

Intended Use

Mission's Total (T.) Bilirubin Calibrator is intended for use as a urine chemistry calibrator for T. bilirubin 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 T. Bilirubin Calibrator is a protein-based liquid product specially formulated for the Mission T. Bilirubin assay.

Principle Of Procedure

The Mission T. Bilirubin Calibrator is used to set calibration of the Mission CA200 T. Bilirubin assay in accordance with the instrument manufacturer's directions. Refer to the assay procedures and to the instrument manual for details.

Composition

The product consists of high purity, ditaurine bilirubin conjugate stabilized in a bovine serum albumin matrix.

Instructions For Use

1. Ensure homogeneity of calibrator solution by gently mixing by inversions several times before opening.
2. Remove bottle cap and stopper.
3. Place required amount of solution in sample cup and place in analyzer.
4. Replace cap and stopper and store unused portion at 2-8°C.

Storage And Stability

Unopened T. Bilirubin calibrator is stable until the expiration date when stored at 2-8°C. Once opened the calibrator solution is stable for five days when stored at 2-8°C.

Our recommendation is to calibrate the bilirubin assay once every two weeks.

Limitations

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

Calibrator Values

T. Bilirubin Calibrator: 18.8 mg/dL

* Also known as Zybio EXC200 Analyzer