

Intended Use

Mission's β-Hydroxybutyrate Linearity Standards are intended for verification of linearity (analytical measuring range) for β-hydroxybutyrate 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 linearity standards is an established procedure for verifying full range of performance for chemistry analyzer systems.

Composition

Mission β-Hydroxybutyrate Linearity Standards are 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 standards from one kit with those from a different lot number.
3. Do not use standards past the expiration date stated on each vial label.

Instructions For Use

1. Mission β-Hydroxybutyrate Linearity Standards are ready-to-use solutions in eye-dropper bottles.
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 β-Hydroxybutyrate Linearity Standards 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.

Linearity Standard Values

Standard 1: Refer to Vial Label, mg/dL

Standard 2: Refer to Vial Label, mg/dL

Standard 3: Refer to Vial Label, mg/dL

Standard 4: Refer to Vial Label, mg/dL

Standard 5: Refer to Vial Label, mg/dL

* Also known as Zybio EXC200 Analyzer