Pre-analytical heat treatment step, to inactivate endogenous Factor VIII

Ready to use components

FACTOR VIII

Excellent repeatability and reproducibility

Reduce inter-laboratory variation

alpha laboratories
supplying quality to science

NEW CRYOcheck™ Factor VIII Inhibitor Kit

For laboratories wishing to determine and quantify the presence of functional FVIII inhibitors, now there is a ready-to-use sample preparation kit to facilitate the performance of a modified Nijmegen-Bethesda assay.

With standardised components and a validated protocol, it brings you excellent repeatability and reproducibility.

CE IVD

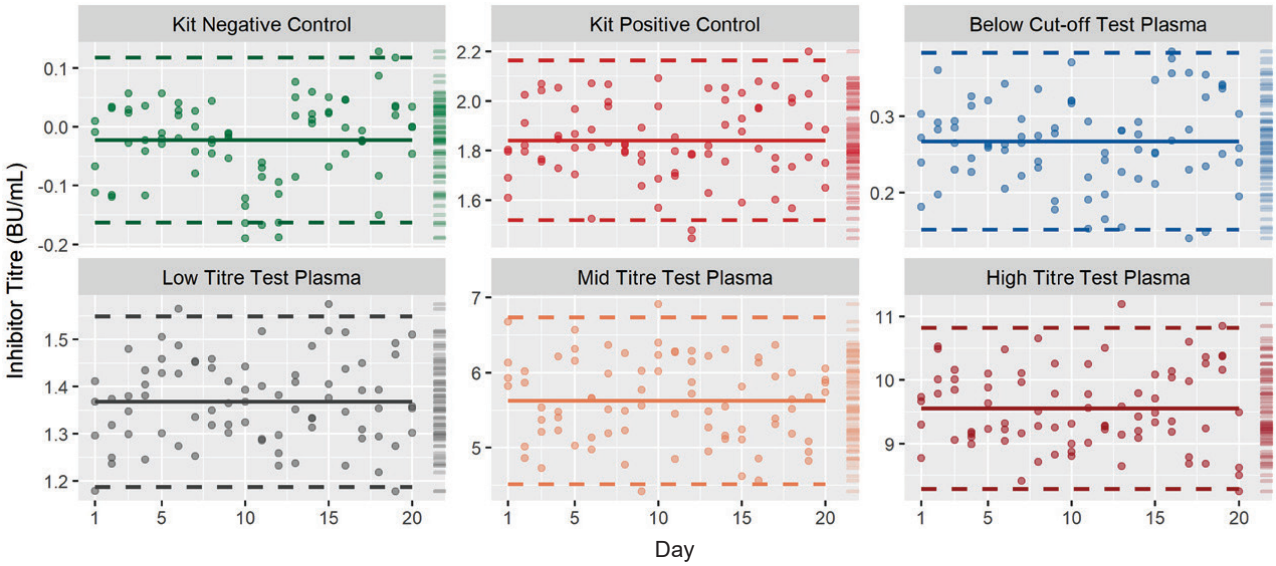
PrecisionBioLogic

Increase Confidence in Your Results

The **CRYO***check*™ FVIII Inhibitor Kit, delivers excellent repeatability and reproducibility to reduce intra and inter laboratory variation.

Repeatability

- Inhibitor-negative and inhibitor positive plasma from patients with haemophilia A were combined to yield a panel of test plasmas at four different levels of inhibitor.
- A **3 lot x 20 day x 2 run x 2 repeat** precision study was performed using the **CRYO***check*™ FVIII Inhibitor Testing Kit to determine the repeatability and within laboratory imprecision.
- Below, the mean measured titre is shown as a solid line, and the 2 standard deviations limit as a dotted line.



Sample	N	Mean Value (BU/mL)	Repeatability		Between-Run		Between-Day		Within Lab	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
Kit Negative Control	80	0	0.0	–	0.0	–	0.0	–	0.1	–
Kit Positive Control	80	1.6	0.1	8.8%	0.1	3.5%	0.1	5.5%	0.2	11%
Below Cut-off Test Plasma	80	0.3	0.1	–	0.0	–	0.0	–	0.1	–
Low Titre Test Plasma	80	1.2	0.1	6.4%	0.0	3.8%	0.0	2.3%	0.1	7.8%
Mid Titre Test Plasma	80	5.3	0.3	5.9%	0.2	3.9%	0.1	1.3%	0.4	7.2%
High Titre Test Plasma	80	8.6	0.6	7.6%	0.4	4.6%	0	0%	0.7	8.9%

The History of Haemophilia

1803 A bleeding disorder that mainly affects men is recognised

1828 This bleeding disorder is given the name haemophilia

1840 The first blood transfusion to treat haemophila

1941 The existence of FVIII inhibitors are reported

1947 Its reported that there is more than one type of haemophilia

1950 The Haemophilia Society is established as a charity

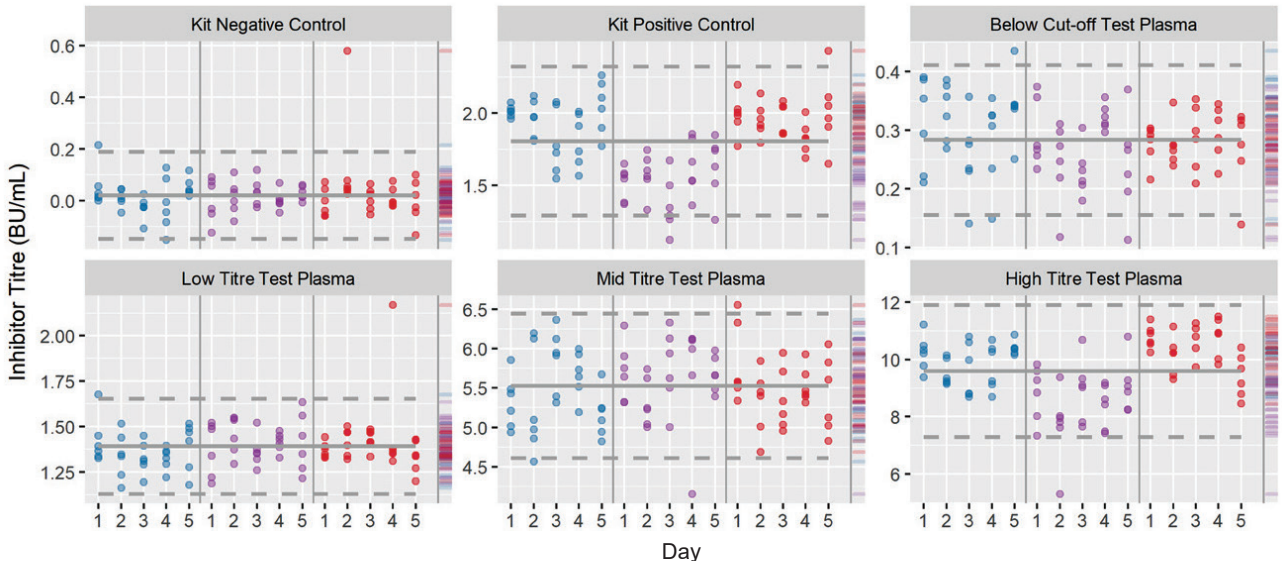
1952 The first identification of 'Christmas disease', now known as haemophilia B

1963 The World Federation of Haemophila is established

1964 The first successful use of cryoprecipitate to treat patients with haemophilia

Reproducibility

- The same panel of inhibitor positive plasmas were subjected to a **3 site x 5 day x 2 run x 3 repeat** precision study using the **CRYOcheck**™ FVIII Inhibitor Testing Kit.
- The testing was performed on three different analysers with three different operators and a single lot of chromogenic FVIII kit.
- Below, the mean measured titre is shown as a solid line, and the 2 standard deviations limit as a dotted line.



Sample	N	Mean Value (BU/mL)	Repeatability		Between-Run		Between-Day		Between Site		Reproducibility	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Kit Negative Control	90	0	0.1	–	0	–	0	–	0	–	0.1	–
Kit Positive Control	90	1.8	0.2	8.8%	0.1	3.4%	0.1	3.4%	0.2	12.4%	0.3	15.9%
Below Cut-off Test Plasma	90	0.3	0.1	–	0	–	0.0	–	0.0	–	0.1	–
Low Titre Test Plasma	90	1.4	0.1	10.1%	0	0%	0.0	1.9%	0.0	1.1%	0.1	10.3%
Mid Titre Test Plasma	90	5.5	0.4	7.8%	0.1	2.2%	0.1	2.0%	0	0%	0.5	8.3%
High Titre Test Plasma	89	9.6	0.7	7.8%	0.4	4.1%	0.3	3.3%	0.9	9.2%	1.3	13.1%

Data source: Douglas CD, et al. [1]

1968 The first commercial FVIII concentrate is manufactured

1968 The UKHCDO is founded

1975 FEIBA, a FVIII inhibitor bypassing agent is launched

1977 Desmopressin is developed as a treatment for patients with haemophila

1991 UKHCDO becomes a registered charity

1992 Recombinant FVIII concentrates are licensed to treat patients with haemophilia

1997 Recombinant FIX products become available

2015 The first extended half-life FVIII treatment is approved in Europe

2018 New subcutaneous treatments for patients with inhibitors becomes available in the UK

Factor VIII Inhibitor Kit

- For use in performing a modified Nijmegen-Bethesda assay
- Standardised components with a validated method, working to reduce inter laboratory variation
- Excellent repeatability and reproducibility
- Platform independent - FVIII activity can be measured using a 1-stage clot based assay or a chromogenic assay on any coagulation analyser
- Ready to use components, simply thaw in a water bath in a few minutes - saving time, improving workflow and eliminating reconstitution errors
- Includes a pre-analytical heat treatment step to inactivate endogenous FVIII
- Bovine Serum Albumin (BSA) has been validated as a practical alternative to FVIII deficient plasma, improving stability and reducing inter laboratory variation from different sources of FVIII deficient plasma[2]
- Includes an additional inhibitor positive and negative control, to increase confidence in your results

CE IVD

Ordering Information

Product Code	Description	Pack Size
CCIK08	Factor VIII Inhibitor Kit	Contains 5 vial sets, enough to prepare five high titer patient samples. Each vial set comprises: 2 x 1.5ml Imidazole Buffered Pooled Normal Plasma (●) 2 x 1.5ml Imidazole Buffered Bovine Serum Albium (●) 1 x 0.5ml Negative FVIII Inhibitor Control (●) 1 x 0.5ml Positive FVIII Inhibitor Control (●)

References

1. Douglas CD, et al. A Standardised Kit for a Chromogenic Modified Nijmegen-Bethesda Assay: Repeatability, Reproduceability, and Analytical Sensitivity. Presented at 60th ASH Annual Meeting, December 1-4, 2018 San Diego, California, USA.

2. Miller CH, et al. Validation of Nijmegen-Bethesda assay modifications to allow inhibitor measurement during replacement therapy and facilitate inhibitor surveillance. Journal of Thrombosis and Haemostasis. 2012; 10: 1055-61

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