CRYO*check*™ Factor VIII Inhibitor Kit

The presence of Factor VIII (FVIII) inhibitors reduces therapy effectiveness and is one of the most complex and costly complications for people with hemophilia A. Because of this, it is important to have a testing system that can accurately and precisely quantify inhibitors in patient samples.

The CRYO*check* Factor VIII Inhibitor Kit was created to address this challenge. It contains standardized components and a validated procedure to prepare patient samples for performing a Modified Nijmegen-Bethesda assay (MNBA) as per the U.S. Centers for Disease Control and Prevention (CDC) recommendation.[1] A Modified Nijmegen-Bethesda assay is used to determine FVIII inhibitor levels in people with hemophilia A.

The kit is an ideal solution for laboratories seeking to standardize sample preparation to limit variability in their MNBA. Excellent vial-to-vial consistency, standardized components, and a validated procedure, all contribute to helping labs reach the goal of improved within-laboratory and between-laboratory precision for the diagnosis and routine monitoring of inhibitor titers.

U.S. FDA cleared, CE Marked, and Health Canada authorized.

[1] Miller CH, Platt SJ, Rice AS, Kelly F, Soucie JM, the Hemophilia Inhibitor Research Study Investigators. Validation of Nijmegen-Bethesda assay modifications to allow inhibitor measurement during replacement therapy and facilitate inhibitor surveillance. *J Thromb Haemost* 2012; **10:** 1055–61.

FEATURES:

- Includes positive and negative FVIII inhibitor controls to ensure your testing system is working within range and give increased confidence in testing results
- Excellent repeatability and reproducibility, making the kit suitable for multi-center clinical studies
- Excellent linearity across a broad reportable range
- Convenient frozen format – ready to use within minutes, no reconstitution errors
- Compact, color-coded packaging for easy storage and identification in freezers

KIT COMPONENTS:

Imidazole Buffered Pooled Normal Plasma (IB-PNP)
Pooled normal plasma from a minimum of 20 donors with a FVIII activity value of approximately 100%; serves as a source of FVIII for test mixes

Imidazole Buffered Bovine Serum Albumin (IB-BSA)
A 4% BSA solution; for creating serial dilutions of patient samples

Negative Factor VIII Inhibitor Control
Pooled normal plasma; for use as a negative inhibitor control

Positive Factor VIII Inhibitor Control
Immunodepleted FVIII deficient plasma to which anti-human FVIII antibodies have been added; for use as a positive inhibitor control

DESCRIPTION	CATALOG #	COMPONENTS	FORMAT	# OF TESTS
CRYO*check* FVIII Inhibitor Kit	CCIK08	IB-PNP	10 x 1.5 mL	5*
		IB-BSA	10 x 1.5 mL	
		NEG CONTROL	5 x 0.5 mL	
		POS CONTROL	5 x 0.5 mL	

** Each kit contains five vial sets – enough to prepare five high titer patient samples.*

PrecisionBioLogic
www.precisionbiologic.com
1.800.267.2796

Frozen diagnostic products. One simple idea, many cool benefits.