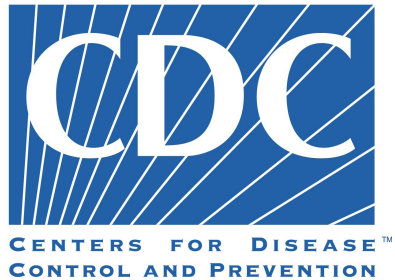


CDC CLINICAL STANDARDIZATION PROGRAMS  
CHOLESTEROL REFERENCE METHOD LABORATORY NETWORK (CRMLN)

# Certificate of Analytical Quality



**Participant:** Polymer Technology Systems Diagnostics

**Location:** Indianapolis, IN 46268

**Analyte:** HDL Cholesterol

**Matrix:** Whole Blood

**Date of Certification:** 6/21/2019

The participant has documented traceability to the CDC CRMLN by performing a direct comparison with the HDL Cholesterol reference method using fresh human specimens covering the concentration range of 23-68 mg/dL. This analytical system is representative of the manufacturer's product and has demonstrated the ability to meet the performance criteria for accuracy and precision described below. The comparison shows the performance of this analytical system is as follows & is valid for **two** years after the date of certification:

**Mean Bias**

4.7%

Mean Bias within suggested range

**Among-Run CV**

0.4%

Among-Run CV within suggested range

**Total Error**

5.6%

Total Error within suggested range

## ANALYTICAL SYSTEM EVALUATED

**Instrument**

Polymer Technology Systems  
Cardio Chek® PLUS®

**Calibrator**

**Reagent**

Polymer Technology Systems  
PTS Panels® Lot#: Q903

## COMPARISON WAS PERFORMED WITH CRMLN LABORATORY AT

**Northwest Lipid Metabolism and Diabetes Research Laboratories**

**Seattle, Washington**

Method Used: HDL Cholesterol by DCM (HDL-C-DCM)

A handwritten signature in blue ink, appearing to read "Hubert W. Vesper".

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Hubert W. Vesper, Ph.D.  
Director, CDC Clinical Standardization Programs

