

Intended Use

Mission's Urobilinogen Calibrator is intended for use as a urine chemistry calibrator for urobilinogen 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 Urobilinogen Calibrator is a lyophilized product prepared from purified chemicals that have been specially formulated for the Mission Urobilinogen assay.

Principle Of Procedure

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

Composition

Mission's Urobilinogen Calibrator is formulated with synthetic urobilinogen and additives to preserve the integrity of the product. The formulation is then lyophilized to improve stability.

User Precautions

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. Store unopened calibrators at $-20\pm 10^{\circ}\text{C}$.
2. Bring one vial of calibrator to room temperature.
3. Add 1.0 mL deionized water to vial.
4. Cap and gently invert multiple times.
5. After 10 minutes, invert several more times and transfer the solution to a sample cup and place in analyzer.
6. Discard after use. Reconstituted solution is not stable beyond 5 hours at $2-8^{\circ}\text{C}$.

Storage And Stability

The lyophilized product is stable through the expiration date stated on the vial labels when stored at $-20\pm 10^{\circ}\text{C}$.

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

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

Calibrator 2: Refer to vial label, mg/dL

* Also known as Zybio EXC200 Analyzer