

Technical Brief

Accuracy of the CardioChek™ P•A and the Cholestech LDX® Systems Compared to Cholesterol Reference Method Laboratory Network (CRMLN) Determinations of Lipids

Abstract

Both the CardioChek P•A and the Cholestech LDX Systems measure lipids (cholesterol, HDL cholesterol and triglycerides) in whole blood. Venous whole blood and serum samples were collected from 43 subjects in the same blood draw. The serum was sent to a CRMLN network laboratory for cholesterol, HDL and triglycerides analysis. The whole blood was run on both the CardioChek P•A and the Cholestech LDX. Accuracy was measured as bias between each method and the CRMLN laboratory results. The CardioChek P•A produced cholesterol, HDL and calculated LDL cholesterol results that had a very small bias to CRMLN laboratory results. The Cholestech LDX System results for cholesterol and calculated LDL cholesterol showed a significant bias when compared to the CRMLN laboratory results, as did Cholestech LDX HDL results at the second HDL clinical cutpoint (60mg/dL HDL).

Introduction

In 1990, the Centers for Disease Control and Prevention (CDC) established the Cholesterol Reference Method Laboratory Network (CRMLN) to provide reference laboratory services to manufacturers so that lipid tests can be confirmed as traceable to the National Reference System for Cholesterol (NRS/Chol). There are currently four CRMLN laboratories in the United States. The Division of Laboratory Sciences of the CDC maintains the manufacturer's certification program for lipids. As the CRMLN laboratories are responsible for confirming lipid traceability to the NRS/Chol, the CRMLN laboratory results are the most appropriate results for assessing accuracy of a laboratory method. Both the cholesterol and HDL cholesterol tests are standardized through the CRMLN. There is currently no standardization program for triglycerides.

The CardioChek P•A (Polymer Technology Systems, Inc., Indianapolis, IN) is a handheld clinical analyzer capable of running a variety of tests on whole blood using disposable test strips.

The Cholestech LDX (Cholestech Corporation, Hayward, CA) is a clinical analyzer capable of running whole blood samples using a disposable cassette.

The objective of this study was to compare the test results for cholesterol, HDL cholesterol, triglycerides and calculated LDL cholesterol from both the CardioChek P•A system and the Cholestech LDX system to test results from a CRMLN reference laboratory.

Method

Forty-three (43) subjects participated in this study. Venous blood was drawn in EDTA, heparin and serum tubes.

The PTS PANELS™ Lipid Panel Test Strips and the Cholestech Lipid Profile cassettes measure cholesterol, HDL cholesterol and triglycerides and calculate LDL cholesterol. The whole blood was tested on both a CardioChek P•A system and a Cholestech LDX system. The PTS PANELS Lipid Panel Test Strips were used with the CardioChek P•A and the Cholestech Lipid Profile cassettes were used with the LDX. The tests were performed according to each manufacturer's instructions.

The serum was sent to a CRMLN reference laboratory for cholesterol, HDL and triglycerides analysis. LDL results were calculated.

The results from each of the CardioChek P•A and Cholestech LDX systems were compared to the CRMLN reference laboratory results using least squares linear regression. The regression results are listed, by test, in Table 1. Accuracy was measured as bias between each method and the CRMLN laboratory results. Bias was assessed two ways: by calculating the mean bias for each method to the CRMLN results for that test and by calculating the bias to the CRMLN results at the clinical cutpoints using each method's regression equation.

The clinical cutpoints used are 200 and 240 mg/dL (cholesterol); 40 and 60 mg/dL (HDL); 150 and 200 mg/dL (triglycerides) and 130 and 160 mg/dL (LDL).

Table 1: Accuracy of Two Analyzers Compared to the CRMLN Reference Laboratory

Test System	Slope	Intercept	Mean Bias	Bias at Cutpoints	Range of samples
Cholesterol (n=43)					112-294 mg/dL
CardioChek P•A vs. CRMLN	0.976	8.46	1.95%	1.83%, 1.13%	
Cholestech LDX vs. CRMLN	1.187	-12.32	12.36%	12.54%, 13.57%	
HDL Cholesterol (n=42)					30-85 mg/dL
CardioChek P•A vs. CRMLN	0.912	2.65	3.32%	2.18%, 4.38%	
Cholestech LDX vs. CRMLN	1.358	-16.00	2.89%	4.20%, 9.13%	
Triglycerides (n=39)					46-411 mg/dL
CardioChek P•A vs. CRMLN	1.151	-33.97	10.62%	7.55%, 1.89%	
Cholestech LDX vs. CRMLN	1.123	-2.07	6.04%	10.92%, 11.27%	
LDL Cholesterol (n=38)					45-209 mg/dL
CardioChek P•A vs. CRMLN	0.804	29.41	5.84%	3.02%, 1.22%	
Cholestech LDX vs. CRMLN	1.181	-1.13	17.15%	17.23%, 17.39%	

Results

Forty-three subjects participated in this study. Results outside of the dynamic range of the test methods were excluded from the data analysis. Table 1 lists the slopes and intercepts from the regression and the mean bias and biases at the clinical cutpoints for cholesterol, HDL cholesterol, triglycerides and calculated LDL.

The Cholestech LDX cholesterol and LDL biases to the CRMLN results were significantly higher than those from the CardioChek P•A.

The HDL cholesterol mean biases compared to the CRMLN results were equivalent for the Cholestech LDX and the CardioChek P•A. However, the HDL cholesterol bias for the Cholestech LDX was significantly higher than for the CardioChek P•A at the second clinical cutpoint (60mg/dL HDL).

Discussion

In comparing lipid results from two different analyzers to the CRMLN reference laboratory results as a measure of the accuracy of the systems, the CardioChek P•A was found to be more accurate for cholesterol, HDL and LDL cholesterol at the clinical cutpoints than the LDX.

Even though there are no National Cholesterol

References:

1. Expert Panel on Detection, Evaluation and Treatment of High Cholesterol in Adults. Executive Summary of the Third Report of the National Cholesterol Education Program, ATP III, JAMA, 2001; 285:2486-97.
2. PTS PANELS Lipid Panel Test Strip package insert, 2003.

Education Program (NCEP) performance guidelines for whole blood lipid analyzers, the CardioChek P•A met the NCEP serum performance bias guideline at both clinical cutpoints for both cholesterol and HDL cholesterol. The Cholestech LDX did not meet the bias guideline at either of the clinical cutpoints for cholesterol. The Cholestech LDX HDL met the bias guideline at the first clinical cutpoint, but failed to meet the bias guideline for HDL at the second clinical cutpoint.

The CardioChek P•A system compares more closely with the CRMLN reference laboratory than does the Cholestech LDX for cholesterol, HDL cholesterol and LDL cholesterol.

The overall conclusion is that the CardioChek P•A Lipid Panel test results were more accurate for cholesterol, HDL cholesterol and LDL cholesterol than the Cholestech LDX.

Acknowledgment

Polymer Technology Systems, Inc. would like to acknowledge the Core Laboratory for Clinical Studies at Washington University School of Medicine in St. Louis, MO for their assistance in this study.

3. Cholestech Lipid Profile package insert, 1999.
4. Bachorik PS, Ross JW, National Cholesterol Education Program Working Group on Lipoprotein Measurement. Clin Chem, 1995,41:1414-20.

CardioChek is a trademark of Polymer Technology Systems, Inc.
Cholestech is a registered trademark of Cholestech Corporation.

©2003 Polymer Technology Systems, Inc, Indianapolis, IN; 317-870-5610; www.ptspanels.com.