

Human Antihemophilic Factor IX

Certificate of Analysis and Data Sheet

➤ Source: Human Plasma	➤ Catalog No. PRO-353
----------------------------------	---------------------------------

➤ **Description :**

Human Factor IX is a glycoprotein, which is synthesized in the liver (1-3). The domain structure of factor IX is similar to that of the other vitamin K dependent coagulation factors. The NH₂-terminal region contains 12 γ-carboxyglutamic acid (gla) residues, which facilitate the calcium dependent binding of factor IX to negatively charged phospholipid surfaces. Two domains which are homologous to epidermal growth factor (EGF) span the region between the NH₂-terminal gla domain and the activation peptide (Ala-146 to Arg-180). Factor IX is activated by either factor XIa or the factor VIIa/tissue factor/phospholipid complex. Cleavage at site A yields the intermediate IXa, which is subsequently converted to the fully active form IXab by cleavage at site B. The NH₂-terminal light chain (GLA and EGF domains) remains covalently attached to the COOH-terminal heavy chain by a disulfide bond. The serine protease catalytic triad (Ser-365, His 221, Asp-269) is located in the heavy chain. Factor IXab is the catalytic component of the "intrinsic factor Xase complex" (factor VIIa/IXa/Ca²⁺/phospholipid) which proteolytically activates factor X to factor Xa.

Factor-IX is purified by proprietary chromatographic techniques

➤ **Physical Appearance:**

Sterile Filtered White Lyophilized (freeze-dried) powder.

➤ **Formulation:**

Factor-IX, at a concentration of 400IU/ml, was lyophilized from a sterile solution containing 10ppm TNBP, 100ppm Polysorbate 80, 500ppm PEG, 1.5% Glycine, 160mM Sodium chloride and 25mM Citrate.

➤ **Solubility:**

It is recommended to reconstitute the lyophilized Factor-IX in sterile 18MO-cm H₂O not less than 100µg/ml, which can then be further diluted to other aqueous solutions.

➤ **Stability:**

Lyophilized Factor-IX although stable at room temperature for 3 weeks, should be stored desiccated below -18 C. For long term storage it is recommended to add a carrier protein (0.1% HSA or BSA).

Please avoid freeze-thaw cycles.

➤ **Purity:**

Greater than 98.0% as determined by:

(a) Analysis by RP-HPLC.

(b) Anion-exchange FPLC.

(c) Analysis by reducing and non-reducing SDS-PAGE Silver Stained gel.

➤ **Dimers and aggregates:**

Less than 1% as determined by silver-stained SDS-PAGE gel analysis.

➤ **Biological Activity:**

This Factor-IX is fully biologically active when compared to standard. The potency per mg was tested and found to be 167 Units/mg.

➤ **Endotoxin:**

Less than 0.1 ng/μg (IEU/μg) of Factor-IX.

➤ **Usage:**

This material is offered for research, laboratory or further evaluation purposes.