

CHOLESTEROL REFERENCE METHOD LABORATORY NETWORK

Certificate of Traceability

This certifies that

*Cholestech Corporation
Hayward, California*

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
2.6%	-0.2%	5.4%

The comparison was performed with

Northwest Lipid Metabolism and Diabetes Research Laboratories
Seattle, Washington

The system evaluated was:

Instrument:
Cholestech LDX® System

Calibrator:
Streck Serum Calibrator
Lot #: CTEC F set (SPC092308)
Set Points:
116, 206, 296, 376, 451 mg/dL

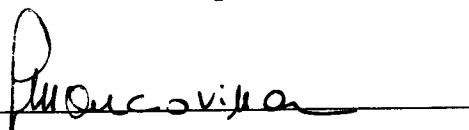
Cholesterol reagent:
Cholestech Lipid Profile
Lot #: C08 7708

Matrix:
Serum

Date of evaluation: April 29, 2009

Date of expiration: April 29, 2011

CRMLN Laboratory Director



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Among-run %CV	Average %Bias	%Total Error
1.5%	2.1%	5.2%

The comparison was performed with

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

The system evaluated was:

Instrument:

Cholestech LDX® System

Calibrator:

Streck Serum Calibrator

Lot #: CTEC F set (SPC092308)

Set Points:

116, 206, 296, 376, 451 mg/dL

Cholesterol reagent:

Cholestech Lipid Profile

Lot #: C08 7751

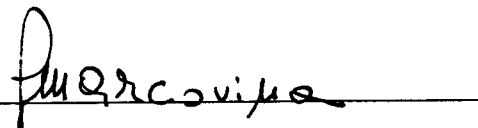
Matrix:

Serum

Date of evaluation: August 6, 2009

Date of expiration: August 6, 2011

CRMLN Laboratory Director



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Among-run %CV	Average %Bias	%Total Error
2.6%	-1.8%	7.0%

The comparison was performed with

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

The system evaluated was:

Instrument:
Cholestech LDX® System

Calibrator:
*Streck Serum Calibrator
Lot #: CTEC F set (SPC092308)*

Set Points:
116, 206, 296, 376, 451 mg/dL

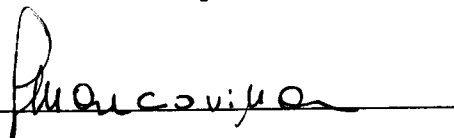
Cholesterol reagent:
*Cholestech Lipid Profile
Lot #: C08 7708*

Matrix:
Whole Blood

Date of evaluation: April 29, 2009

Date of expiration: April 29, 2011

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Among-run %CV	Average %Bias	%Total Error
1.6%	0.1%	3.2%

The comparison was performed with

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

The system evaluated was:

Instrument:

Cholestech LDX® System

Calibrator:

Streck Serum Calibrator

Lot #: CTEC F set (SPC092308)

***Set Points: 116, 206, 296, 376, 451
mg/dL***

Cholesterol reagent:

Cholestech Lipid Profile

Lot #: C08 7751

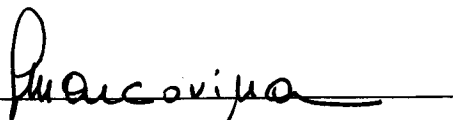
Matrix:

Whole Blood

Date of evaluation: August 6, 2009

Date of expiration: August 6, 2011

CRMLN Laboratory Director



CHOLESTEROL REFERENCE METHOD LABORATORY NETWORK

Certificate of Traceability

This certifies that

*Cholestech Corporation
Hayward, California*

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
2.2%	0.3%	4.7%

The comparison was performed with

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

The system evaluated was:

Instrument:

Cholestech LDX® System

Calibrator:

Streck Serum Calibrators

Lot #: CTEC F Sets

Set Points: 116, 206, 296, 376

451 mg/dL

Cholesterol reagent:

Cholestech LDX® System

Lot #: C107713

Separation Method:

Matrix:

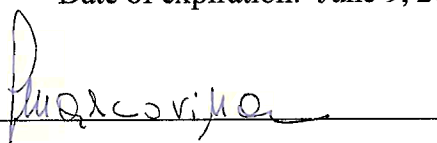
Venous Serum

Precipitation Reagent:

Date of evaluation: June 9, 2009

Date of expiration: June 9, 2011

CRMLN Laboratory Director



CHOLESTEROL REFERENCE METHOD LABORATORY NETWORK

Certificate of Traceability

This certifies that

Cholestech Corporation Hayward, California

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
2.2%	2.3%	6.7%

The comparison was performed with

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

The system evaluated was.

Instrument:

Cholestech LDX® System

Calibrator:

Streck Serum Calibrators

Lot #: CTEC F Sets

Set Points: 116, 206, 296, 376

451 mg/dL

Cholesterol reagent:

Cholestech LDX® System

Lot #: C087689

Matrix:

Venous Serum

Separation Method:

Precipitation Reagent:

Date of evaluation. June 9, 2009

Date of expiration. June 9, 2011

CRMLN Laboratory Director

