

Intended Use

Mission's β-Hydroxybutyrate (BHB) Calibrator is intended for use as a urine chemistry calibrator for BHB 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 BHB Calibrator is a liquid product prepared from purified chemicals that have been specially formulated for the Mission BHB assay.

Principle Of Procedure

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

Composition

Mission's BHB 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. Not to be used internally. Normal precautions exercised in handling laboratory reagents should be followed.
2. Do not mix or use calibrators from one kit with those from a different lot number.
3. Do not use calibrators past the expiration date stated on each calibrator label.

Instructions For Use

1. Mission's BHB Calibrator is a 15 mg/dL solution in an eye-dropper bottle.
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

Storage And Stability

The Mission BHB Calibrator should be stored between 2-8°C. The product is stable through the expiration date stated on the vial labels.

Limitations

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

Calibrator Values

Calibrator 1: 0 mg/dL (deionized water, not provided)

Calibrator 2: 15 mg/dL

* Also known as Zybio EXC200 Analyzer

Distributed by: Mission Diagnostics LLC, 1 Burton Dr., Meredith, NH 03246

Manufactured by: Diamond Diagnostics Inc., 333 Fiske St., Holliston, MA 01746

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