

— FACTOR IX · CHRISTMAS FACTOR · HAEMOPHILIA B · ACTIVITY & ANTIGEN

Factor IX — *three methods*, one complete panel.

Factor IX deficiency causes **haemophilia B**. Its measurement spans **diagnosis and severity grading**, **FIX concentrate and extended half-life / gene-therapy product potency**, and the well-documented **one-stage vs chromogenic discrepancies** seen in non-severe haemophilia B and with modified products. Measure it by **chromogenic activity**, **one-stage clotting**, or **antigen ELISA** — pairing activity with antigen resolves quantitative (type I) from qualitative (type II) defects — all backed by matched calibration and QC.

THREE MEASUREMENT METHODS

CHROMOGENIC · ACTIVITY

BIOPHEN™ Factor IX

Two-stage assay: **FXIa** activates the sample's FIX → FIXa, which with **FVIIIa**, **phospholipid** and **Ca²⁺** generates FXa, read on a chromogenic substrate. Human-protein design; robust for **concentrates & EHL products**. 2x2.5 mL.

A221802

RUO · CE-IVD

\$593

CLOTTING · ONE-STAGE

FIX:C — Deficient Plasma

Classic **aPTT-based one-stage** FIX:C assay, run on **Factor IX Deficient Plasma** (<1% residual) as substrate. Pairs with a CEPHEN™ APTT reagent on standard analyzers.

ADP050K · 6x1 mL

RUO

\$385

ANTIGEN · ELISA

ZYMUTEST™ Factor IX

Two-site immunoassay for **FIX antigen** in citrated plasma — quantifies protein independent of activity, to classify a deficiency. Kit of 96 tests.

ARK032A

RUO

\$768

CALIBRATED & CONTROLLED — EVERY METHOD, MATCHED

REFERENCE CALIBRATOR & QC PLASMAS

BIOPHEN™ Plasma Calibrator

18-analyte reference plasma; assigns FIX and calibrates both clotting & chromogenic. **A222101**

The ZYMUTEST™ FIX ELISA includes its own antigen calibrator and controls.

Normal Control Plasma

Normal-range QC across factor activities · 12x1 mL. **A223201**

Abnormal Control Plasma

Pathological-range QC, covering FVII-X. **A223301**

WHERE FACTOR IX IS MEASURED

Haemophilia B (Christmas disease)

Severity grading

FIX concentrate potency

Extended half-life / rFIXFc

Gene-therapy FIX monitoring

Carrier & family studies

SELECTED REFERENCES The BIOPHEN™ FVIII and FIX chromogenic assays (two-stage, human proteins) used for potency assignment of plasma-derived and recombinant long-acting concentrates — Samama et al. (HYPHEN BioMed). · BIOPHEN™ Factor IX (A221802) used to determine recombinant FIX-Fc fusion-protein activity — US Pat. 11,472,863. · One-stage vs chromogenic FIX discrepancies in non-severe haemophilia B, with lower interlaboratory variability for chromogenic methods — *Int. J. Lab. Hematol.* 2020 / 2024.

Regulatory: BIOPHEN™ Factor IX (A221802) is **For Research Use Only** in the United States and **CE-IVD** in Europe; ZYMUTEST™ Factor IX (ARK032A) and Factor IX Deficient Plasma (ADP050K) are **For Research Use Only**. The BIOPHEN™ Plasma Calibrator (A222101) and Normal / Abnormal Control Plasmas (A223201 / A223301) are RUO (US), CE-IVD (EU) and **Health Canada** licensed (-CAN configurations). Activity (chromogenic, clotting) and antigen (ELISA) methods measure different properties and are not interchangeable. Pricing shown is US list and subject to change. © 2026 Aniara Diagnostica, Inc.