

Global Coagulation Factor IX (Human) Market Growth 2026-2032

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Abstracts

The global Coagulation Factor IX (Human) market size is predicted to grow from US\$ 326 million in 2025 to US\$ 444 million in 2032; it is expected to grow at a CAGR of 4.5% from 2026 to 2032.

Coagulation Factor IX (Human) is a single-factor plasma-derived blood product manufactured by isolating and purifying factor IX from qualified human plasma, followed by validated viral inactivation or removal processes. It is generally supplied as a white or off-white lyophilized powder and reconstituted into a clear or slightly opalescent solution for intravenous infusion. The active ingredient is human coagulation factor IX, with stabilizers, buffer salts, and other formulation excipients as applicable, and potency is expressed in international units. The product belongs to plasma protein products, antihemorrhagic agents, and coagulation factor replacement therapies. Its key technical requirements include traceable plasma sourcing, protein purification, viral safety control, sterility assurance, lyophilized stability, potency testing, impurity control, and thrombogenicity-related quality control. Mechanistically, Coagulation Factor IX (Human) replaces deficient or missing factor IX in patients and, after activation within the coagulation cascade, participates in factor X activation, thrombin generation, and fibrin clot formation. It is mainly used for the treatment, prevention, and perioperative management of bleeding associated with hemophilia B or factor IX deficiency, subject to the approved label in each jurisdiction.

Market opportunities are mainly supported by the essential treatment needs of hemophilia B patients, improved access to rare disease medicines, broader reimbursement, hospital stockpiling demand, and better utilization of plasma fractions. Although Coagulation Factor IX (Human) serves a small patient population, acute bleeding control, perioperative hemostasis, and selected prophylaxis settings require

reliable supply, giving the product resilient demand and strong clinical necessity. For plasma-product manufacturers, it improves the value extracted from coagulation-related plasma fractions and strengthens portfolio synergy with albumin, immunoglobulin, prothrombin complex concentrates, and other hemostatic products. Markets such as China still have room for better clinical access and domestic substitution.

The main challenges are constrained plasma supply, complex manufacturing, strict quality supervision, high batch-consistency requirements, and the direct impact of viral safety, sterility assurance, and thrombogenicity control on product approval and clinical confidence. The product is not being banned or phased out, but traditional plasma-derived preparations face substitution pressure in premium long-term prophylaxis markets. Recombinant factor products, extended half-life recombinant products, non-factor subcutaneous therapies, and gene therapies may divert some patients, especially in markets with strong reimbursement and mature home-treatment systems. As a result, Coagulation Factor IX (Human) will increasingly be positioned around supply security, emergency bleeding control, perioperative management, cost-sensitive markets, and selected replacement-therapy use cases.

Downstream demand is evolving from purely on-demand hemostasis toward a structure combining standardized diagnosis, hospital reserves, perioperative management, and selected long-term prophylaxis. Mature markets focus more on safety records, infusion convenience, real-world effectiveness, and the long-term value of alternative therapies, while emerging markets emphasize supply stability, reimbursement coverage, hospital procurement, and basic treatment availability. Future procurement will place greater weight on cost per unit of potency, batch quality stability, plasma-resource capability, viral safety systems, and continuous supply reliability. Overall, the product is unlikely to disappear quickly, but market growth will be steady rather than high-growth, with competition shifting toward quality, safety, price, and supply-chain strength.

LP Information, Inc. (LPI) ' newest research report, the "Coagulation Factor IX (Human) Industry Forecast" looks at past sales and reviews total world Coagulation Factor IX (Human) sales in 2025, providing a comprehensive analysis by region and market sector of projected Coagulation Factor IX (Human) sales for 2026 through 2032. With Coagulation Factor IX (Human) sales broken down by region, market sector and sub-sector, this report provides a detailed analysis in US\$ millions of the world Coagulation Factor IX (Human) industry.

This Insight Report provides a comprehensive analysis of the global Coagulation Factor

IX (Human) landscape and highlights key trends related to product segmentation, company formation, revenue, and market share, latest development, and M&A activity. This report also analyzes the strategies of leading global companies with a focus on Coagulation Factor IX (Human) portfolios and capabilities, market entry strategies, market positions, and geographic footprints, to better understand these firms' unique position in an accelerating global Coagulation Factor IX (Human) market.

This Insight Report evaluates the key market trends, drivers, and affecting factors shaping the global outlook for Coagulation Factor IX (Human) and breaks down the forecast by Type, by Application, geography, and market size to highlight emerging pockets of opportunity. With a transparent methodology based on hundreds of bottom-up qualitative and quantitative market inputs, this study forecast offers a highly nuanced view of the current state and future trajectory in the global Coagulation Factor IX (Human).

This report presents a comprehensive overview, market shares, and growth opportunities of Coagulation Factor IX (Human) market by product type, application, key manufacturers and key regions and countries.

Segmentation by Type:

High-Purity Coagulation Factor IX (Human)

Intermediate-Purity Coagulation Factor IX (Human)

Others

Segmentation by Dosage Form:

Lyophilized Powder for Solution for Injection

Liquid Solution for Injection

Others

Segmentation by Vial Strength:

250 IU and Below

Above 250 IU to 500 IU

Above 500 IU to 1000 IU

Above 1000 IU

Segmentation by Viral Safety Processing Route:

Solvent-Detergent Treated Products

Virus-Filtered Products

Heat-Treated or Pasteurized Products

Multi-Step Viral Inactivation and Removal Products

Segmentation by Application:

Hospital

Personal Clinic

Others

This report also splits the market by region:

Americas

United States

Canada

Mexico

Brazil

APAC

China

Japan

Korea

Southeast Asia

India

Australia

Europe

Germany

France

UK

Italy

Russia

Middle East & Africa

Egypt

South Africa

Israel

Turkey

GCC Countries

The below companies that are profiled have been selected based on inputs gathered from primary experts and analysing the company's coverage, product portfolio, its market penetration.

CSL Behring

Takeda

Grifols Biologicals

Octapharma

Kedrion

Bio Products Laboratory

LFB

Biotest

KM Biologics

Intas Pharmaceuticals

Shandong Taibang Biological Products

Sichuan Yuanda Shuyang Pharmaceutical

Key Questions Addressed in this Report

What is the 10-year outlook for the global Coagulation Factor IX (Human) market?

What factors are driving Coagulation Factor IX (Human) market growth, globally and by region?

Which technologies are poised for the fastest growth by market and region?

How do Coagulation Factor IX (Human) market opportunities vary by end market size?

How does Coagulation Factor IX (Human) break out by Type, by Application?

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