

Intended Use

Mission's Hemoglobin Linearity Standards are intended for verification of linearity (analytical measuring range) for hemoglobin 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 full reportable range of performance for chemistry analyzer systems.

Composition

The Mission Hemoglobin Linearity Standards are 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 standards from one kit with those from a different lot number. Do not use standards past the expiration date stated on each vial label.

Instructions For Use

1. Mission Hemoglobin Linearity Standards are ready-to-use solutions in eye-dropper bottles.
2. Place 5 to 7 drops of each standard 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.

Linearity Standard Values

Standard 1: Refer to Vial Label, mg/dL

Standard 2: Refer to Vial Label, mg/dL

Standard 3: Refer to Vial Label, mg/dL

Standard 4: Refer to Vial Label, mg/dL

Standard 5: Refer to Vial Label, mg/dL

* Also known as Zybio EXC200 Analyzer