

Intended Use

The Pointe ASO Calibrator is intended to be used to calibrate the Pointe ASO assay for quantifying serum anti-streptolysin O (ASO). FOR IN VITRO DIAGNOSTIC USE. **Rx Only.**

Summary

The calibrators provided are human serum, tested and found negative for HBsAb and HIV Ab. The calibrators contain known quantities of anti-streptolysin O (ASO). These calibrators are to be used with the Pointe ASO Reagent Set.

Kit composition

Calibrators (Liquid Stable)

MATERIALS PROVIDED

Calibrator A-E Human serum 5 x 1mL

Calibrators contain pooled human serum with assigned values for anti-streptolysin O.

Warnings and Precautions

For *In Vitro* Use Only. Rx only.

Not to be used internally in humans or animals. Normal precautions in handling laboratory reagents should be followed.

Calibrators contain pooled human serum from ASO positive human serum. The serum has been tested and found nonreactive for the presence of HBsAg and HIV antibody by an FDA approved method. However, it is not possible to guarantee that any human source material is free of these infectious agents. Therefore, all products containing human serum should be handled in accordance with good laboratory practices using appropriate precautions as described in the CDC/NIH Manual, "Biosafety in Microbiological and Biomedical Laboratories," 2nd ed., 1988, HHS Publication No. (CDC) 88-8395

Do not use calibrators past their expiration date stated on each control container label.

Calibrators in this set contain <0.1% w/v sodium azide as a preservative. Sodium azide may form explosive compounds in metal drain lines. When disposing of calibrators through plumbing fixtures, flush with copious amounts of water. For further information, refer to "Decontamination of Laboratory Sink Drains to remove Azide Salts," in the Manual Guide Safety Management No. CDC-22 issued by the Centers for Disease Control, Atlanta, Georgia.

Do not pipette by mouth. Avoid ingestion and contact with skin.

Calibrator Preparation

The calibrators are ready to use and do not require reconstitution.

Storage and Handling

All calibrators should be stored refrigerated (2-8°C). Return all calibrators to 2-8°C promptly after use. Unopened calibrators can be used for one year from the date of manufacturing as indicated on the expiration date on the package and bottle labels.

Calibrator Stability

Discard calibrators if they become contaminated. Evidence of cloudiness or particulate material in solution is cause to discard. Once opened, the calibrator is stable for 1 month. Store at 2-8°C when not in use.

Instrument

Measurements of absorbance are to be made with a clinical chemistry analyzer able to accurately read absorbance at 570nm. Refer to the instrument manual from the manufacturer regarding the following:

- Use or function
- Installation procedures and requirements
- Principles of operation
- Performance characteristics, operating instructions
- Calibration procedures including materials and / or equipment to be used
- Operational precautions, limitations, and hazards
- Service and maintenance information

Procedure

Materials Supplied

Calibrators should be used as specified in the Pointe ASO assay package insert.

| | |
|--------------|----------|
| Calibrator A | 1 x 1 mL |
| Calibrator B | 1 x 1 mL |
| Calibrator C | 1 x 1 mL |
| Calibrator D | 1 x 1 mL |
| Calibrator E | 1 x 1 mL |

Materials Required But Not Supplied

Pointe Anti-streptolysin O (ASO) assay (A7567).

Two-reagent clinical chemistry analyzer capable of accurate absorbance reading at 570 nm, accurately dispensing the required volumes, and maintaining 37°C.

Details of Procedure

NOTE: Allow all reagents and specimens to come to room temperature. Mix all reagents gently before using.

The Pointe ASO Calibrator set is assayed using the same procedure as the patient test samples run in the test procedure. See the package insert for the Pointe ASO Reagent Set (A7567) for details.

A calibration curve is generated by assaying this series of calibrators with known concentrations of anti-streptolysin O. Concentrations of the patient samples are interpolated from the calibration curve.

Calibrator Values

Lot: 331802 Exp: 2024-09-30










| ASO Calibrator | Value (IU/mL) |
|----------------|---------------|
|----------------|---------------|





| | |
|--------------|-------|
| Calibrator A | 0 |
| Calibrator B | 125 |
| Calibrator C | 250 |
| Calibrator D | 500 |
| Calibrator E | 1,000 |




The ASO Calibrators have been standardized against the WHO (World Health Organization) NIBSC Anti-Streptolysin O standard material.

The expected values for the Pointe ASO Calibrators are continually being revised through ongoing quality control. As a result, the expected values may change from lot to lot. Please refer to this lot-specific package insert for the exact calibrator values.

Symbol Key

| | |
|---|---|
|  Use by (YYYY-MM-DD) |  Lot and batch code |
|  Catalog number |  Manufacturer |
|  <i>In vitro</i> diagnostic medical device |  Temperature limitation |
|  Consult instructions for use | Rx Only: Prescription Use Only |
|  CE mark |  Authorized representative in the European Community |

 A7567-CAL Manufactured for HORIBA Instruments Incorporated - Pointe Brand
5449 Research Drive Canton, MI 48188   2°C-8°C 

| | |
|---|---|
|  | Manufactured by Kamiya Biomedical Company 12779 Gateway Drive, Seattle, WA 98168 USA |
|  | Advena Ltd. Tower Business Centre, 2 nd Flr., Tower Street, Swatar, BKR 4013 Malta |
| |  |

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. 11/23

P803-A7567-02