



RayBiotech, Inc.

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Certificate of Analysis and Data Sheet

Native Human Coagulation Factor VIII

Catalog No.
228-10437

Source:
Human Plasma

Synonyms:

Coagulation factor VIII, Procoagulant component, Antihemophilic factor, AHF, F8, F8C, F8B, HEMA, FVIII, DXS1253E, F8 protein.

Introduction:

Coagulation factor VIII participates in the intrinsic pathway of blood coagulation; factor VIII is a cofactor for factor IXa which, in the presence of Ca^{+2} and phospholipids, converts factor X to the activated form Xa. This gene produces two alternatively spliced transcripts. Transcript variant 1 encodes a large glycoprotein, isoform a, which circulates in plasma and associates with von Willebrand factor in a noncovalent complex. This protein undergoes multiple cleavage events. Transcript variant 2 encodes a putative small protein, isoform b, which consists primarily of the phospholipid binding domain of factor VIIIc. This binding domain is essential for coagulant activity. Defects in this gene results in hemophilia A, a common recessive X-linked coagulation disorder.

Description:

Human Factor VIII produced from Human Plasma is effective in the correction and prevention of severe bleeding episodes attributed to Factor VIII deficiency.

The Factor-VIII is purified by proprietary chromatographic techniques.

Physical Appearance:

Sterile Filtered White lyophilized (freeze-dried) powder.

Formulation:

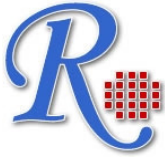
The lyophilized protein 200IU/ml was lyophilized from a sterile solution containing 1.5% Glycine, 160mM Calcium chloride and 25mM NaCitrate and 25mM NaCl.

Solubility:

It is recommended to reconstitute the lyophilized Factor-VIII in sterile 18M Ω -cm H₂O at a concentration of 200IU/ml, which can then be further diluted to other aqueous solutions.

Make sure that the vial has reached room temperature prior to its reconstitution, otherwise it might precipitate.

The products are furnished for LABORATORY RESEARCH USE ONLY.
Not for diagnostic or therapeutic use.



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Stability:

Lyophilized Factor-VIII although stable at room temperature for 1 week, should be stored desiccated between 2-8°C. Upon reconstitution Factor-VIII should be stored at 4°C.

Biological Activity:

The potency per mg was tested and found to be 150 Units/mg.

Human Virus Test:

The plasma is collected from donors with Hepatitis B vaccinated.
Each unit of plasma has been tested for HBsAg, Anti-HIV-1/2 plus O and Anti-HCV by using the imported kits which are approved by Federal Drug Administration (FDA).

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