Pointe Lipoprotein(a) Reagent Set

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Intended Use
The Pointe Lipoprotein(a) Assay is intended as a latex particle enhanced immunoturbidimetric assay for the in vitro quantitative determination of Lipoprotein(a) concentration in human serum or plasma on Clinical Chemistry Systems. The measurement of Lipoprotein(a) is useful in evaluating lipid metabolism disorders and assessing atherosclerotic cardiovascular diseases in specific populations, when used in conjunction with clinical evaluation. For *in vitro* diagnostic use only.
Rx Only

Clinical Significance
Lipoprotein (a) is a cholesterol-rich lipoprotein particle found in human serum. There is substantial evidence linking lipoprotein(a) excess to a high risk for premature coronary heart disease (CHD), increased risk of myocardial infraction (MI) and stroke, and restenosis after angioplasty (PTCA) and coronary bypass procedures.[1-8] Assessment should be based on Patient history, Clinical findings and other laboratory tests.

Test Principle
The Pointe Lipoprotein(a) Assay is based on a latex enhanced immunoturbidimetric assay. Lipoprotein(a) in the sample binds to specific anti-Lipoprotein(a) antibody, which is coated on latex particles, and causes agglutination. The degree of the turbidity caused by agglutination can be measured optically and is proportional to the amount of Lipoprotein(a) in the sample.

Reagents
R1: Tris Buffer Solution
R2: Latex particles coated with anti-Lipoprotein antibodies

Precautions
1. For *in vitro* diagnostic use only. RX only.
2. Caution: Federal law restricts this device to sale by or on the other of a physician or other practitioner licensed by laws of the State in which he/she practices, to use or order the use of the device.
3. Each laboratory should follow federal, state, and local guidelines for testing QC material.
4. Do not use the reagents, calibrator, and controls after the expiration date labeled on the outer box.
5. The assay should be recalibrated and controls run with each new lot of reagents.
6. Samples containing precipitates should not be used.
7. Specimens containing human sourced materials should be handled as if potentially infectious using safe laboratory procedures, such as those outlined in Biosafety in Microbiological and Biomedical Laboratories (HHS Publication Number [CDC] 93-8395).
8. Avoid ingestion and contact with skin and eyes. See the Safety Data Sheet (SDS).
9. The REAGENT contains <0.1% sodium azide, NaN_3, as preservative. Sodium azide may react with lead and copper to form highly explosive metal azide. On disposal, flush with a large volume of water to prevent azide buildup.
10. Additional safety information concerning storage or handing of this product is provided within the Safety Data Sheet (SDS) for this product. To obtain an SDS, please contact our customer service department at 800-445-9853.

Reagent Handling
1. The Pointe Lipoprotein(a) Assay REAGENT provided is ready to use.
2. Physiological saline is needed to dilute high lipoprotein (a) samples.

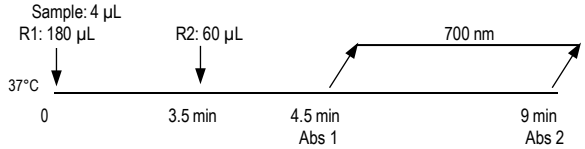
Reagent Stability and Storage
The Pointe Lipoprotein (a) Assay REAGENT should be stored at 2-8°C. **DO NOT FREEZE**. The reagents are stable when stored at 2-8°C until the expiration date on the label. Do not mix reagent from different lots.

Specimen Collection and Handling
Serum or K2 EDTA plasma samples or Li-Heparin Plasma samples can be used for the Lipoprotein (a) assay. Analyze fresh specimens if possible. Repeated freeze/thaw cycles should be avoided to minimize potential protein degradation.[9]
It is the responsibility of the individual laboratory to use all available references and/or its own studies to determine specific stability criteria for its laboratory.[16]

Materials Provided
Reagents – R1 and R2

Materials Required but not Provided
The Pointe Lipoprotein(a) Calibrator Set (L7597-CAL) and saline for calibration and Lipoprotein(a) Controls (L7597-CTL) for validating the performance of the Pointe Lipoprotein(a) Assay reagents are provided separately.

Assay Procedures
The Pointe Lipoprotein (a) Assay was validated on the Beckman Coulter AU400. The assay procedure for the Beckman Coulter AU400 chemistry analyzer is shown below. Please refer to the instrument parameter sheet for input.



Calibration
Five levels of liquid-stable calibrators are needed for calibration, along with saline. The lot specific calibrator values are stated in the Package Insert.

Quality Control
We recommend that each laboratory use Lipoprotein(a) controls to validate the performance of Lipoprotein (a) reagent. A set of normal and abnormal ranges of Lipoprotein(a) control is available from HORIBA Medical. The range of acceptable control limits should be established by individual laboratories.

Results
Results are printed out in mg/dl.

Reference Range
Studies have shown the expected range for Lipoprotein(a) has been reported to be between 10 and 30 mg/dl.[10,11] Some studies have indicated that Lipoprotein (a) concentrations in African Americans may differ from Caucasians with African American ranges higher.[12,13,14] Increased serum Lipoprotein (a) concentrations are associated with increased risk of premature coronary artery disease and stroke. Because Lipoprotein(a) levels are highly heritable, Lipoprotein (a) may be an important marker for premature CHD, especially among Caucasians. Although Lipoprotein(a) levels are higher in African Americans than in Caucasians, associated CHD risk appears to be less.[15]

Each laboratory, however, is recommended to establish a range of normal values for the population in their region. Lipoprotein(a) values should be interpreted in conjunction with clinical evaluation and other lipoprotein tests when assessing atherosclerotic cardiovascular disease in specific populations.

Limitations
1. Harmonization efforts for Lipoprotein(a) assay methods have suggested an impact of Apo A size heterogeneity on Lipoprotein(a) measurement methods.[12,13] The effects of the impact of Apo A size have not been assessed for this assay.

2. Store the reagents at 2-8°C. Do not freeze the reagents.
3. Assessment should be based on Patient history, Clinical findings and other laboratory tests.

Performance Characteristics

The assay performance was established on Beckman Coulter AU400 with a 6-point calibration using saline and separately provided calibrator levels 1-5. Results obtained from individual laboratories may vary.

Accuracy

Correlation studies were performed by testing 99 serum samples ranging from 6.1 to 93.2 mg/dl in comparison with an existing commercial Lipoprotein (a) assay method. The correlation coefficient between the two methods was 0.9868, slope was 0.9828, and y intercept was 1.0033.

Precision

The precision of the Pointe Lipoprotein(a) Assay was evaluated according to Clinical and Laboratory Standards Institute EP5-A2 guideline. In the study, five levels of serum specimens containing Lipoprotein(a) covering assay AMR were tested with 2 runs per day with duplicates over 20 working days on Beckman Coulter AU400 using three lots of the reagents. The results of the within-run, between-run, between-day, and total CV% for three lots of the reagent combined are listed in the following table (N=240):

Sample	Mean	Within-Run		Between-Run		Between-Day		Total	
		SD	%CV	SD	%CV	SD	%CV	SD	%CV
Serum 1	7.9	0.29	3.7%	0.18	2.3%	0.72	9.2%	0.80	10.1%
Serum 2	14.6	0.43	2.9%	0.00	0.0%	0.83	5.7%	0.93	6.4%
Serum 3	20.1	0.63	3.1%	0.00	0.0%	1.03	5.1%	1.21	6.0%
Serum 4	57.6	0.85	1.5%	0.00	0.0%	1.49	2.6%	1.71	3.0%
Serum 5	95.9	0.75	0.8%	0.51	0.5%	1.12	1.2%	1.44	1.5%

Linearity

The assay has an analytical measuring range (AMR) up to 100 mg/dl.

Detection Limits

The limit of detection (LOD) for Lipoprotein(a) Assay is determined to be 1.3 mg/dl and the limit of Quantitation (LOQ) for Lipoprotein(a) assay is 3.2 mg/dl. The Limit of Quantitation is the lowest analyte concentration that can be reproducibly measured with a precision of 20 % CV. The assay has measuring range of 5.4 to 100 mg/dl.

Interference

Interference studies were conducted according to the CLSI EP7-A2 guidelines. The acceptance criterion was set at 10% or less deviation between the spiked sample and the control. The assay's results were not significantly affected by the following substances:

Interference	Concentration
Triglyceride	1000 mg/dl
Ascorbic Acid	176 mg/dl
Bilirubin	40 mg/dl
Bilirubin Conjugated	40 mg/dl
Hemoglobin	1000 mg/dl

Hook Effect

No high dose hook effect was observed up to 500 mg/dL Lipoprotein (a).

References

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Symbol Key

Use by (YYYY-MM-DD)	LOT Lot and batch code
REF Catalog number	Manufacturer
IVD *In vitro* diagnostic medical device	Temperature limitation
Consult instructions for use	**Rx Only:** Prescription Use Only
CE mark	EC REP Authorized representative in the European Community

REF L7597-40

Manufactured for
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2°C 8°C IVD

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Certified to Perform Reagents

The Pointe reagents are certified to be manufactured according to specified parameters. Any Pointe reagent product not meeting specifications through its listed expiration date will be remedied immediately without charge.

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