

FIB Calibrator

ASSAYED FIBRINOGEN REFERENCE PLASMA



SUMMARY

FIB Calibrator is intended for use as a normal reference standard for routine fibrinogen quantitation on citrated plasma.

PRINCIPLE OF THE PROCEDURE

FIB Calibrator may be used in all testing in the same manner as any citrated plasma sample. **FIB Calibrator** may be used to generate a standard reference curve for fibrinogen determination or as a quality control check for stored reference curves in daily fibrinogen testing.

REAGENT

FOR IN-VITRO DIAGNOSTIC USE ONLY

Ingredients: **FIB Calibrator** is prepared from a pool of fresh citrated plasma from people with normal coagulation parameters. The pooled plasma is buffered and lyophilized to maximize stability of all plasma constituents.

Packaged as 10 x 1 mL vials **FIB Calibrator**

WARNING: Potential Biohazard: **FIB Calibrator** has been found negative for Hepatitis B Antigen (HBsAg) and antibodies to HCV and HIV by FDA licensed tests. However, the control should be handled with the same precautions as those observed when handling potentially infectious patient plasmas.

Preparation for Use: **FIB Calibrator** should be reconstituted with 1.0 mL of deionized or distilled water. Swirl gently; do not shake. Allow control to stand for 15 minutes at room temperature to insure complete dissolution before use.

Storage and Stability: The lyophilized **FIB Calibrator** is stable until the expiration date printed on the vial when stored at 2 to 8°C. After reconstitution, the control is stable for 8 hours stored at 2 to 8°C. Keep covered.

INSTRUMENTS

FIB Calibrator may be used as a reference when performing tests on any mechanical or photo-optical coagulation instrument in conjunction with suitable commercial reagents.

PROCEDURE

FIB Calibrator is treated in the same manner as the reference standard in accordance with the instructions outlined in the procedures used by each laboratory.

LIMITATIONS

Although **FIB Calibrator** is a normal reference plasma, the times or results obtained on testing should not be used as a reference range for a particular patient population. Reference range is a function of individual populations. Each institution should determine its own reference range on a statistically valid sample of its patient population. The results obtained with **FIB Calibrator** depend on several factors associated with instrumentation, types of reagents and laboratory-to-laboratory variation.

REFERENCE VALUES AND PERFORMANCE CHARACTERISTICS

Fibrinogen values are stated as a mean value. For best results, laboratories should establish the mean values and expected reference ranges for their particular laboratory's instrument-reagent system. The fibrinogen value for each lot is found on the vial label between the lot number and the expiration date.

