

Intended Use

Mission's Leukocyte Esterase Calibrator is intended for use as a urine chemistry calibrator for leukocyte esterase 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 Leukocyte Esterase Calibrator is a liquid product prepared from purified chemicals that have been specially formulated for the Mission Leukocyte Esterase assay.

Principle Of Procedure

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

Composition

Mission's Leukocyte Esterase Calibrator is a ready for use 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 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. Proceed with sampling following the instructions of the assay procedure and as directed by the instrument manufacturer.
2. Store unused material, capped and refrigerated between 2-8°C.

Storage And Stability

The Mission Leukocyte Esterase Calibrator should be stored between 2-8°C. The product is stable through the expiration date stated on the vial labels. 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 open vial to ambient air and/or technical errors associated with instrumentation or reagents.

Calibrator Values

Calibrator 1: 20 EAU/L (Enzyme Activity Units/L)

Calibrator 2: 50 EAU/L

Calibrator 3: 100 EAU/L

* Also known as Zybio EXC200 Analyzer