

Intended Use

Mission's Hemoglobin Calibrator is intended for use as a chemistry calibrator for hemoglobin assays 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 the Mission Hemoglobin Calibrator is an established procedure for optimal performance of the Mission CA200 analyzer. The Mission Hemoglobin Calibrator is a liquid product prepared from purified constituents specially formulated for the Mission Hemoglobin assay.

Procedure Principle

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

Composition

The Mission Hemoglobin Calibrator is a treated human serum-based preparation to which chemical constituents have been added to attain selected concentration levels. Additives are included to preserve the integrity of the product.

User Precautions

Human serum was used in the manufacture of this product. This product has been tested for the Anti-HCV 3, Anti-HIV-1/2, HBsAg, and STS (RPR) by test kits approved by the FDA. The treated serum was also found negative for HIV-1 and HCV by PCR. However, as no method can offer complete assurance as to the absence of infectious agents, handle this product with the same care as would be exercised with any patient sample.

Do not mix or use calibrators from one kit with those from a different lot number. Do not use calibrators past the expiration date stated on each calibrator label.

Instructions For Use

1. Mission Hemoglobin Calibrators are ready to use solutions in eye-dropper bottles.
2. Place 5 to 7 drops of each calibrator in sample cups and place in analyzer.

Storage And Stability

The product is stable through the expiration date stated on the vial label when stored at 2-8°C. Once opened, product is stable for at least 30 days stored at 2-8°C and capped while not in use.

Limitations

Erroneous results may occur from prolonged exposure of calibrator solutions to ambient temperatures and/or technical errors associated with instrumentation or reagents.

Expected Values

Calibrator 1: 0 mg/dL (deionized water)

Calibrator 2: 2.45 mg/dL

Calibrator 3: 25 mg/dL

* Also known as Zybio EXC200 Analyzer