

Intended Use

Mission's Glucose Calibrator is intended for use as a urine chemistry calibrator for glucose 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 and Explanation

The use of specific calibrators is an established procedure for optimal performance of analyzer systems. The Mission Glucose Calibrator is a ready-to-use liquid product prepared from chemicals that have been specially formulated for the Mission Glucose assay, MD-101110.

Principle Of Procedure

The Mission Glucose Calibrator is utilized by the analyst to set calibration of Mission CA200 Glucose assay in accordance with the instrument manufacturer's directions. Refer to the assay procedure and to the instrument manual for details.

Composition

Mission's Glucose Calibrator is a liquid formulation of synthetic glucose in a buffered media. Additives have been included to preserve the integrity of the product.

User Precautions

1. Not to be used internally. Normal precautions exercised in handling laboratory reagents should be followed.
2. Do not mix or use calibrator solutions from one bottle with previously opened bottles.
3. Do not use calibrators past the expiration date stated on each calibrator label.

Instructions For Use

1. The Mission Glucose Calibrator is a ready-to-use solution.
2. Proceed with sampling following the instructions of the assay procedure and as directed by the instrument manufacturer.
3. Store unused calibrator capped and refrigerated between 2-8°C.

Storage And Stability

The Mission Glucose Calibrator is stable until the expiration date when stored at 2-8°C.

Limitations

Erroneous results may occur from prolonged exposure of opened vial to ambient temperature and air.

Calibrator Value

MD-101210: 100 mg/dL Glucose

* Also known as Zybio EXC200 Analyzer