

## Intended Use

The Pointe Lipoprotein(a) Control Set is intended for use in monitoring the quality control of results obtained with the Pointe Lipoprotein(a) Assay reagents by turbidimetry. For *in vitro* diagnostic use, Rx only.

## Summary

The Pointe Lipoprotein(a) [Lp(a)] Control Set is a set of two control levels. These two levels are to be used as a quality control check 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 (NaN<sub>3</sub>) <0.1%

The Pointe Lipoprotein(a) Control Set is a two-level set that is supplied in liquid stable form (2 x 1 mL). The control is manufactured from human serum. The concentration of the control is lot specific and the Lipoprotein(a) concentrations are expressed in mg/dL.

## Control Values

Control	Lot Number	Expiration Date	Range (mg/dl)
Level 1	329201	2025-02-21	22.5 ± 5.6
Level 2	329201	2025-02-21	58.8 ± 8.8

## 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 Control 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) Control Set is supplied in liquid stable form and is ready to use. Mix carefully before each use.

## Storage and Stability

Store at 2 to 8°C. **DO NOT FREEZE.**

Note: Store controls 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) Control Set consists of 2 vials.

## Materials required (but not provided)

- Pointe Lipoprotein(a) Assay reagents (REF L7597)
- Pointe Lipoprotein(a) Calibrator Set (REF L7597-CAL)
- General laboratory equipment

## Assay

Prepare Controls 1 and 2 as stated in the Handling section. Run the same as a patient sample.

Manufactured for HORIBA Instruments Inc.- Pointe Brand  
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**REF** L7597-CTL



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## Symbol Key



Use by (YYYY-MM-DD)



Lot and batch code



Catalog number



Manufacturer



*In vitro* diagnostic medical device



Temperature limitation



Consult instructions for use



**Rx Only:** Prescription Use Only



CE mark



Authorized representative in the European Community

## Certified Performance Guarantee

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.