# Certificate of Analysis

**Severe Factor VIII Inhibitor Plasma (Lyophilized)**
(Art.no. F8-INH3)

**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 50 mM HEPES and stabilizers

**Storage:** Lyophilized plasma should be stored at 2-8°C.

Stability after reconstitution: 8 hours at room temperature (18-25°C) or 2 months frozen at -20°C or below in its original vial or in a plastic tube (before use, thaw in a water bath at 37°C for at least 15 minutes).

**Presentation:** Lyophilized, 1 mL FVIII inhibitor plasma.

**Reconstitution:** Reconstitute the vial with 1 mL of distilled water; mix gently until complete dissolution of the content (vortex), let for 15 minutes at room temperature (18-25°C); homogenize before each use.

**Specifications:** Assay results:

| | |
|---|---|
| PT (Thrombophen, Hyphen BioMed) | 13.9 sec |
| APTT (Cephen, Hyphen BioMed) | 99.1 sec |
| Fibrinogen (clottable) | 2.23 g/L |
| FVIII (activity) | < 0.01 U/mL |
| FVIII Inhibitor activity (Bethesda assay)* | 58.0 BU/mL |

*Bethesda assay performed at a 1/60 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.

The lyophilized 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.

For Research Use Only. Not for Use in Diagnostic Procedures.

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