

### Intended Use

For *in vitro* use only.

This five level calibrator set is intended for use in the quantitative determination of Lp(a) in human serum by immunoturbidimetric analysis on selected automated clinical chemistry analyzers. Contact Pointe Scientific's technical service department for available instrument application guides.

The Lp(a) calibrators of this kit must be used with Pointe Scientific's Lp(a) Reagent. Pointe Scientific does not support the use of Lp(a) Serum Calibrator with other reagents and methods except those which are specifically supplied by Pointe Scientific.

### Contents

Lp(a) calibrators are prepared from pooled human serum which was tested for the detection of Hepatitis B Surface Antigen (HbsAG), HCV and Human Immunodeficiency virus (HIV) antibody and was found to be negative or non-reactive. The calibrators are provided in a lyophilized form containing five different concentrations of Lp (a) and contain non-reactive stabilizers.

NOTE: See PRECAUTIONS for information regarding the handling of kit components.

Human serum, 1.0 ml per vial (5 vials). Lp(a) concentration listed in mg/dL and nmol/L. See chart for assigned values.

### Precautions

1. For *in vitro* diagnostic use.
2. Avoid ingestion and contact with skin.
3. As the color of caps vary according to Lp(a) levels in the vial, care should be taken not to interchange the caps.
4. When removing the rubber cap, avoid dispersing any lyophilized powder attached to the insides of the cap. Use appropriate laboratory gloves, clothing, etc. when handling and wash hands thoroughly after use.
5. All human sera used in the manufacture of this kit have been tested by FDA approved detection methods for Hepatitis B Surface Antigen (HbsAG), HCV and human immunodeficiency virus and were found to be negative or non-reactive. **WARNING: POTENTIALLY BIOHAZARDOUS MATERIALS.** Since no test method can assure that products derived from human blood do not contain HIV and Hepatitis B viruses, calibrators and patient samples should be handled as though capable of transmitting infectious diseases.
6. Once dispensed, calibrators should never be returned to the original vial.
7. The calibrators should be used according to this kit insert. Otherwise, the performance is not guaranteed.

### Calibration Preparation

1. Carefully remove the rubber cap from the vial and add 1.0 ml distilled water to the vial.
2. Recap and leave at room temperature for 15 minutes, inverting gently to dissolve contents.
3. For use with selected automated clinical chemistry analyzers.

### Materials Required but not Provided

1. Automated clinical chemistry analyzer.
2. Pointe Scientific Lp(a) Reagent, deionized water and system consumables.

### Storage and Stability

1. Store the kit in a refrigerator at 2-8°C. Protect from light. The unopened vials of the kit are stable until the expiration date shown on the labels. **DO NOT FREEZE CALIBRATORS.**
2. Once reconstituted, calibrators are stable for two weeks when stored at 2-8°C.
3. Calibrator sera must be tightly capped and stored at 2-8°C when not in use.

### Procedure

1. Allow Lp (a) calibrators to come to room temperature.
2. Pipette the required amount of each calibrator serum into analyzer deliver cup; refer to instrument specific Application Guide and Lp(a) Reagent package insert for detailed procedure.
3. Calibrate the test system using deionized water as Cal-1 (zero Lp(a) concentration) and Pointe Scientific Lp(a) Calibrator serum levels 1 through 5 as Cal 2 through Cal 6 to generate a six point calibration curve.

### Calibrator Values

**LOT: 506901    Exp: 2016-08**

	Lp(a) concentration (mg/dL)	Lp(a) concentration (nmol/L)*
Calibrator 1	7.2 mg/dL	---
Calibrator 2	15.8 mg/dL	---
Calibrator 3	35.0 mg/dL	---
Calibrator 4	63.8 mg/dL	---
Calibrator 5	101.0 mg/dL	---

\* Concentrations listed in nmol/L not available for this lot.

### Limitations

1. Pointe Scientific Lp(a) calibrator values are specific for use with the Pointe Scientific Lp(a) Reagent only. Use of these calibrators with other reagents is not recommended.
2. Dust particles or particulate matter in the reaction solution may result in extraneous turbidimetric signals giving rise to variable calibration curves.
3. Calibrators must not be frozen and must not be allowed to stand for repeatedly long periods of time (over 2 hours) at room temperature. Keep calibrator vials tightly capped and stored at 2-8°C when not in use to avoid microbial contamination and evaporation.

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