Certificate of Analysis

Moderate Factor VIII Inhibitor Plasma (Frozen)
(Art.no. F8-INH1F)

Lot / Exp.: XXXXXX / XXXX-XX

Preparation: Normal citrated human plasma depleted of Factor VIII using antibodies directed to FVIII immobilized on agarose beads. A polyclonal antibody inhibitory to FVIII has been added to provide FVIII neutralizing activity. Plasma contains 20 mM HEPES.

Storage: Frozen plasma should be stored at or below -60°C.

Once thawed plasma is stable for 4 hours at 2-8°C in original vial.

Presentation: Frozen, 1 mL FVIII inhibitor plasma.

Preparation: Thaw 1 mL vials in 37˚C waterbath for 5 minutes; for bulk volumes, thawing time will be dependent on bottle size.

Specifications: Assay results:

PT (Thrombophen, Hyphen BioMed)	14.0 sec
APTT (Cephen, Hyphen BioMed)	83.5 sec
Fibrinogen (clottable)	2.77 g/L
FVIII (activity)	< 0.01 U/mL
FVIII Inhibitor activity (Chromogenic Bethesda assay)*	Mean: 6.78 BU/mL Range: 4.96 - 8.60 BU/mL
FVIII Inhibitor activity (One stage Clotting Bethesda assay)*	Mean: 6.01 BU/mL Range: 4.92 - 7.10 BU/mL

*Bethesda assay performed at a 1/7 dilution, then mixed with an equal volume of normal plasma and incubated at 37°C for 120 minutes.

The FVIII activity was measured by one stage clotting (OSCA) and chromogenic assay. The residual FVIII activity was calculated as a percentage activity compared to a buffer control run in parallel in each assay. The residual FVIII activity is converted to Bethesda units using the Bethesda chart or graph. The Bethesda value derived (BU/mL) is multiplied by the initial dilution of the sample to obtain the corrected inhibitor concentration. Mean and Range (Mean +/- 2SD) in each assay are reported. The results for the OSCA mean value determines the type of inhibitor (mild, moderate, or severe).

The plasma contains stabilizers and HEPES. Although this material was prepared with plasma collected from donors screened for CJD and which was tested at source and found negative for HBsAG, syphilis and antibodies to HIV, HCV and non-reactive for HIV-1 rNA and HCV rNA by FDA approved tests, it should be handled by personnel trained in the proper procedure for handling potential viral contaminants.

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