters.

Precision

Overall and within-run precision was very good at all levels. Overall precision was collected on multiple meters, strip containers, and control bottles over multiple days. The testing yielded the following results:

Aqueous material

	Within-run precision		Overall precision	
N	10	10	127	125
Mean (mg/dL)	207	240	203	240
SD (mg/dL)	3.9	7.4	6.0	13.1
CV %	1.9	3.1	2.9	5.5

Accuracy

Trained technician study

Studies were conducted by trained technicians at six professional sites, where patient results were compared to a serum Abell-Kendall reference. These studies, where N = 490 different patients, yielded the following accuracy data:

$$y = 1.057x - 14.9 \quad r = 0.920$$

At 200 mg/dL, bias was -2.3 % with a total error of 15 %. At 240 mg/dL, bias was -0.2 % with a total error of 13 %.

Consumer study

Studies were conducted by untrained patients at six professional sites, where patient results were compared to a serum Abell-Kendall reference. These studies, where N = 490 different patients, yielded the following accuracy data:

$$y = 1.023x - 11.8 \quad r = 0.881$$

At 200 mg/dL, bias was -4.4 % with a total error of 19 %. At 240 mg/dL, bias was -1.8 % with a total error of 18 %.

References

- Report of the Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults. National Cholesterol Education Program coordinated by the National Heart, Lung, and Blood Institute: Arch Intern Med 1988;148:37.
- "What Does My Cholesterol Level Mean?", Roche Diagnostics, 1990.
- Siedel J, et al. Clin Chem 1983;29:1075.
- Trinder P. Ann Clin Biochem 1969;6:24.
- Roschlau P, et al. Z Klin Chem Klin Biochem 1974;12:403.
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- Atkin SH, Dasmahapatra A, et al. Fingerstick Glucose Determination In Shock. Annals of Internal Medicine 1991;114:1020-1024.












Accutrend Cholesterol



- 8 Sandler M, Low-Beer T. Misleading Capillary Glucose Measurements. Practical Diabetes 1990;7:210.
- 9 Wickham HWR, Achar KN, et al. Unreliability of Capillary Blood Glucose in Peripheral Vascular Disease. Practical Diabetes 1986;3:100.

Symbols

Roche Diagnostics uses the following symbols and signs for this product.

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