

Intended Use

This Microalbumin Multi-Calibrator Set is intended to be used for the calibration of Pointe Microalbumin immunoturbidimetric assay for quantitating albumin in urine specimens. For *in vitro* diagnostic use. **Rx Only**

Summary

The calibrators in this kit contain known quantities of human albumin. There is also a calibrator containing only diluent (150 mM sodium chloride). These calibrators are to be used as calibrators with Pointe's Microalbumin immunoturbidimetric assay.

Kit Composition

Calibrator A:	150 mM Sodium Chloride	1x1ml
Calibrator B-F:	Human Albumin in 150 mM Sodium Chloride	5x1ml

Warnings and Precautions

- FOR IN VITRO DIAGNOSTIC USE.
- Not to be used internally in humans or animals. Normal precautions exercised in handling laboratory reagents should be followed.
- Albumin was isolated from pooled human serum which was tested and found negative for HbsAg and HIV-1 antibodies by an FDA approved method. However, all products that contain human source material should be treated in accordance with good laboratory practices and appropriate control. See the National Institute of Health Manual, "Biosafety in Microbiology and Biomedical Laboratories," 2nd ed., 1988.
- Do not mix or use calibrators from one kit with those from a different lot number.
- Do not use calibrators past the expiration date stated on each calibrator label.
- Do not pipette by mouth. Avoid ingestion and contact with skin.
- Calibrators in this kit contain 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.

Preparation

Calibrators are ready to use and do not require reconstitution.

Storage and Handling

Calibrators should be stored refrigerated (2-8°C). Return calibrators to 2-8°C promptly after use. Unopened calibrators can be used up to the expiration date on the package and bottle labels.

Stability

Discard calibrators if they become contaminated. Evidence of cloudiness or particulate material in solution is cause to discard.







Procedure




- Allow Microalbumin calibrators to come to room temperature.
- Mix all calibrators gently before using.
- Pipette the required amount of each calibrator serum into analyzer deliver cup; refer to instrument specific Application Guide and Pointe's Microalbumin Reagent package insert for detailed procedure.
- Calibrate the test system using Microalbumin Calibrator serum levels A through F to generate a six point calibration curve.

Calibrator Values

Refer to the vial label for each lot for the exact calibrator values.

Symbol Key

 Use by (YYYY-MM-DD)	LOT Lot and batch code
REF Catalog number	 Manufacturer
IVD <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

REF M7562-CAL  Manufactured by HORIBA Instruments Incorporated
5449 Research Drive, Canton, MI 48188   2°C-8°C **IVD**

Manufactured by HORIBA Instruments Incorporated: Pointe Brand
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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.

Rev. 07/22 P803-M7562-05