

CHOLESTEROL REFERENCE METHOD LABORATORY NETWORK

Certificate of Traceability

This certifies that

Polymer Technology Systems, Inc.
Indianapolis, Indiana

has documented traceability to the **National Reference System for Cholesterol** by performing a direct comparison with the cholesterol reference method using fresh human specimens which cover the National Cholesterol Education Program medical decision points. This analytical system is representative of the manufacturer's product and has demonstrated the ability to meet the NCEP's performance criteria for accuracy and precision. The comparison shows that the performance of this analytical system is as follows:

Among-run %CV	Average %Bias	%Total Error
2.0%	-1.9%	5.9%

The comparison was performed with

Northwest Lipid Metabolism and Diabetes Research Laboratories
Seattle, Washington

The system evaluated was:

Instrument:

Polymer Technology Systems, Inc.
CardioChek® and CardioChek® PA

Calibrator:

Cholesterol reagent:

PTS PANELS® CardioChek®
Lot #: C904

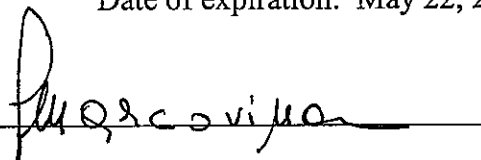
Matrix:

Whole Blood

Date of evaluation: May 22, 2009

Date of expiration: May 22, 2011

CRMLN Laboratory Director



CHOLESTEROL REFERENCE METHOD LABORATORY NETWORK

Certificate of Traceability

This certifies that

Polymer Technology Systems, Inc.
Indianapolis, Indiana

has documented traceability to the **National Cholesterol Education Program's recommended accuracy base for HDL Cholesterol** by performing a direct comparison with a CRMLN laboratory using fresh human specimens which cover the NCEP medical decision points. This analytical system is representative of the manufacturer's product and has demonstrated the ability to meet the NCEP's performance criteria for accuracy and precision. The comparison shows that the performance of this analytical system is as follows:

Among-run %CV	Average %Bias	%Total Error
0.9%	-1.6%	3.4%

The comparison was performed with

Northwest Lipid Metabolism and Diabetes Research Laboratories
Seattle, Washington

The system evaluated was:

Instrument:

CardioChek®/ CardioChek® PA

Calibrator:

N/A

Cholesterol reagent:

N/A

Matrix:

Whole Blood

Separation Method:

N/A

Precipitation Reagent:

N/A

Date of evaluation: August 13, 2009

Date of expiration: August 13, 2011

CRMLN Laboratory Director

