

### Intended Use

The Mission Hemoglobin Calibrator is intended for in vitro diagnostic use only in the calibration of Mission Diagnostics Affirm C200\* and Beckman AU680 Analyzers in accordance with the instrument manufacturer's directions.

### Summary And Explanation

The use of a Mission Hemoglobin Calibrator is an established procedure for optimal performance of Affirm C200 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 check calibration of Affirm C200 automated hemoglobin assay in accordance with the instrument manufacturer's directions. Refer to the assay procedure and to the instrument manual for details.

### Reagent

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.

Each liter contains: 0.025 g Human hemoglobin and non-reactive ingredients.

### User precaution

The treated serum-based control 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 human blood sample. Not to be used internally.

Normal precautions exercised in handling laboratory reagents should be followed. 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.

Do not pipette by mouth. Avoid ingestion and contact with skin.

### Instructions For Use

- 1) Bring the Mission Hemoglobin Calibrator to room temperature (18-26°C).
- 2) Proceed with sampling following the instructions of the assay procedure and as directed by instrument manufacturer.
- 3) Store unused material, refrigerated between 2-8°C, until additional samples are required.
- 4) Be sure to tightly cap vial prior to storage.

### 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. Prolonged exposure of an opened Calibrator vial to ambient air should be avoided.

### Limitations

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

### Expected Values

Calibrator 1: 0 mg/dl

Calibrator 2: 1 mg/dl

Calibrator 3: 5 mg/dl

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\* Also known as Zybio EXC200 Analyzer