



An important first step in identifying those at risk for Cardiovascular disease

The Accutrend® Plus system: from the makers of the ACCU-CHEK® and CoaguChek® systems





Cardiovascular disease: the #1 killer in the United States

Cardiovascular disease (CVD) is the leading cause of death in United States, accounting for an average of 1 death every 39 seconds. Because CVD can be asymptomatic, treatment and therapy decisions are often made too late. Today, over 33 million, or 15%, of all adults in the United States have high total cholesterol levels, a preventable CVD risk factor that costs the US healthcare system over \$286 billion each year.¹

Early Detection Can Save Lives

Early CVD risk detection can significantly raise awareness of key risk factors and empower patients with immediate, actionable information that can be used for lifestyle modification.

The Accutrend Plus system, one meter delivering *both* total cholesterol *and* glucose test results, can help preventive healthcare providers at:

- **Community Health Events.** A community health screening with Accutrend Plus allows local organizations to promote the value of preventive healthcare and increase public awareness of CVD risk factors.
- **Corporate Wellness Programs.** An on-site employee health screening with Accutrend Plus may help employers improve employee productivity, improve employee morale, and lower rates of absenteeism.²
- **Health Promotion Events.** A promotional health screening with Accutrend Plus can be an effective marketing tool for hospitals, physician offices, walk-in clinics, and pharmacies to increase public awareness of their facilities and recruit new patients through physician referrals.

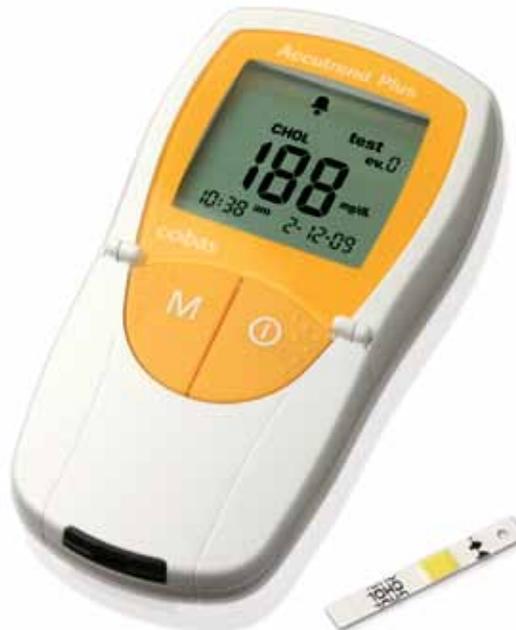
Know the numbers, recommend next steps

Total Cholesterol and Glucose Matter: Why?

It's simple. High total cholesterol is a major risk factor for coronary heart disease, heart attack, and stroke.

Clinical studies have shown that a 10% decrease in total cholesterol can lead to a 30% decrease in coronary heart disease.³ Because total cholesterol levels are strongly correlated to LDL, or "bad," cholesterol levels,⁴ a total cholesterol test in a primary prevention setting can be an important first step in identifying people with CVD risk.

Diabetes is another major risk factor for CVD. Diabetic patients have a significantly higher risk of developing cardiovascular events than non-diabetic patients.⁵ A blood glucose test at a community health event can provide a diabetic patient with potentially lifesaving information that can be used to assess glycemic control and avoid life-threatening complications.



NCEP Risk Classification of Total Cholesterol⁶

Total Cholesterol Level Risk Category

Total Cholesterol Level	Risk Category
<200 mg/dL	Desirable
200 - 239 mg/dL	Borderline High
≥ 240 mg/dL	High

Total cholesterol levels are largely affected by a person's dietary and lifestyle choices, which means that healthy change is possible, if people know their risk.

The National Cholesterol Education Program (NCEP) identifies three categories for assessing a person's risk of developing CVD using a total cholesterol test (see left). When patients with abnormal cholesterol levels are identified, their healthcare providers can help them begin an effective treatment program.

Normal Adult Blood Glucose Ranges for Non-Diabetics⁷

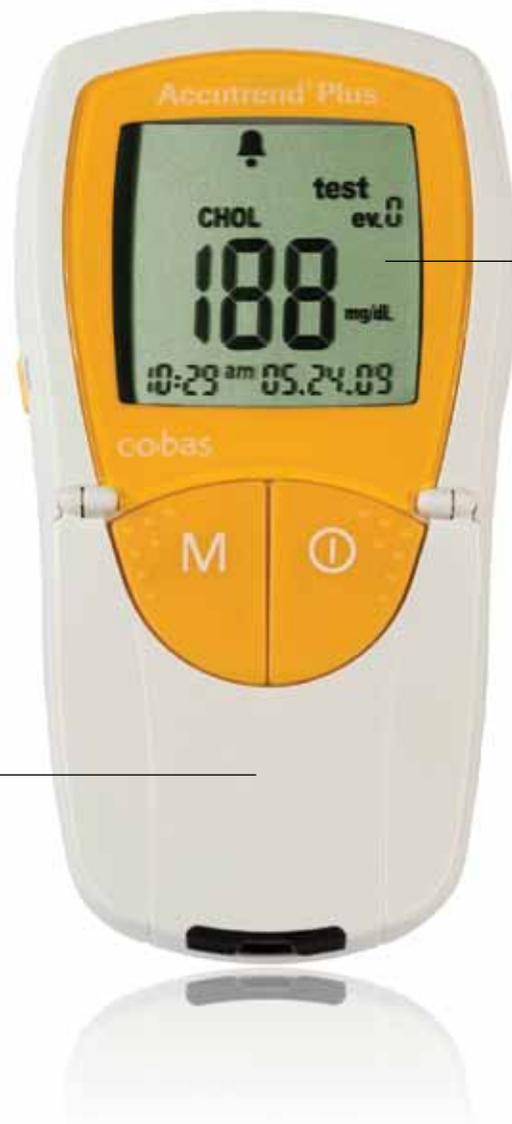
70-105 mg/dL	Fasting
<140 mg/dL	1 to 2 Hours Post-Meal

***Note: A patient's physician should determine the blood glucose range that is appropriate for that patient.**

Blood glucose levels can be affected by a variety of factors including dietary choices, exercise, stress, and medication dosages. The American Diabetes Association has established normal adult blood glucose ranges for non-diabetic patients (see left). Monitoring blood glucose levels in diabetic patients is an important first step toward timely therapeutic intervention by a physician.

The Accutrend Plus system: two vital numbers, in about three minutes

The Accutrend Plus system is a handheld device providing both CLIA-waived total cholesterol and glucose testing on a single meter. With fast, reliable test results, enhanced memory, and direct-on-strip dosing, the Accutrend Plus system is designed to meet the needs of today's preventive healthcare providers.



Fast, Reliable Test Results: Test for total cholesterol in 3 minutes and blood glucose in 12 seconds

Large Display: Easy-to-read screen helps user view results and interpret them accurately

Event Flags: Characterize a particular value with regard to special circumstances, such as meals or exercise

Enhanced memory: Store up to 100 results for each test parameter - 200 in total

Onboard QC: Built-in performance and quality control uses multiple checks to help ensure accurate and reliable results

Convenient: Test both cholesterol and glucose with one easy-to-use, handheld meter

Room Temperature Test Strip Storage: No need for special storage, such as refrigeration

Out-of-Meter Dosing: Blood sample touches the strip, not the meter

Glucose test strip not shown

Performance characteristics

The data shown below represent typical performance results for the Accutrend Plus system.

Accutrend Cholesterol⁶

Sample Volume	Hanging drop of blood									
Test Time	180 seconds									
Measuring Range	150-300 mg/dl									
Accuracy	<p>Studies were conducted by trained technicians at six professional sites, where patient results were compared to a serum Abell-Kendall reference.</p> <p>N = 490 $y = 1.057x - 14.9$ Correlation Coefficient = 0.920</p>									
Precision	<p>Overall precision was collected on multiple meters, strip containers, and control bottles over multiple days.</p> <table border="0"> <tr> <td>Within-Run Precision</td> <td>Overall Precision</td> </tr> <tr> <td>N = 10</td> <td>N = 127</td> </tr> <tr> <td>Mean = 207 mg/dl</td> <td>Mean = 203 mg/dl</td> </tr> <tr> <td>CV = 1.9%</td> <td>CV = 2.9%</td> </tr> </table>		Within-Run Precision	Overall Precision	N = 10	N = 127	Mean = 207 mg/dl	Mean = 203 mg/dl	CV = 1.9%	CV = 2.9%
Within-Run Precision	Overall Precision									
N = 10	N = 127									
Mean = 207 mg/dl	Mean = 203 mg/dl									
CV = 1.9%	CV = 2.9%									

Accutrend Glucose⁷

Sample Volume	Hanging drop of blood									
Test Time	12 seconds									
Measuring Range	20-600 mg/dl									
Accuracy	<p>Studies were conducted by trained technicians at two professional sites, where patient results were compared to a whole blood glucose hexokinase reference.</p> <p>N = 106 $y = 0.973x - 0.4$ Correlation Coefficient = 0.988</p>									
Precision	<p>Within-run precision testing was performed using aqueous materials.</p> <table border="0"> <tr> <td>Low Level</td> <td>High Level</td> </tr> <tr> <td>N = 10</td> <td>N = 10</td> </tr> <tr> <td>Mean = 72 mg/dl</td> <td>Mean = 184 mg/dl</td> </tr> <tr> <td>SD = 1.8 mg/dl</td> <td>CV = 2.4%</td> </tr> </table>		Low Level	High Level	N = 10	N = 10	Mean = 72 mg/dl	Mean = 184 mg/dl	SD = 1.8 mg/dl	CV = 2.4%
Low Level	High Level									
N = 10	N = 10									
Mean = 72 mg/dl	Mean = 184 mg/dl									
SD = 1.8 mg/dl	CV = 2.4%									



Choose dependability

Providers of preventive healthcare services need to correctly identify patients at risk for CVD and promptly refer them to a physician – so they need test results they can depend on. This is why instrument performance is so important.

Independent, peer-reviewed published data often provide the fairest and most balanced assessment of a cholesterol analyzer's real-world performance. While some systems calculate LDL or HDL cholesterol, key targets for CVD risk assessment, these test results are only as clinically useful as their accuracy and precision.

At community health screenings, where immediate, reliable LDL or HDL tests may be unavailable or difficult to obtain, a reliable total cholesterol test may be the most clinically useful option for preliminary CVD risk assessment.

Results of comparative clinical studies

Use your mobile device to access the study abstract

Instruments	Clinical Study Reference	Discussion	Link to Abstract
Accutrend Plus vs. CardioChek PA	Mendez-Gonzalez, J. et al. "Lipid Profile in Ambulatory Patients Using 3 Point-of-Care Devices and Comparison With Reference Methods." <i>Point of Care</i> . Volume 8, Number 3, September 2009. Pages 110-116.	<p>The total error of the Accutrend Cholesterol test was "in accordance with NCEP recommendations (<9.0%). In contrast, the CardioChek device showed higher inaccuracy, both in the control material and blood samples, also higher total imprecision than the Accutrend systems, and an unacceptable total error of 25.1%, largely exceeding NCEP recommendations."</p> <p>"LDL cholesterol calculation with CardioChek results showed very poor results, with an inaccuracy and a bias at the clinical relevant cut-point values of approximately 30%; these data corroborated previous reports, largely unmet the NCEP criteria, and are unacceptable in any clinical setting."</p> <p>"Therefore, the CardioChek advantage of providing an LDL-C level estimation was counteracted by the unacceptability of its results. In this sense, for clinical purposes, an unbiased TC level measurement would seem preferable to a largely biased LDL-C level calculation."</p>	 <p><i>Scan this code with your mobile device to access the study abstract on the journal's website.⁸</i></p>
CardioChek PA vs. Cholestech LDX	Shephard, M. et al. "Comparative Performance of Two Point-of-Care Analysers for Lipid Testing." <i>Clin. Lab</i> . Volume 53, 2007. Pages 561-566.	<p>"The Cholestech LDX readily met NCEP goals for total error except for LDL cholesterol."</p> <p>"The CardioChek PA system only met the NCEP total error goal for triglyceride. The significant biases observed with the CardioChek device in this study are difficult to explain..."</p> <p>"The observation that both POCT analyzers did not meet the [NCEP] goal for total error for LDL cholesterol is of some concern, given the importance of this marker for cardiovascular risk management."</p>	 <p><i>Scan this code with your mobile device to access the study abstract on PubMed.⁹</i></p>
CardioChek PA vs. Cholestech LDX	Dale, R. et al. "Comparison of Two Point-of-Care Lipid Analyzers for Use in Global Cardiovascular Risk Assessments." <i>The Annals of Pharmacotherapy</i> . Volume 42, May 2008. Pages 633-639.	<p>"We observed better reproducibility with the Cholestech LDX versus the CardioChek PA analyzer compared with laboratory analysis of venous blood. Moreover, the CardioChek PA analyzer resulted in more misclassifications of HDL-C and Total Cholesterol categories required for calculating the Framingham Risk Score..."</p> <p>"Most lipid values, in particular all HDL-C levels, were underestimated by the CardioChek PA. This may result in a need for further testing if the venue is solely for screening, as well as under- or overtreatment with lipid modifying drugs if the test is used as a diagnostic decision aid. Underestimation of HDL-C also has the potential to lead to overdiagnosis of the metabolic syndrome."</p>	 <p><i>Scan this code with your mobile device to access the study abstract on PubMed.¹⁰</i></p>
CardioChek PA	Williams, A. et al. "Evaluation of the CardioChek Portable Whole Blood Analyzer for Use in the Fitness Industry." <i>Journal of Exercise Physiology</i> . Volume 14, Number 6, December 2011. Pages 62-71.	<p>"The main findings from this study are that for all measured variables, there were significant differences between results obtained from the CardioChek and the laboratory analyses, which could result in false positives or false negatives if the CardioChek is used to identify risk factors in accordance with pre-exercise screening questionnaires."</p> <p>"The hand-held analyzer produced values that were significantly lower than those obtained from the standard laboratory methods for measuring Total Cholesterol, HDL, and Blood Glucose. It also produced a significantly higher calculated TC/HDL risk ratio, suggesting questionable CardioChek effectiveness as a pre-exercise risk screening instrument."</p>	 <p><i>Scan this code with your mobile device to access the study abstract on the journal's website.¹¹</i></p>



Save steps, gain efficiencies

Saving steps saves time. Efficient test procedures help achieve short patient turnaround times and maximize patient throughput. And that means healthcare professionals can concentrate on getting the results they need to make appropriate recommendations.

For community health screenings, the Accutrend Plus system helps save steps and delivers total cholesterol results in just three steps - and three minutes.

Accutrend Plus system testing: step-by-step.



1 Perform the fingerstick and apply a drop of whole blood directly onto test strip.



2 Insert test strip into the meter to begin test.



3 Allow 3 minutes to view total cholesterol test result. Or allow 12 seconds to view glucose test result.

Accutrend Plus system's features help streamline work processes and maximize screening efficiency.

Feature	Importance at a Screening Event	Accutrend Plus ¹²	CardioChek PA ^{13,14}	Cholestech LDX ^{15,16}
No Fasting Requirement	Allows health screenings to be conducted at all times of the day.	•	•*	•*
Handheld	Provides flexibility in a highly mobile or decentralized screening environment where access to power and space may be difficult.	•	•	
Direct Dosing	Eliminates the need to use capillary tubes, pipettes, or plungers to collect a patient sample.	•		
Room Temperature Storage	Eliminates the need to refrigerate test strips and accessory components prior to the screening.	•	•	
Outside-of-Meter Dosing	Designed to reduce risk of cross-contamination.	•		•
Large Memory Capacity	Provides the user with the ability to review previous patient results long after the initial test has been performed.	200 patient results	30 patient results	1 patient result
Short Test Time	Improves patient throughput and reduces patient turnaround time.	Glucose: 12 seconds TC: 180 seconds	Glucose & TC: 120 seconds	Glucose & TC: 300 seconds

* (TC & Glucose tests)

Control costs

Cost containment is also important to the providers of community health screenings. Patients may expect community health screenings to be provided at low prices—even free. Frequently, preventive healthcare services are provided without insurance reimbursement due to the decentralized nature of the events or the lack of health insurance coverage among those receiving testing.

The Accutrend Plus system allows preventive healthcare providers to achieve reliable total cholesterol and glucose results without compromising cost. The table below compares the relative end user costs associated with a single, 50-patient total cholesterol screening event.

Single Event	Accutrend Plus ¹⁷	CardioChek PA ¹⁸	Cholestech LDX ¹⁹
Analyzer Cost	\$200 <i>(Analyzer only)</i>	\$618 <i>(Analyzer only)</i>	\$1,489 <i>(Analyzer only)</i>
Test Strip/ Cassette Cost	\$176 <i>(2 boxes at \$88 each)</i>	\$180 <i>(2 boxes at \$90 each)</i>	\$215 <i>(5 boxes at \$43 each)</i>
Controls Cost	\$56 <i>(2 boxes at \$28 each)</i>	\$86 <i>(2 boxes at \$43 each)</i>	\$82 <i>(1 dual box at \$82 each)</i>
Capillary Tube & Plunger Cost	\$0	\$13	\$21
EST. TOTAL COST	\$432	\$897	\$1,807

Single Event = 50 patients (50 Total Cholesterol tests)

*All costs are shown as end user prices and rounded to the nearest dollar.
Promotional configurations are not included.*



Take the next step

For more information or to order the Accutrend Plus system for your next health screening event, contact your authorized Roche distributor or call your Roche Account Manager at 1-800-852-8766.

Ordering Information

Product	Catalog Number
Accutrend Plus Meter Kit	05346754160
Accutrend Cholesterol Test Strips (25/vial)	05213312160
Accutrend Cholesterol Controls	05219957001
Accutrend Glucose Test Strips (25/vial)	11447475160
Accutrend Glucose Controls	05213231160
ACCU-CHEK Safe-T-Pro Lancets (200/box)	03136752001
ACCU-CHEK Safe-T-Pro Plus Lancets (200/box)	03448622001

- 1 Roger, V. L. et al. "Heart Disease and Stroke Statistics – 2011 Update." *Journal of the American Heart Association*. <http://circ.ahajournals.org/content/123/4/e18>. Accessed 31 October 2011. Page 4.
- 2 American Institute for Preventive Medicine. "The Health & Economic Implications of Worksite Wellness Programs." Accessed January 18, 2012. http://www.healthylife.com/documents/white%20paper%20charts_low.pdf.
- 3 Roger, V. L. et al. "Heart Disease and Stroke Statistics – 2011 Update." *Journal of the American Heart Association*. <http://circ.ahajournals.org/content/123/4/e18>. Accessed 31 October 2011. Page 119.
- 4 Mendez-Gonzalez, J. et al. "Lipid Profile in Ambulatory Patients Using 3 Point-of-Care Devices and Comparison With Reference Methods." *Point of Care*. Volume 8, Number 3, September 2009. Pages 110-116.
- 5 Roger, V. L. et al. "Heart Disease and Stroke Statistics – 2011 Update." *Journal of the American Heart Association*. <http://circ.ahajournals.org/content/123/4/e18>. Accessed 31 October 2011. Page 140.
- 6 Accutrend Cholesterol Test Strips package insert. Indianapolis, IN. Roche Diagnostics Corporation, 2008.
- 7 Accutrend Glucose Test Strips package insert. Indianapolis, IN. Roche Diagnostics Corporation, 2009.
- 8 http://mobile.journals.lww.com/poctjournal/_layouts/oaks.journals.mobile/abstractviewer.aspx?year=2010&issue=06000&article=00007
- 9 <http://www.ncbi.nlm.nih.gov/m/pubmed/18257461/?i=1&from=Comparative%20performance%20of%20two%20point-of-care%20analysers%20for%20lipid%20testing>
- 10 <http://www.ncbi.nlm.nih.gov/m/pubmed/18413684/?i=4&from=cardiochek>
- 11 http://faculty.css.edu/tboone2/asep/JEPonlineDecember2011_Williams.pdf
- 12 Accutrend Plus User's Manual. Indianapolis, IN. Roche Diagnostics Corporation, 2010.
- 13 Cholesterol + Glucose Package Insert. Polymer Technology Systems. Indianapolis, IN. http://www.cardiochek.com/index.php?option=com_docman&task=doc_download&gid=33&Itemid=152. Accessed 31 October 2011.
- 14 CardioChek PA User's Manual. Polymer Technology Systems. Indianapolis, IN. http://www.cardiochek.com/index.php?option=com_docman&task=docdownload&gid=156&Itemid=152. Accessed 31 October 2011.
- 15 Cholestech LDX System User Manual. Inverness Medical. San Diego, CA. http://www.cholesteck.com/docs/ldx/LDX_UM_EN.pdf. Accessed 31 October 2011.
- 16 Total Cholesterol and Glucose Panel Package Insert. Inverness Medical. San Diego, CA. http://www.cholesteck.com/docs/ldx/LDX_LipidGLU_PI_EN.pdf. Accessed 31 October 2011.
- 17 Accutrend Plus costs are estimated at distribution list pricing with a 25% margin.
- 18 Cost estimate for CardioChek PA system is shown as the average cost published on the websites of five authorized distributors listed on the CardioChek website on 1/18/12. List of authorized distributors obtained from www.cardiochek.com. Data on file.
- 19 Cost estimate for Cholestech LDX system is shown as the average cost in a review of five Cholestech LDX distributors on 1/18/12. Data on file.