

Intended Use

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

Composition

Mission Leukocyte Esterase Linearity Standards are 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 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. 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 Linearity Standards 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.

Linearity Standard Values

- Standard 1: Refer to Vial Labels.
Standard 2: Refer to Vial Labels.
Standard 3: Refer to Vial Labels.
Standard 4: Refer to Vial Labels.
Standard 5: Refer to Vial Labels.

* Also known as Zybio EXC200 Analyzer