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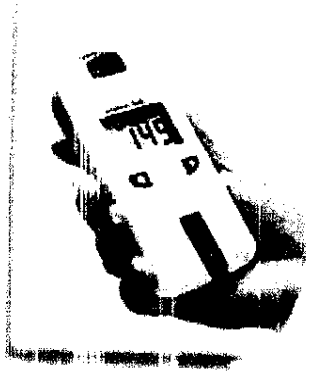
CardioChek P•A™
Point of Care Test System

CardioChek P•A Technology
The underlying technology of the CardioChek P•A System employs innovative concepts to emulate the comple chemical analysis, sample preparation and measurement methods of clinical labs in a simple format suitable fo untrained operators.

Operating Principle
A precise volume of whole blood is dispensed on to the application window of a PTS Panels Test Strip that has been inserted into a CardioChek P•A analyzer. Red cells and other non-plasma components are removed from the plasma. The plasma reacts in a precisely controlled manner with a series of chemically impregnated membranes, ultimately producing a color change in the final membrane layer. The analyzer measures the color intensity from the color spectral profile and compares to lot-specific calibration information contained in the MEMo Chip to calculate an accurate result. The analyzer then displays the result, simultaneously triggers a printout (if the dedicated printer is attached), and stores the test information in memory for later recall.



CardioChek P•A™ Analyzer
The CardioChek P•A is a state-of-the-art, hand-held, battery-operated, software-driven reflectance spectrophotometer.

PTS Panels Test Strips
PTS Panels Test Strips are composed of several layers of reagent-impregnated membranes sandwiched toget plastic carrier. Each membrane layer performs specific functions to process and facilitate chemical reactions. T phase chemistry membranes are typically stable at room temperatures for 18 to 24 months.

MEMo Chip
MEMo Chips are individualized for each lot of PTS Panels Test Strips and contain calibration settings, expiration dating and other information that calibrates the CardioChek P•A analyzer to every strip it "reads." A MEMo Chip is packaged with every vial of strips to ensure accurate calibration specific to each lot of strips.

Benefits of CardioChek P•A Technology

- Accurate. Factory calibrated with MEMo Chip
- Fast. Results in approximately 1-2 minutes*
- Versatile. Ability to test multiple-test panels or individual tests
- Convenient. Small sample (15-40µL, fingerstick or venous (EDTA or heparin))
- Reliable. No moving parts
- Easy, simple. Stick finger > collect sample > dispense sample > read results
- CLIA-Waived.*
- Stable. Room temperature strip storage 18-24 months (no refrigeration required*)
- Portable. Test anywhere, any time (pocket-size, battery-operated)
- Inexpensive.
- Profitable. Covered by most US payors for medically-indicated testing
- Memory. Stores last 30 tests for recall
- Printer and Computer Connectivity. Optional

*Creatinine requires refrigeration, provides test results in 8 minutes, and is not CLIA-Waived.

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CardioChek

CardioChek Systems™

Customer Service

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Medical Distributors
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Product Specifications

CardioChek P•A
CardioChek
PTS Panels Test Strips
CardioChek P•A Printer

CardioChek Analyzers

CardioChek P•A:
Length: 5.5 in. (14.0cm)
Width: 3.0 in. (7.6 cm)
Height: 1.0 in. (2.5 cm)
Weight: 4.3 oz. (121.9 g)
Requires 2 AAA batteries
Battery life: approximately 300 tests
CLIA: Waived

CardioChek:
Length: 5.5 in. (14.0cm)
Width: 3.0 in. (7.6 cm)
Height: 1.0 in. (2.5 cm)
Weight: 4.3 oz. (121.9 g)
Requires 2 AAA batteries
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PTS Panels Multiple Test Strips

Lipid Panel:

Range:	Total Cholesterol:	100-400 mg/dL (2.59-10.36 mmol/L)
	HDL Cholesterol:	15-100 mg/dL (0.39-2.59 mmol/L)
	Triglycerides:	50-500 mg/dL (0.56-5.65 mmol/L)
Time:		about 2 minutes
Sample:		35-40 µL whole blood (fingerstick or venous)
Analyzer:		CardioChek P•A only
CLIA:		Waived

Cholesterol + Glucose:

Range:	Total Cholesterol:	100-400 mg/dL (2.59-10.36 mmol/L)
	Glucose:	20-600 mg/dL (1.11-33.3 mmol/L)
Time:		about 2 minutes
Sample:		25-30 µL whole blood (fingerstick or venous)
Analyzer:		CardioChek P•A only
CLIA:		Waived

Cholesterol + HDL:

Range:	Total Cholesterol:	100-400 mg/dL (2.59-10.36 mmol/L)
	HDL Cholesterol:	15-100 mg/dL (0.39-2.59 mmol/L)
Time:		about 2 minutes
Sample:		35-40 µL whole blood (fingerstick or venous)
Analyzer:		CardioChek P•A only

PTS Panels Individual Test Strips

Total Cholesterol:

Range:	100-400 mg/dL (2.59-10.36 mmol/L)
Time:	about 2 minutes
Sample:	15 µL whole blood (fingerstick or venous)
Analyzer:	CardioChek P•A or CardioChek
CLIA:	Waived

HDL Cholesterol:

Range:	25-85 mg/dL (0.65-2.20 mmol/L)
Time:	about 1 minute
Sample:	15 µL whole blood (fingerstick or venous)
Analyzer:	CardioChek P•A or CardioChek
CLIA:	Waived

LDL Cholesterol:

Range:	50-200 mg/dL (1.3-5.18 mmol/L)
Time:	about 2 minutes
Sample:	15 µL whole blood (fingerstick or venous)
Analyzer:	CardioChek P•A only
CLIA:	Waived

Ketone:

Range:	2-70 mg/dL (0.19-6.72 mmol/L)
Time:	about 2 minutes
Sample:	15 µL whole blood (fingerstick or venous)
Analyzer:	CardioChek P•A or CardioChek
CLIA:	Waived

Triglycerides:

Range:	50-500 mg/dL (0.56-5.65 mmol/L)
Time:	about 1 minute
Sample:	15 µL whole blood (fingerstick or venous)
Analyzer:	CardioChek P•A or CardioChek
CLIA:	Waived

Glucose:

Range:	20-600 mg/dL (1.11-33.3 mmol/L)
Time:	about 1 minute
Sample:	15 µL whole blood (fingerstick or venous)
Analyzer:	CardioChek P•A or CardioChek
CLIA:	Waived

Creatinine:

Range:	0.2-10 mg/dL (17.8-885 µmol/L)
Time:	within about 8 minutes
Sample:	20 µL whole blood (fingerstick or venous)
Analyzer:	CardioChek P•A
CLIA:	Moderate Complexity

CardioChek P•A Printer

Input: 100-240 VAC, 47-63 Hz, 1.5 A
Output: +20vdc, 2.5A
Length: 7.0 in. (17.78 cm)
Width: 3.5 in. (8.89 cm)
Height: 5.5 in. (13.97 cm)
Weight: 2.0 lbs. (0.97 kg)
Printer Label Specifications: Size: 2 ¼" x 3" per label, 500 labels per roll
Printer Paper Specifications: Size: 2 ¼" x 200 ft. roll

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NCEP Guidelines

Total System Error
The generally accepted standard for quality of a result from any test method relates to the difference between t result obtained and the reference value. That difference is referred to as "Total System Error", which is a meas both accuracy of the system (i.e., the bias of the system, or how close the average of a series of results on the sample are to the reference value) and precision (i.e., the reproducibility of the system, or how a close a series results on the same sample are to each other).

Reference Value
Because there is variability and system error in all commercial methods for determining lipid concentration, det the reference value can be difficult. The reference value is typically defined as the result given by the standard methods established by the Center for Disease Control and Prevention (CDC) for lipid analyses (the "National Reference System for Cholesterol" (NRS/Chol)).

CRMLN Reference Labs
The CDC established reference laboratories in the US ("Cholesterol Reference Method Laboratory Network" (C to evaluate and certify manufacturers' lipid products against reference standards.

NCEP Guidelines for Total System Error
The National Institutes of Health (NIH), through its National Cholesterol Education Program (NCEP), has estab test protocols and guidelines for acceptable deviation from "truth", or the NRS/Chol reference value. These gui state that Total System Error (TSE) should be within the following limits from reference when these test protoc followed:

Analyte	Total Error
Total Cholesterol	±8.9%
HDL Cholesterol	±13%
Triglycerides	±15%
LDL Cholesterol (direct measured)	±12%

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Training
Accuracy
NCEP Guidelines
Proficiency Surveys
Technical Documentation
In-Office Testing

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Proficiency Surveys

Proficiency Survey Tests
CLIA regulations require that all blind moderately-complex and highly-complex clinical laboratories (and in som even waived laboratories) regularly participate in "Proficiency Surveys" using unknown specimens to monitor a and precision of results obtained by the methods and products they utilize. There are several US and internatio proficiency testing programs, including surveys conducted by the American Proficiency Institute (API) and the C of American Pathologists (CAP).

Standards for Acceptable Results
In these proficiency surveys the target value is usually regarded as the average of results submitted by all parti of the survey across all methods and products. Lipid results that are within ±2 standard deviations of the mean analyzer type used are usually considered acceptable.

Examples of Accuracy and Precision of Common Commercial Lipid Test Methods
In the 2004, 3rd Test Event proficiency survey conducted by the American Proficiency Institute (See API's Parti Data Summaries) with 2,636 participants, even large automated analyzers reported significant bias from the me value and significant variation in results, even within labs using the same methodologies. For example:

Total Cholesterol	Mean	Bias*	SD	CV*	Range
All Participants	195.1		8.7	4.5%	175-215
Beckman Synchron CX	194.2	+0.5%	5.3	2.7%	174-214
Cholestech LDX	203.8	+4.5%	7.4	3.6%	189-219
Dade Dimension	186.5	-4.4%	4.3	2.3%	167-206
OCD Vitros	199.6	+2.3%	6.1	3.1%	179-220
Roche Hitachi	198.3	+1.6%	7.4	3.7%	178-219

Bias is defined herein as the difference between the mean result for the test system and the mean result for all participants.
CV is defined herein as the Standard Deviation as a percent of the Mean.

HDL Cholesterol	Mean	Bias*	SD	CV*	Range
All Participants	45.3		8.1	17.9%	31-59
Beckman Synchron CX	54.8	21.0%	4.0	7.3%	38-72
Cholestech LDX	43.6	-3.8%	7.8	17.9%	28-60
Dade Dimension	46.7	3.1%	6.2	13.3%	32-61
OCD Vitros 250-950	39.7	-12.4%	3.8	9.6%	27-52
Roche Hitachi	34.9	-23.0%	2.2	6.3%	24-46

Triglycerides	Mean	Bias*	SD	CV*	Range
All Participants	150.6		9.0	6.0%	112-189
Beckman Synchron CX	150.5	-0.1%	8.2	5.1%	112-189
Cholestech LDX	159.5	5.9%	8.2	5.1%	143-176
Dade Dimension	153.6	2.0%	5.8	3.8%	115-192
OCD Vitros 250-950	159.0	5.6	6.0	3.8%	119-199
Roche Hitachi	154.8	2.8%	3.9	2.5%	116-194

Direct LDL	Mean	Bias*	SD	CV*	Range
All Participants	87.1		20.2	23.2%	46-128
Beckman Synchron CX	64.4	-26.1%	4.2	6.5%	56-73
Cholestech LDX	Not Available				
Dade Dimension	84.3	-3.2%	5.4	6.4%	73-96
Roche Hitachi	111.1	27.6%	2.9	2.6%	105-117

CardioChek P•A System Proficiency
Launched in mid-2003 the CardioChek P•A System was too new to participate in 2003 and 2004 proficiency su

will, however, be listed in 2005. In the meantime, data submitted to the FDA as part of the 510(k) clearance prc demonstrate that the CardioChek P•A with Lipid Panel strips and the new direct LDL strips perform comparably above survey statistics:

	Mean	SD	CV
Total Cholesterol*	197.2	8.4	4.3%
HDL-Cholesterol*	39.2	2.5	6.4%
Triglycerides*	157.0	6.1	3.9%
LDL-Cholesterol, Direct**	113.6	6.11	5.4%

* Data from Lipid Panel package insert.

** Data from LDL package insert.

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