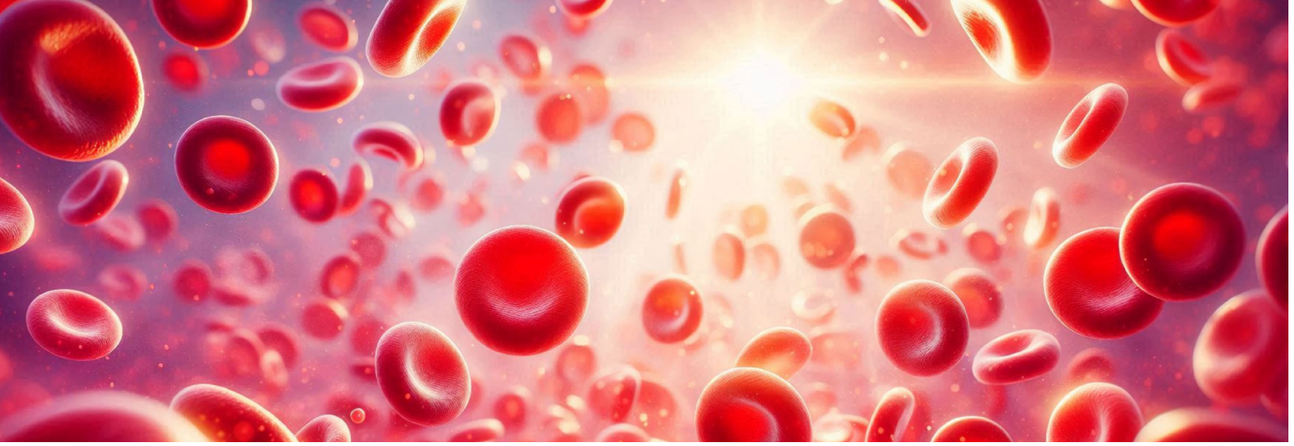

Improved CRYOcheck™ Chromogenic Factor VIII

Evolving Haemophilia Treatments: Why Laboratories Need Interference Free FVIII Testing

Angel Sumajit, Product Manager, Alpha Laboratories Ltd.

Haemophilia A is caused by a deficiency of factor VIII (FVIII), resulting in prolonged or spontaneous bleeding. With no cure currently available, patients rely on lifelong prophylaxis to prevent potentially life threatening haemorrhages.

For decades, management has centred on intravenous FVIII replacement three to four times per week. While effective, this regimen is demanding particularly for individuals with FVIII inhibitors, rendering standard treatment ineffective. The emergence of novel non-factor replacement therapies has reshaped the clinical landscape. Today, these innovations are transforming not only how haemophilia is treated but also how laboratories need to test.

The Rise of Bispecific Antibodies (bsAbs)

FVIII is essential for normal blood clot formation, acting as a cofactor for FIXa to activate FX and drive fibrin generation. Two FVIII-mimetic bispecific antibodies that target the FIXa-FX interaction, are reshaping haemophilia A management.

Emicizumab restores haemostasis by bridging FIXa and FX without the need for FVIII. Given subcutaneously, it substantially reduces treatment burden and is effective in patients with or without inhibitors. Mim8, a newer FVIII mimetic, is designed to further enhance thrombin generation and offers an emerging al ternative for prophylaxis.

Together, these therapies improve access to effective, low-burden prophylaxis and reduce the need for infusions. However, because they mimic FVIII, they interfere with standard FVIII activity assays creating a growing need for laboratory methods that can reliably measure true FVIII levels.

The UK Landscape: New Therapies

Recent developments highlight just how quickly treatment patterns are evolving:

- NHS England now commissions emicizumab for routine prophylaxis in:
  - Congenital haemophilia A with inhibitors (2018)[1]
  - Severe congenital haemophilia A without inhibitors (2019)[2]
  - Moderate haemophilia A without inhibitors (2025)[3]
- NHS Wales JCC approved commissioning emicizumab for congenital haemophilia A with inhibitors (2025).[4]
- The Haemophilia Society estimates approximately 68% of people with severe haemophilia A in the UK are already receiving emicizumab and adoption is rising.[5]
- NICE is advancing its appraisal of Mim8 on March 2026, for preventing bleeding episodes in haemophilia A in people of any age.[6]

The trend is clear: haemophilia care is becoming bispecific dominant, and laboratory testing must evolve accordingly.

The Testing Challenge: Assay Interference

Bispecific antibodies interfere significantly with many traditional FVIII activity assays, including one stage clotting assays and chromogenic assays for monitoring the extended half-life coagulation factor replacements.[7,8] This can produce misleading FVIII activity results, complicate management during breakthrough bleeding or surgery, and hinder care for patients with inhibitors. Bovine chromogenic FVIII assays have been found to be less prone to interference from bispecific antibodies.[7] Accurate factor measurement is essential for correct dosing and for avoiding thrombotic or bleeding risks.

As haemophilia care moves toward use of emicizumab and emerging agents like Mim8, the risk of incorrect results rises. Laboratories must ensure assays accurately measure native and replacement FVIII, without an interference-free approach there is risk generating results that could misdirect clinical decisions.

The Optimised CRYOcheck™ Chromogenic Factor VIII Assay

The Chromogenic FVIII Assay has been specifically engineered to reduce bispecific interference while maintaining robust analytical performance.[9]

In a poster presented at ISTH 2025, the novel bovine FIXa and FX reagent formulation of CRYOcheck Chromogenic Factor VIII showed:[10]

- No interference at clinically relevant concentrations of emicizumab (50 μg/mL) and Mim8 (5 μg/mL)
- Demonstrates reduced Mim8 interference across all FVIII levels

Ensures accurate FVIII measurement even in the presence of potent FVIII mimetic antibodies.

For more information or view the to CRYOcheck™ range, please scan the QR code or visit: **alphalabs.co.uk/chromogenic-fviii**

References:
1.https://www.england.nhs.uk/publication/clinical-commissioning-policy-emicizumab-as-prophylaxis-in-people-with-congenital-haemophilia-a-with-factor-viii-inhibitors-all-ages/ 2.https://www.england.nhs.uk/publication/emicizumab-as-prophylaxis-in-people-with-severe-congenital-haemophilia-a-without-factor-viii-inhibitors-all-ages/ 3.https://www.england.nhs.uk/publication/emicizumab-for-prophylaxis-of-bleeding-episodes-in-people-with-moderate-haemophilia-a-without-inhibitors/ 4.https://jcc.nhs.wales/clinical-policies/cancer-and-blood/emicizumab-as-prophylaxis-in-people-with-congenital-haemophilia-a-with-factor-viii-inhibitors-all-ages-policy-position-statement-pps167-september-2025-pdf/ 5. https://haemophilia.org.uk/haemophilia-a-treatment-extended-to-moderates/ 6. https://www.nice.org.uk/guidance/awaiting-development/gid-ta11509 7.https://precisionbiologic.com/content/user_files/2025/05/Performance-of-a-Novel-Bovine-Chrom-FVIII-Assay_ISLH2025.pdf 8. The effect of a next generation factor VIII mimetic bispecific antibody (Mim8) on assays of factor VIII activity and thrombin generation - Journal of Thrombosis and Haemostasis 9. https://precisionbiologic.com/precision-biologic-leads-the-way-in-hemophilia-testing/ 10. https://precisionbiologic.com/content/user_files/2025/06/PB0158-ISTH-2025.pdf

