

Intended Use

The Pointe Lipoprotein(a) Calibrator Set is intended for use in establishing the calibration curve for the Pointe Lipoprotein(a) Assay reagents by turbidimetry. For in vitro diagnostic use only. **Rx Only**

Summary

The Pointe Lipoprotein(a) [Lp(a)] Calibrator Set (REF L7597-CAL) is a set of five CALIBRATOR levels. These five levels and saline are to be used for a six-point calibration of the Pointe Lipoprotein(a) Assay; which is a latex immunoturbidimetric assay for the quantification of Lipoprotein(a) in human serum and plasma.

Reagents – Working Solutions

Reactive components

- Human serum and additives

Non-reactive components

- Sodium azide (NaN₃) <0.1%

The Pointe Lipoprotein(a) Calibrator Set is a five-level set that is supplied in liquid stable form (5 x 1 mL). The CALIBRATOR is manufactured from human serum. The concentration of the CALIBRATOR is lot specific and the Lipoprotein(a) concentrations are expressed in mg/dL.

Calibrator Values

LOT 328901 2025-02-21

	Lp(a) Concentration (mg/dL)
Calibrator 1	13.6
Calibrator 2	23.8
Calibrator 3	48.7
Calibrator 4	76.9
Calibrator 5	115.2

Precautions and Warnings

- For in vitro diagnostic use.
- Exercise the normal precautions for handling all laboratory reagents. Each donor unit of serum used in the preparation of this Calibrator Set was tested by FDA-approved methods and found negative for the Human Immunodeficiency Virus Antibody (HIV I/II Ab), Hepatitis B Surface Antigen (HBsAg), and Hepatitis C Virus Antibody (HCV). Because no method can offer complete assurance as to the absence of infectious agents, however, this material and all patient samples should be handled as though capable of transmitting infectious disease and disposed of accordingly.
- Additional safety information concerning storage and handling of this product is provided within the Safety Data Sheet for this product. To obtain an SDS, please contact our customer service department at 800-445-9853.
- Avoid contact with skin and eyes.
- Contains sodium azide, which may react with lead or copper plumbing to form explosive compounds. Flush drains with copious amounts of water when disposing of this reagent.

Handling

The Pointe Lipoprotein(a) Calibrator Set is supplied in liquid stable form and are ready to use. Mix carefully before each use.

Storage and Stability

Store at 2 to 8°C. **DO NOT FREEZE.**

Note: Store CALIBRATOR tightly capped when not in use.

Stability

- Unopened Vials: stability is up to the expiration date on label when stored at 2 to 8°C.
- Opened Vials: open vials are stable up to 45 days when stored at 2 to 8°C.

Materials Provided

The Pointe Lipoprotein(a) Calibrator Set consists of 5 vials.

Materials required (but not provided)

- Pointe Lipoprotein(a) Assay reagents
- 0.9% saline solution
- General laboratory equipment

Assay

Prepare CALIBRATOR 1 through 5 as stated in the Handling section.

Note: A saline solution is required to generate a 6-point calibration.

EC	REP
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REF

L7597-CAL



Manufactured for
HORIBA Instruments Incorporated:
Pointe Brand
5449 Research Drive
Canton, MI 48188



2°C 8°C



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

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.

Rev. 10/23

P803-L7597-05