

CHOLESTEROL REFERENCE METHOD LABORATORY NETWORK

Certificate of Traceability

This certifies that

***Polymer Technology Systems Diagnostics
Indianapolis, IN***

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
1.1%

Average Bias
2.9%

Total Error
5.1%

The comparison was performed with

***Northwest Lipid Metabolism and Diabetes Research Laboratories
Seattle, Washington***

The system evaluated was:

Instrument:

***PTS Diagnostics
Cardio Chek® Plus®***

Calibrator:

Lot #:

Set Point(s):

Cholesterol reagent:

PTS Diagnostics

Matrix:

Whole Blood

Lot #: P632

Date of evaluation: 6/15/2017

Date of expiration: 6/15/2019

CRMLN Laboratory Director

