

CHOLESTEROL REFERENCE METHOD LABORATORY NETWORK

Certificate of Traceability

This certifies that

Axis-Shield PoC AS
Rodelokka, Oslo, Norway

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
2.4%	0.9%	5.7%

The comparison was performed with

Northwest Lipid Metabolism and Diabetes Research Laboratories
Seattle, Washington

The system evaluated was:

Instrument:
Axis-Shield PoC AS
Afinion™ AS100

Calibrator:
N/A
Lot #:

Set Point:

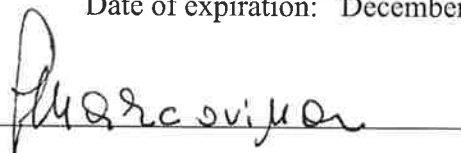
Cholesterol reagent:
Axis-Shield PoC AS
Afinion™ Lipid Panel Lot #: 10157679

Matrix:
Venous Serum

Date of evaluation: December 18, 2012

Date of expiration: December 18, 2014

CRMLN Laboratory Director



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Among-run CV	Average Bias	Total Error
2.9%	0.5%	6.3%

The comparison was performed with

Northwest Lipid Metabolism and Diabetes Research Laboratories
Seattle, Washington

The system evaluated was:

Instrument:
Axis-Shield PoC AS
Afinion™ AS100

Calibrator:
N/A
Lot #:

Set Point:

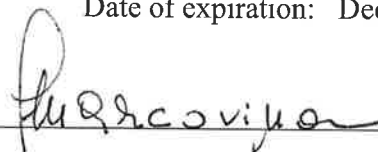
Cholesterol reagent:
Axis-Shield PoC AS
Afinion™ Lipid Panel Lot #: 10157679

Matrix:
Venous Serum

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Among-run CV	Average Bias	Total Error
2.4%	0.3%	5.1%

The comparison was performed with

Northwest Lipid Metabolism and Diabetes Research Laboratories
Seattle, Washington

The system evaluated was:

Instrument:
Axis-Shield PoC AS
Afinion™ AS100

Calibrator:
N/A

Lot #:
Set Point:

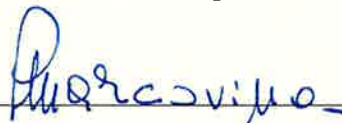
Cholesterol reagent:
Axis-Shield PoC AS
Afinion™ Lipid Panel Lot #: 10157679

Matrix:
Plasma

Date of evaluation: December 18, 2012

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Among-run CV	Average Bias	Total Error
2.9%	1.0%	6.8%

The comparison was performed with

Northwest Lipid Metabolism and Diabetes Research Laboratories
Seattle, Washington

The system evaluated was:

Instrument:
Axis-Shield PoC AS
Afinion™ AS100

Calibrator:
N/A
Lot #:

Set Point:

Cholesterol reagent:
Axis-Shield PoC AS
Afinion™ Lipid Panel Lot #: 10157679

Matrix:
Plasma Li-Heparin

Date of evaluation: December 18, 2012

Date of expiration: December 18, 2014

CRMLN Laboratory Director

