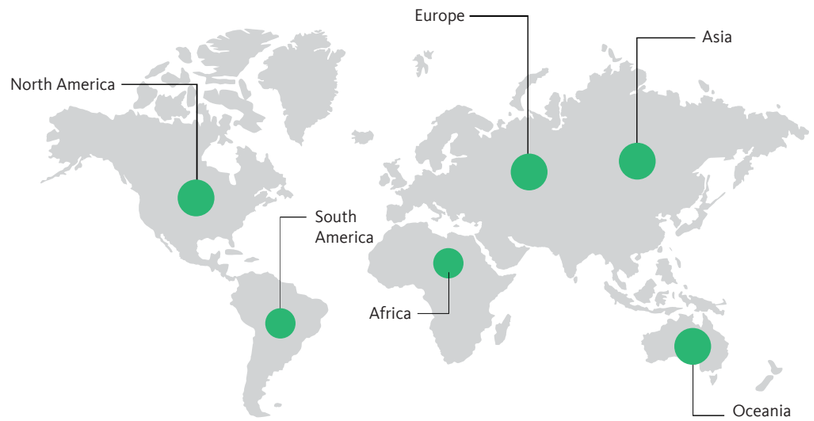
Available Worldwide



From the INNOVATION LEADER in Thrombosis & Hemostasis

More information on HYPHEN BioMed and product catalog is available at :
www.hyphen-biomed.com

HYPHEN BioMed
155 rue d'Eragny, 95000 Neuville-sur-Oise, France • Tel: +33 (0)1.34.40.65.10 • info@hyphen-biomed.com • www.hyphen-biomed.com

HYPHEN BioMed (France) - " destination " générique " - Réf : HBM018_v2_EN- Date de création : 07/2017 - Révision: 12/2018

Lire attentivement les instructions figurant sur l'étiquetage et/ou la notice d'utilisation des réactifs.

HYPHEN BioMed
A Sysmex Group Company

Chromogenic FXIII Activity assay
BIOPHEN™ FXIII

HYPHEN BioMed
155 rue d'Eragny, 95000 Neuville-sur-Oise, France • Tel: +33 (0)1.34.40.65.10 • URL : www.hyphen-biomed.com

Chromogenic FXIII Activity Assay: BIOPHEN™ FXIII

Chromogenic activity assay as First-line test for measuring FXIII: congenital or acquired deficiencies; FXIII substitutive therapy.

Convenient, and Economical with extended stability:

- **Stable after opening:**
  5 days onboard*,
  7 days at 2-8°C,
  2 days at 18-25°C
  2 months when frozen <20°C
- **Long shelf life** at 2-8°C in original packaging

* example on Sysmex CS-series

Specific and reliable assay:

- **Specificity verified on FXIII deficient plasma:** FXIII % < LOD
- **No interference of plasma contents and anticoagulants:** Hemoglobin, Bilirubin, Intralipids, Fibrinogen, Ammonium, Heparins, DOACs

Extended measurement range useful to explore various contexts:

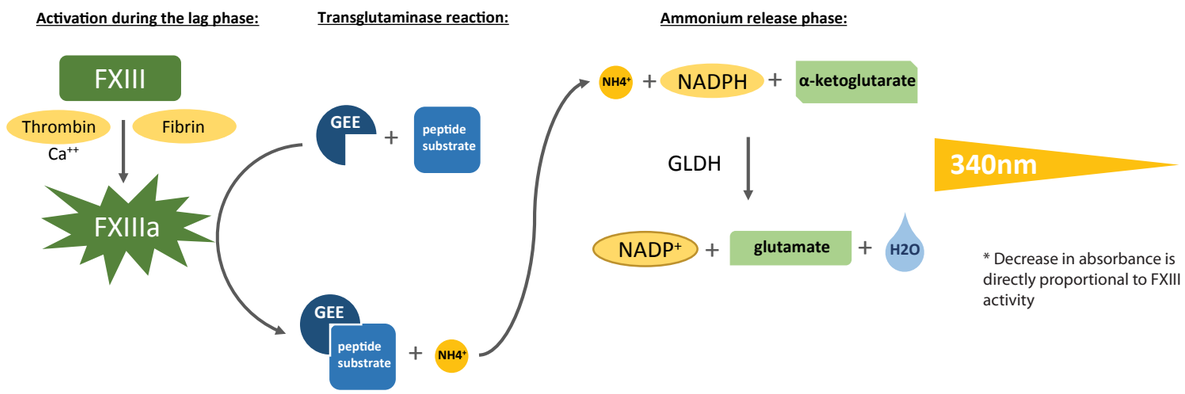
- Extended measurement range of 5-300% (with redilution)
- High specificity verified at very low concentration <15%

Automatable and standardised:

- **Automated:** validated application guide on Sysmex CS-series
- Calibrators & Controls **traceable to WHO International Standard**

Reagent

FXIII in the tested sample, is converted into activated Factor XIII (FXIIIa) by the combined effect of thrombin and calcium[2]. Soluble fibrin, also generated by the action of thrombin, accelerates the reaction while an antipolymerization peptide avoids the clot formation. FXIIIa transglutaminase activity between a synthetic peptide substrate and glycine ethyl ester (GEE) leads to the formation of ammonium ($NH4^+$). Ammonium is then assayed through the reaction of glutamate dehydrogenase (GLDH) converting NADPH into $NADP^+$, in the presence of ammonium and alpha ketoglutarate. The conversion of NADPH into $NADP^+$ can be detected at 340 nm, and the slope of the absorbance decrease at 340nm is directly proportional to the concentration of FXIII in the tested sample.



* Decrease in absorbance is directly proportional to FXIII activity

Reference

1. Kohler HP *et al.* Diagnosis and classification of factor XIII deficiencies. J Thromb Haemost. 2011;9:1404-6
2. Karpati L *et al. A modified, optimized kinetic photometric assay for the* determination of blood coagulation factor XIII activity in plasma. Clin Chem. 2000
3. Dorgalaleh A *et al.* Laboratory Diagnosis of Factor XIII Deficiency in Developing Countries: An Iranian Experience. Laboratory Medicine. 2016;47:3:220-226

FXIII and its deficiency

FXIII is a protransglutaminase of tetramer structure ($FXIII\text{-}A_2B_2$), with the A subunit being the functional form. When activated to FXIIIa, it has a major role in the final stage of blood coagulation, serving as the fibrin stabilizing factor. FXIII deficiency may be congenital, or acquired as a result of hyperconsumption or presence of autoantibodies. Low FXIII levels have been associated with bleeding complications, eg in situations such as trauma or surgery. FXIII is also involved in various other processes such as wound healing and maintenance of pregnancy. [1, 2]

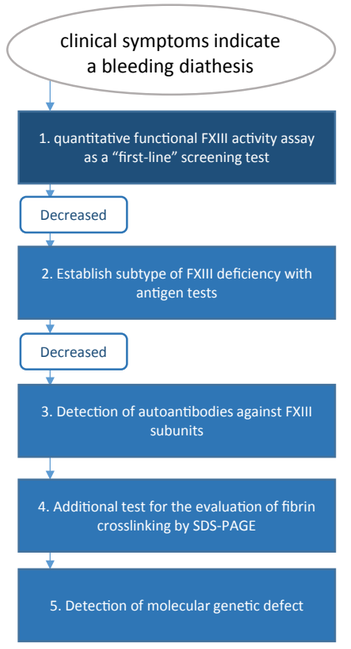
Assaying FXIII activity in human plasma may help in the diagnosis of congenital or acquired FXIII deficiencies. Inherited FXIII-A deficiency is a rare bleeding disorder that affects one individual out of 1–3 million and prophylactic replacement therapy is mandatory if the diagnosis of severe congenital FXIII deficiency is confirmed.[1] Because FXIII (as a coagulation factor) is not involved in the formation of an early unstable clot, all routine coagulation tests, including bleeding time (BT), prothrombin time (PT), and activated partial thromboplastin time (APTT), show normal results in FXIII.[3]

Expected FXIII activity values and antigen concentrations in FXIII deficiencies[1]

Deficiency			Plasma				Platelet	
			FXIII activity	FXIII-A_2B_2 Ag	FXIII-A Ag	FXIII-B Ag	FXIII activity	FXIII-A Ag
Inherited	FXIII-A deficiency	Type I (quantitative)	↓↓↓	↓↓↓	↓↓↓	>30%	↓↓↓	↓↓↓
		Type II (qualitative)	↓↓↓	↓-N	↓-N	>30%	↓↓↓	↓-N
	FXIII-B deficiency		↓↓	↓↓↓	↓↓	↓↓↓	N	N
Autoantibody against FXIII	Anti-FXIII-A	Neutralizing	↓↓↓	↓-N	↓-N	>30%	N	N
		Non-neutralizing	↓↓↓	↓↓↓	↓↓↓	>30%	N	N
	Anti-FXIII-B		↓↓↓	↓↓↓	↓↓↓	↓↓↓	N	N
Other aquired deficiencies			↓	↓	↓	↓-N	NA	NA

↓↓↓, highly decreased activity/concentration usually below 3%;
↓↓, considerably decreased activity/concentration, usually 5–10%;
↓, slightly decreased activity, usually 20–70%;
N, normal; NA, non-applicable.

Overview of ISTH SSC recommended algorithm for diagnosis of FXIII deficiencies[1]



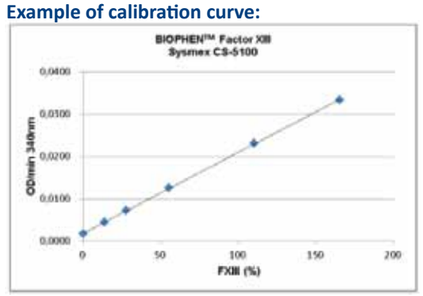
Performance characterstics

Precision

Control	Intra-assay				Inter-assay			
	N	Mean %	CV %	SD	N	Mean %	CV %	SD
Normal	40	102.3	2.7	2.8	30	102.6	1.5	1.5
Abnormal	40	28.8	4.9	1.4	30	31.2	1.9	0.6

The inter -assay variability is evaluated with laboratory controls over 5 days, 2 series per day and 3 repetitions in each series for each level of control.

Example of calibration curve:



Range of measurement:

Measurement Principle	Calibration Range	
Chromogenic method	Concentration of FXIII (%)	0 – 165*
	Raw values (OD/min)	0.0017 – 0.0334**

* Values dependent on the calibrator.
** These values are given for information and may vary from one batch to another and from one analyzer to another.

Ordering information

	Product name	Kit presentation	Ref N°:	Status
Chromogenic assay for quantitation of FXIII activity	BIOPHEN™ Factor XIII	R1: Thrombin Reagent (3 x 4mL) R2: Detection Reagent (3 x 5 mL)	227005	CE-IVD

Additional products required:

	Product name	Ref N°:	Status
Calibrator	BIOPHEN™ Plasma Calibrator	222101	CE-IVD
Controls	BIOPHEN™ Normal Control Plasma BIOPHEN™ Abnormal Control Plasma	223201 223301	CE-IVD CE-IVD
Buffer	Physiological Saline Buffer	-	-

Related products:

	Product name	Ref N°:	Status
ELISA	ZYMUTEST™ Factor XIII-A	RK034A (On-demand)	RUO
Deficient Plasma	FXIII Deficient Plasma	DP200A/K	RUO

Please contact your local distributor found on our website: www.hyphen-biomed.com