

Intended use

Mission Bilirubin Calibrator is intended for use as a urine chemistry calibrator for methods run on Mission Diagnostics Affirm C200* and Beckman AU680 Analyzers in accordance with the instrument manufacturer's directions.

Summary and Explanation

The use of specific calibrators is an established procedure for optimal performance of analyzer systems. The Mission Bilirubin Calibrator is a lyophilized product prepared from chemicals that have been specially formulated for the Mission urine Total Bilirubin assay.

Principle Of Procedure

The Mission Bilirubin Calibrator is utilized by the analyst to check calibration of Affirm C200 automated Total Bilirubin assay in accordance with the instrument manufacturer's directions. Refer to the assay procedure and to the instrument manual for details.

Reagent

The product consists of lyophilized human material and a diluent for reconstitution. The lyophilate contains additives to provide the defined assay values.

User Precaution

For in vitro diagnostic use only. Human serum was used in the manufacture of this product. Each donor unit was tested for antibodies to HIV1/2, HCV and found to be non-reactive for HBsAg and HIV-1Ag by FDA accepted test methods. Because no test method can offer complete assurance that products derived from blood will not transmit infectious agents, it is recommended that this product be handled with the same precautions used for patient specimens. In the event of exposure, the directives of the responsible health authorities should be followed. Disposal of all waste material should be in accordance with local guidelines.

Instructions For Use

Carefully open one bottle, avoiding the loss of lyophilate. Using a volumetric pipette, add exactly 5.0 ml of diluent to the lyophilized serum.

Gently invert the vial intermittently over a period of 20 minutes to ensure complete dissolution of contents. Immediately prior to use, gently invert the vial 5 – 10 times.

Preparation of Calibrator 1: Combine 100 µL of reconstituted lyophilate (Calibrator 2) and 400 µL diluent in a tube. Mix well.

Storage And Stability

Unreconstituted chemistry calibrator is stable until the expiration date when stored at -20°C. Reconstituted Bilirubin calibrator is stable for 24 hours when stored at 2-8°C. Store calibrator tightly capped and protected from light when 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 opened vial to ambient air and/or technical errors associated with instrumentation or reagents.

Expected Values

Calibrator 1: 1 mg/dL

Calibrator 2: 5 mg/dL

* Also known as Zybio EXC200 Analyzer