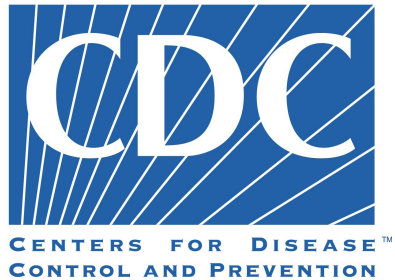


CDC CLINICAL STANDARDIZATION PROGRAMS
CHOLESTEROL REFERENCE METHOD LABORATORY NETWORK (CRMLN)

Certificate of Analytical Quality



Participant: Polymer Technology Systems, Inc.

Location: Indianapolis, IN 46268

Analyte: Total Cholesterol

Matrix: Whole Blood

Date of Certification: 6/14/2019

The participant has documented traceability to the CDC CRMLN by performing a direct comparison with the Total Cholesterol reference method for **recertification** using fresh human specimens covering the concentration range of 142-345 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

-1.3%

Mean Bias within suggested range

Among-Run CV

0.2%

Among-Run CV within suggested range

Total Error

1.7%

Total Error within suggested range

ANALYTICAL SYSTEM EVALUATED

Instrument

Polymer Technology Systems
Cardio Chek® PA®

Calibrator

Reagent

Polymer Technology Systems
PTS Panels ® Lot#: P838

COMPARISON WAS PERFORMED WITH CRMLN LABORATORY AT

Northwest Lipid Metabolism and Diabetes Research Laboratories

Seattle, Washington

Method Used: Total Cholesterol by Abell-Kendall (TC-AK)

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

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

