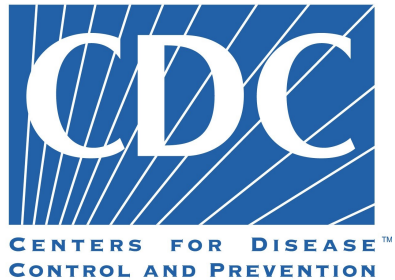CDC CLINICAL STANDARDIZATION PROGRAMS
CHOLESTEROL REFERENCE METHOD LABORATORY NETWORK (CRMLN)

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	Among-Run CV	Total Error
4.4%	0.0%	4.4%
Mean Bias within suggested range	Among-Run CV within suggested range	Total Error within suggested range

ANALYTICAL SYSTEM EVALUATED

Instrument	Calibrator	Reagent
Polymer Technology Systems Cardio Chek® PA®		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 (HDLC-DCM)

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