ANIARA
DIAGNOSTICA INC

YOUR LAB DESERVES A PARTNER.
Not a vendor.

— FACTOR VIII ACTIVITY · CHROMOGENIC & CLOTTING · EMICIZUMAB-INSENSITIVE MEASUREMENT

Measure FVIII activity — *even when emicizumab is present.*

Emicizumab mimics activated FVIII and distorts standard FVIII assays. The bovine-FX **BIOPHEN™ FVIII Variant** is insensitive to emicizumab — it reads **endogenous or infused FVIII** in the sample; the human-reagent **FVIII:C** is the routine assay and the one that **measures emicizumab**; a **one-stage clotting** method completes the panel — all backed by matched calibration and QC.

FEATURED · EMICIZUMAB-INSENSITIVE

BIOPHEN™ FVIII Variant

A227102
$461
RUO (US) · CE-IVD (EU)

Bovine Factor X · insensitive to emicizumab

- Chromogenic FVIII:C on **bovine Factor X** — emicizumab does not react with bovine FX, so the assay reads only the sample's FVIII.
- Complete kit — R1 bovine FX, R2 activation reagent, R3 SXa-11 substrate, R4 buffer.
- Quantifies **endogenous or infused FVIII** separately from emicizumab — plasma or concentrates, automated.
- For **FVIII deficiency** & factor-replacement testing (except emicizumab).

STANDARD METHODS — ACTIVITY BY CHROMOGENIC OR CLOTTING

CHROMOGENIC · HUMAN REAGENTS

BIOPHEN™ FVIII:C

Routine chromogenic FVIII:C for **plasma & concentrates**, two working ranges. Human FIXa/FX — validated to **measure emicizumab** FVIII-like activity. **2×2.5 mL** (A221402) · **2×6 mL** (A221406).

A221402 / A221406
RUO · CE-IVD · HCL
$549–965

CLOTTING · ONE-STAGE (APTT)

FVIII:C — Deficient Plasma

Classic **one-stage APTT-based** FVIII:C, run on **FVIII:C Deficient Plasma with VWF** (<1% residual) as substrate. **Oversensitive when emicizumab is present — use the Variant instead.**

ADP040K · 6×1 mL
RUO · CE-IVD · HCL
$385

CALIBRATED & CONTROLLED — EVERY METHOD, MATCHED

REFERENCE CALIBRATOR & QC PLASMAS

BIOPHEN™ Plasma Calibrator
18-analyte reference plasma; assigns FVIII and calibrates both clotting & chromogenic. **A222101**

Normal Control Plasma
Normal-range QC across factor activities · 12×1 mL. **A223201**

Abnormal Control Plasma
Pathological-range QC plasma. **A223301**

The chromogenic FVIII Variant and FVIII:C kits contain their working reagents; activity is assigned against the Plasma Calibrator above.

Complete the workup — ZYMUTEST™ Anti-FVIII IgG · inhibitor ELISA (ARK039A)

SELECTED REFERENCES BIOPHEN™ FVIII:C (human factors) used for FVIII/emicizumab pharmacodynamics in the pivotal **HAVEN 1** trial — *Res. Pract. Thromb. Haemost.* (PMC7895541). · One-stage vs bovine- vs human-chromogenic (BIOPHEN FVIII:C) in emicizumab-treated patients — *Blood* 2021;138(Suppl 1):4234. · Analytical performance & diagnostic accuracy of BIOPHEN™ FVIII:C in haemophilia A — Novembrino et al., *Int. J. Lab. Hematol.* 2019.

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SEARCH "FVIII VARIANT" · OR ASK YOUR ANIARA REP

HYPHEN BioMed Aniara Diagnostica, Inc. is a distributor for HYPHEN BioMed