

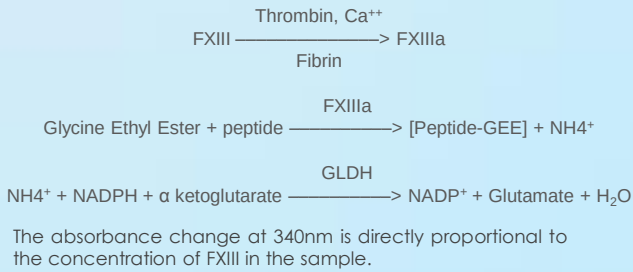
BIOPHEN™ Factor XIII

Product Ref. N°	A227005-RUO
Kit presentation	Chromogenic automated method, R1: Thrombin; R2: Detection reagent
Status	RUO

Intended use:

Chromogenic automated method for the quantitative determination of Factor XIII (FXIII) activity in human citrated plasma.

Assay principle:



Key Characteristics & Advantages:

Factor XIII in practice

- FXIII protransglutaminase circulates in plasma as A2B2 tetramer, the A subunit being the functional form. When activated by thrombin and calcium to FXIIIa, it acts in the last step of the coagulation cascade and contributes to Fibrin stabilization and clot stiffness.
- Research Applications:**
 - Congenital or acquired FXIII deficiency (eg hyperconsumption, autoantibodies).
 - Low FXIII associated with bleeding complications.
- Market requirements & challenges:**
 - ✓ Automated, highly performing, stable FXIII assay with limited pre-analytical influence and low levels detection.

Innovative alternatives to support your needs



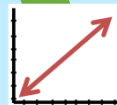
Easy and fast Automation:

- Simple, rapid (10min), fully automatable on any biochemistry or coagulation analyzer with 340nm wavelength.
- Method applications: Sysmex CS-series



Optimized consumption with high extended stability

- 5 days onboard (CS),
- Long shelf life or reconstituted stability at 2-8°C in original packaging



Extended measurement range (5-300% FXIII) useful to explore various contexts

High specificity for FXIII, verified at very low level <15%

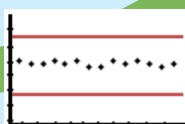


Excellent Precision with very low CVs:

- Within-run < 4.9% (example of CS-5100)
- Between-run < 1.9% (example of CS-5100)

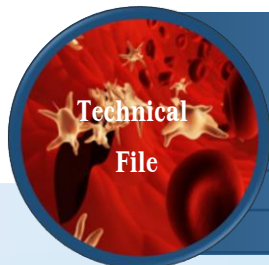


Specific and reliable assay, without interferences related to sample content (Hemoglobin, bilirubin, triglycerides, heparins, DOACs, usual Fibrinogen, high ammonium (up to 0.5mM))



Safe and standardized method for optimal testing

- Improved lot-to-lot variability; High quality raw materials used
- Calibrators/controls traceable to WHO International Standard

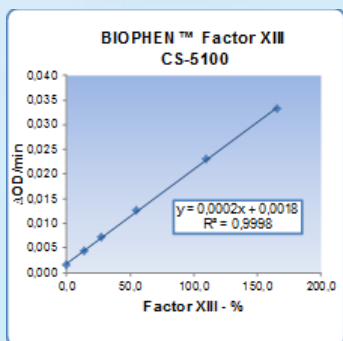


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Assay Characteristics*: Automated, highly stable, extended measurement range with good specificity & sensitivity at low levels <15%, no DOACs interferences

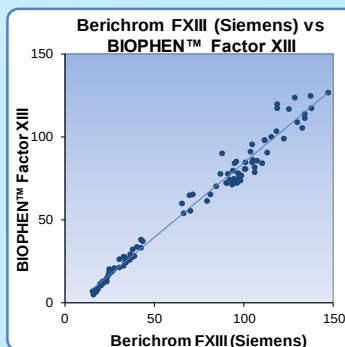
Calibration curve & measurement range:



Measurement range :
5-300%
(automatic redilution
> 150%)

Detection Limit:
LLOD <0.5%

Method Comparison (CS-2500):



Samples N=102:
56 normal samples
46 pathological low levels
(diluted normal samples)

**Good correlation with
other device:**

$y=0.90x-5.84$
 $r=0.989$ $P<0.0001$

Interferences and specificity:

High Specificity

- Expected normal concentrations: 60-146%
- Good recovery at very low FXIII levels: <15%
- Specificity verified on FXIII immunodepleted plasma : FXIII% < LOD

No interference of anticoagulant drugs

- Bias % was globally <5% on controls (2IU/mL Heparins; 400ng/mL DOACs : Apixaban, Edoxaban, Rivaroxaban, Dabigatran)

No interference of usual interferents and Plasma content

- Bias% was globally within 0.6-10% on normal control (60 mg/dL Bilirubin, 250 mg/dL Hb or Intralipids, 0.8 - 6g/L Fbg, 0.5mM Ammonium)

Precision (CS-5100):

Intra-series

- N=40 determinations
- CV% 2.7% (FXIII= 102%)
- CV% 4.9% (FXIII= 29%)

Inter-series

- n=30 determinations (5 days, 10 runs)
- CV% 1.5% (FXIII= 103%)
- CV% 1.9% (FXIII= 31%)

Example of stability and lot-to-lot variability:

- 3 lots on CS-5100
- Normal 91-93%
- Middle 67-69%
- Low 33-34%

Lot-to-lot
variability
on same
controls

Shelf life in
original
packaging

- 30 months at 2-8°C

Stable 7
days 2-8°C;
2 days RT;
2 months -
20°C

Onboard:
5 days on
CS-5100

- Fresh vs stored:
 $\Delta\%$ (OD/min at
~100%) was < 5%
(on CS)

- Bias % was <5% on
controls

Kit presentation:



Kit contents: 3x4 mL (R1) and 3 x5 mL (R2)

* The values cited for the assay characteristics of the assay represent example of typical results and are not to be regarded as specifications for the test

Related products:

Needed	Product name	Ref N°:
Calibrator / Controls	BIOPHEN™ Plasma Calibrator BIOPHEN™ Normal Control Plasma BIOPHEN™ Abnormal Control Plasma	A222101-RUO A223201-RUO A223301-RUO
Buffer	Physiological Saline Buffer	-

For information	Product name	Ref N°:
ELISA Deficient Plasma	ZYMUTEST™ Factor XIII-A FXIII Deficient Plasma	ARK034A-MIN ADP200A/K