

Intended Use

The Mission β-Hydroxybutyrate Calibrator is intended for in vitro diagnostic use only in the calibration of Mission Diagnostics Affirm C200* and Beckman AU680 Analyzers in accordance with the instrument manufacturer's directions.

Summary and Explanation

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

Principle Of Procedure

The Mission β-Hydroxybutyrate Calibrator is utilized by the analyst to check calibration of Affirm C200 automated β-hydroxybutyrate assay in accordance with the instrument manufacturer's directions. Refer to the assay procedure and to the instrument manual for details.

Reagent

Mission β-Hydroxybutyrate Calibrator is a liquid formulation to which chemical constituents have been added to attain selected concentration levels. Additives are included to preserve the integrity of the product.

User Precaution

1. For in vitro diagnostics use.
2. Not to be used internally. Normal precautions exercised in handling laboratory reagents should be followed.
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. Do not pipette by mouth. Avoid ingestion and contact with skin.

Instructions For Use

Preparation of Calibrator 2: Combine 200 µL of Calibrator 3 and 800 µL distilled water in a tube. Mix well.

- 1) Bring Mission β-Hydroxybutyrate Calibrator to room temperature (18-26°C).
- 2) Proceed with sampling following the instructions of the assay procedure and as directed by the instrument manufacturer.
- 3) Store unused material, capped and refrigerated between 2-8°C, until additional samples are required.
- 4) Be sure to tightly cap vial prior to storage.

Storage And Stability

The product is stable through the expiration date stated on the vial labels. Prolonged exposure of an opened Calibrator vial to ambient air should be avoided. The Mission β-Hydroxybutyrate Calibrator should be capped and stored between 2-8°C. Once opened, product is stable for at least 30 days when treated and stored as directed.

Limitations

Erroneous results may occur from prolonged exposure of opened vial to ambient air and/or technical errors associated with instrumentation or reagents.

Expected Values

Calibrator 1: 0 mg/dl
Calibrator 2: 3 mg/dl
Calibrator 3: 15 mg/dl

* Also known as Zybio EXC200 Analyzer