

Intended Use

Mission's Microalbumin Calibrator is intended for use as a urine chemistry calibrator for microalbumin assays run on Mission CA200* and Beckman AU680 analyzers in accordance with the instrument manufacturer's directions.

For Research Use Only. Site validation required for Lab Developed Test (LDT), 510K approval pending.

Summary

The use of specific calibrators is an established procedure for optimal performance of analyzer systems. The Mission Microalbumin Calibrator is a liquid product prepared from purified chemicals that have been specially formulated for the Mission Microalbumin assay.

Composition

Six concentration levels of human serum albumin in 150 mM sodium chloride with surfactant.

Warnings and Precautions

1. Not to be used internally in humans or animals. Normal precautions exercised in handling laboratory reagents should be followed.
2. 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.
3. Do not mix or use calibrators from one kit with those from a different lot number.
4. Do not use calibrators past the expiration date stated on each calibrator label.
5. Calibrators in this kit contain sodium azide as a preservative. Sodium azide may form explosive compounds in metal drain lines.

Instructions for Use

1. Allow Microalbumin Calibrators to come to room temperature.
2. Mix all calibrators gently before using.
3. Transfer the required amount of each calibrator into analyzer sample cup; refer to instrument specific guide and Mission's Microalbumin Reagent package insert for detailed procedure.
4. Calibrate the test system using Microalbumin Calibrator serum levels to generate a six-point calibration curve.

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.

Calibrator Values

Refer to the vial labels for the exact calibrator values.

* Also known as Zybio EXC200 Analyzer