

Certificate of Analysis

Product: Human Factor VIII Inhibitor Plasma, Severe, Lyophilized

Reference Number: 5D-49119L

Lot Number: 546349

Expiration Date: 2028-09

Preparation: Normal citrated human plasma depleted of Factor VIII using antibodies directed to Factor VIII immobilized on agarose beads. A polyclonal antibody inhibitory to Factor VIII has been added to provide Factor VIII neutralizing activity. Plasma contains 50 mM HEPES and stabilizers.

Storage: Prior to reconstitution, dried plasma should be stored at 2-8°C.

Presentation: Each vial lyophilized from 1 mL FVIII inhibitor plasma.

Reconstitution: Reconstitute one vial with 1 mL of reagent grade water. Allow contents to dissolve for 15 minutes at room temperature with occasional swirling. Stability after reconstitution is 4 hours at ambient (18-25°C), or 30 days at -20°C.

Specifications: Lot specific assay results:

PT	17.1 sec
APTT	95.5 sec
Fibrinogen (clottable)	2.23 g/L
FVIII (activity)	<0.01 U/mL
FVIII Inhibitor activity (Bethesda assay)*	66.7 BU/mL

*Bethesda assay performed at a 1/70 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 of clotting assay and the residual FVIII activity was calculated as a percentage activity compared to a buffer control run in parallel. The residual FVIII activity is converted to Bethesda units using the Bethesda chart. The Bethesda value derived (BU/mL) is multiplied by the initial dilution of the sample to obtain the corrected inhibitor concentration

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 and 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 procedures for handling potential viral contaminants.

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