

CHOLESTEROL REFERENCE METHOD LABORATORY NETWORK

Certificate of Traceability

This certifies that

Axis-Shield PoC AS Rodelokka, Oslo, Norway

has documented traceability to the **National Reference System for Cholesterol** by performing a direct comparison with the cholesterol reference method for **certification** 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
2.1%	-1.1%	5.3%

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
AS-16777

Calibrator:
N/A

Lot #:
Set Point:

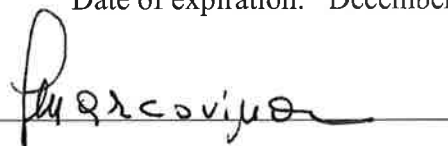
Cholesterol reagent:
Axis-Shield PoC AS
Afinion™ Lipid Panel Lot #: 10157679

Matrix:
Venous Serum

Date of evaluation: December 19, 2012

Date of expiration: December 19, 2014

CRMLN Laboratory Director



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Among-run CV	Average Bias	Total Error
2.3%	-1.3%	5.9%

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
AS-14717

Calibrator:
N/A
Lot #:

Set Point:

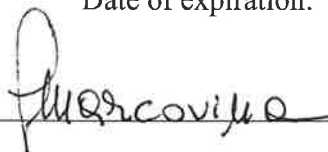
Cholesterol reagent:
Axis-Shield PoC AS
Afinion™ Lipid Panel Lot #: 10157679

Matrix:
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Among-run CV	Average Bias	Total Error
2.1%	-2.5%	6.7%

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
AS-16777

Calibrator:
N/A

Lot #:
Set Point:

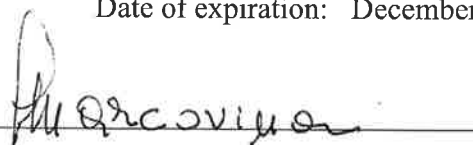
Cholesterol reagent:
Axis-Shield PoC AS
Afinion™ Lipid Panel Lot #: 10157679

Matrix:
Plasma Li-heparin

Date of evaluation: December 19, 2012

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Among-run CV	Average Bias	Total Error
2.3%	-2.8%	7.5%

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
AS-14717

Calibrator:
N/A

Lot #:
Set Point:

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

Matrix:
Plasma Li-heparin

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