

RayBiotech, Inc.

3607 Parkway Lane suite 100 Norcross, GA 30092 Tel: 770-729-2992, 1-888-494-8555

Fax: 770-206-2393

Website: www.raybiotech.com Email: info@raybiotech.com

Certificate of Analysis and Data Sheet

Recombinant Human Coagulation Factor VIII

Catalog No. Source:

228-10436 CHO cells (Chinese Hamster Ovarian Cells)

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

Antihemophilic Factor Human Recombinant produced in CHO is a glycosylated polypeptide chain having a total amino acids of 1438 (170kd) and consisting of two dimer chains 80 kD and 90 kD. The Factor-VIII is purified by proprietary chromatographic techniques.

Physical Appearance

Sterile Filtered White lyophilized (freeze-dried) powder.

Formulation

The protein was lyophilized from a solution containing 50mM histidine, 0.3M NaCl, 5mM CaCl2, 0.02% Tween 80, 20mM sucrose, pH- 6.8.

Solubility

It is recommended to reconstitute the lyophilized Factor-VIII in 1ml sterile 18M Ω -cm H2O, which can then be further diluted to other aqueous solutions.



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Stability

Lyophilized Factor-VIII although stable at room temperature for 3 weeks, should be stored desiccated below -18°C. Upon reconstitution Factor-VIII should be stored at 4°C between 2-7 days and for future use below -18°C.

Please prevent freeze-thaw cycles.

Purity

Greater than 97.0% as determined by SDS-PAGE.

Biological Activity

The specific activity was found to be 7428IU/mg.