

REF

5800200

TECHNOFLUOR FXIII Activity

ENG

DEU

NED

ITA

ESP

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IVD

CE

TECHNOFLUOR FXIII Activity - English

INTENDED USE

FXIII activity assay based on its isopeptidase function for the automated, quantitative determination of FXIII activity in citrated human plasma on the Ceveron s100.

SUMMARY

Factor XIII (FXIII) plays a key role in clot stabilization, maturation and composition. FXIII belongs to the transglutaminase family of which the most characteristic catalytic function is the formation of isopeptide bonds between the side chains of susceptible protein bound glutamine and lysine residues. In plasma, the non-covalent FXIII-A₂B₂ heterotetramer is bound to fibrinogen. Activation by thrombin and calcium binding yields activated FXIII (FXIIIa), which recognises fibrin as the key substrate. The activated plasma transglutaminase - in an orchestrated sequence - covalently crosslinks abutting fibrin γ-chains and α-chains thereby providing mechanical stability to the fibrin network. In parallel, FXIIIa incorporates α2-antiplasmin rendering the clot biochemically stable by preventing premature fibrinolysis by plasmin. Congenital or acquired deficiency may be associated with a severe bleeding diathesis, underlining the clinical relevance of FXIII.

In the TECHNOFLUOR assay, FXIII is activated by thrombin in the presence of calcium. Activated FXIII then cleaves the side-chain carboxamide bond of the assay's substrate and thereby releases the dark quencher (2,4-dinitrophenyl) linked to the cadaverine spacer. Subsequently, the increase of fluorescence results from the N-terminally attached fluorophore N-Methyl-2-aminobenzoic acid (N-Me-Abz). The fluorescent signal is proportional to the FXIII activity in the plasma sample.

REAGENTS

The TECHNOFLUOR FXIII Activity contains:

	Reagent / Content	Description
2 x 2 mL	Reagent	Activator reagent containing bovine thrombin, calcium chloride and a fibrin polymerization inhibitor
2 x 2 mL	Substrate (SUB)	Factor XIII specific substrate with dark quencher
2 x 3 mL	Buffer (BUF)	Factor FXIII buffer for sample dilution

Material required (not supplied with the kit)

- Distilled water
- Precision pipettes
- Calibration Plasma*
 - REF 5220110 Coagulation Reference 5 x 1 mL
 - Control Plasma*
- - REF 5020040 Coagulation Control N 5 x 1 mL
 - REF 5021055 Coagulation Control A 5 x 1 mL
- Laboratory timer
- * or any other package sizes.

Warning and precautions

- IVD for in vitro diagnostic use only.
- This kit is intended for use by personnel trained in laboratory procedures and universal precautions for the use of chemicals and potentially biohazardous substances must be applied.
- All human blood or plasma products as well as test samples must be considered as potentially infectious. They have to be handled with appropriate care and in strict observance of safety regulations. The rules pertaining to disposal are the same as applied to disposing hospital waste.
- Get a Material Safety Data Sheet for this product from www.technoclone.com.

Stability and storage

The expiry date printed on the labels is only applicable to storage of the unopened containers at 2...8 °C.

Stability opened/ in use:

Reagent / Content	Ceveron s100 (open vial)	2...8 °C (closed vial)	< -20 °C (closed vial)
Reagent	3 days	1 month	2 months
Substrate (SUB)	3 days	1 month	2 months
Buffer (BUF)	3 days	2 months	Do not freeze

Reagent and Substrate should only be frozen once. Thawing must be performed rapidly in a water bath kept at 37 °C.

TEST PROCEDURE

Preparation of plasma samples

Collect nine parts of freshly drawn venous blood in one part trisodium citrate (3.2 %). Refer to CLSI Document H21-A5 for instructions on specimen collection, handling, and storage.

Thaw frozen samples rapidly at 37 °C and centrifuge and separate if necessary. Gently mix before testing. After thawing, the assay must be performed within 2 hours. Samples may be frozen once at -70 °C.

Preparation of reagents

Before starting the test, all the required components must be brought to room temperature.

Avoid foam formation when reconstituting plasmas and mixing reagents or buffers.

- **Reagent:** Dissolve each bottle of lyophilized reagent in 2.0 mL distilled water and swirl gently. Allow the reconstituted material to stand for 10 minutes at room temperature before use. For standardizing tests, a reconstitution time of 30 minutes is recommended. Swirl to mix before use.
- **Substrate:** Dissolve each bottle of lyophilized substrate in 2.0 mL distilled water and swirl gently. Allow the reconstituted material to stand for 10 minutes at room temperature before use. For standardizing tests, a reconstitution time of 30 minutes is recommended. Swirl to mix before use.
- **Buffer:** The FXIII buffer is ready to use.

Performance of the test

The TECHNOFLUOR FXIII Activity is performed on the Ceveron s100 with the respective applicator.

Calibration is performed using a serial dilution of Coagulation Reference in assay buffer. Normal and abnormal controls are recommended for a complete quality control program. Coagulation Control N and Coagulation Control A are designed for this program. Each laboratory should establish its own mean and standard deviation for a quality control program in order to monitor laboratory testing. Controls should be analyzed before validating patient results in accordance with good laboratory practice.

LIMITATION OF THE TEST

FXIII results on Ceveron s100 are not affected by hemoglobin up to 500 mg/dL, bilirubin* up to 18 mg/dL, lipemia up to 1400 mg/dL Intralipid™, fibrinogen up to 6 g/L and ammonia up to 2 mM.

*In case of clear visual presence of icterus in the plasma sample, a pre-dilution of the sample 1:2 using 0.9 % sodium chloride solution is recommended. The result from the diluted sample must be multiplied by the dilution factor (x2).

INTERPRETATION OF RESULTS

FXIII Activity results are reported in % of Normality. The results can also be converted into IU/mL where 100 % equals 1.00 IU/mL. The assay results should be used with other information, including the clinical context, in forming a diagnosis.

REFERENCE RANGE

Reference range (n= 154) for TECHNOFLUOR FXIII activity: 47 – 136 % (equivalent to 0.47 – 1.36 IU/mL)

It is recommended that individual laboratories establish their own reference range.

PERFORMANCE CHARACTERISTICS

Performance data are given below. Results obtained in individual laboratories may differ.

Clinical Performance

Precisie

De reproduceerbaarheid werd bepaald met verschillende monsters.

Monster code	Toegekende waarde [IU/ml]	CV % within run	CV % between run
Coagulation Control N	88.1	4.2 %	6.3 %
Coagulation Control A	36.7	3.1 %	4.1 %
Plasma Sample 1	98.2	3.8 %	7.6 %
Plasma Sample 2	58.3	3.7 %	6.0 %
Plasma Sample 3	29.3	4.8 %	7.5 %
Plasma Sample 4	14.7	4.9 %	9.2 %

Beperking van kwantificatie en bereik bepaling

Detectie ondergrens: 0,8 %

Lineair bereik: 1,0 – 150 %

STANDAARDISATIE

Coagulation Reference (kalibrator) is gekalibreerd met TECHNOFLUOR FXIII Activity en herleidbaar naar de WHO International Standard voor FXIII activiteit, de ranges voor Coagulation Control N en Coagulation Control A zijn toegekend via Analyse met deze kalibrator i.c.m. het reagens.

LITERATUUR

Neem contact op met Technoclone of uw lokale distributeur.

EDITORAL NOTE

Dit document is beschikbaar in verschillende talen. De vertalingen zijn gemaakt met behulp van het hoofddocument in het Engels. In geval van twijfel discrepanties heeft de tekst in het Engelstalige hoofddocument voorrang.

TECHNOFLUOR FXIII Attività - Italiano

INTENTO D'USO

Saggio di attività di FXIII basato sulla funzione isopeptidasicca per la determinazione automatizzata e quantitativa dell'attività di FXIII nel plasma umano citrato su Ceveron s100.

RIASSUNTO

Il fattore XIII (FXIII) svolge un ruolo chiave nella stabilizzazione, maturazione e composizione del coagulo. FXIII fa parte della famiglia delle transglutaminasi la cui funzione catalitica più caratteristica è la formazione di legami isopeptidici tra le catene laterali delle proteine suscettibili legate a residui di glutammina e lisina. Nel plasma, l'eterotetramero non-covalente FXIII-A₂B₂ è legato al fibrinogeno. L'attivazione da parte del legame della trombina e del calcio attiva il FXIII (FXIIa), che riconosce la fibrina come substrato chiave. La transglutaminasi del plasma attivata - in una sequenza orchestrata – si lega covalentemente alle catene y e α della fibrina fornendo stabilità meccanica alla rete della fibrina. In parallelo, FXIIa incorpora α2-antiplasmina che rende il coagulo biochimicamente stabile prevenendo la fibrinolisi prematura da parte della plasmina. La carenza congenita o acquisita può essere associata a una grave diatesi emorragica, sottolineando la rilevanza clinica di FXIII.

Nel saggio TECHNOFLUOR, FXIII è attivato dalla trombina in presenza di calcio. FXIII attivato spezza quindi il legame carbossilamminico a catena laterale del substrato del test e quindi rilascia il quencher scuro (2,4-dinitrofenile) legato al distanziatore cadaverina. Successivamente, l'aumento della fluorescenza deriva dal fluoroforo N-terminale dell'acido N-Metil-2-aminobenzoico (N-Me-Abz). Il segnale di fluorescenza è proporzionale all'attività di FXIII nel campione di plasma.

REAGENTI

TECHNOFLUOR Factor XIII Activity contiene:

	Reagenti / Contenuto	Descrizione
2 x 2 mL	Reagente	Reagente attivatore contenente trombina bovina, calcio chloride e un inibitore della polimerizzazione della fibrina
2 x 2 mL	Substrato (SUB)	Substrato specifico per il Fattore XIII legato ad un quencher scuro
2 x 3 mL	Soluzione tampone (BUF)	Tampone Fattore FXIII di diluizione dei campioni

Materiali necessari ma non forniti con il kit:

- Acqua distillata
- Pipette di precisione
- Plasma di calibrazione*
- **REF**

5220110 Coagulation Reference

 5 x 1 mL
- **Plasma di controllo***

REF

5020040 Coagulation Control N

REF 5021055 Coagulation Control A

 5 x 1 mL
- Timer di laboratorio
- * o qualsiasi altro confezionamento.

Avvertenze e precauzioni

- IVD per uso diagnostico in vitro.
- Questo kit deve essere utilizzato da personale addestrato nelle procedure di laboratorio e precauzioni universali per l'uso di prodotti chimici e di sostanze potenzialmente a rischio biologico.
- Tutti i prodotti derivanti da sangue o plasma così come tutti i campioni devono essere considerati come potenzialmente infettivi. Devono essere maneggiati con particolare attenzione e in stretta osservanza delle regole di sicurezza. Le regole riguardanti lo smaltimento dei rifiuti sono le stesse applicate allo smaltimento dei rifiuti ospedalieri.
- La Scheda di Sicurezza è disponibile su www.technoclone.com.

Stabilità'e conservazione

La data di scadenza riportata sull'etichetta è relativa alla conservazione della fiala non aperta a +2...8 °C.

La stabilità dopo ricostituzione/apertura:

Reagenti / Contenuto	Ceveron s100 (fiala aperta)	2...8 °C (fiala chiusa)	< -20 °C (fiala chiusa)
Reagente	3 giorni	1 mese	2 mesi
Substrato (SUB)	3 giorni	1 mese	2 mesi
Soluzione tampone (BUF)	3 giorni	2 mesi	Non congelare

Il reagente e il substrato possono essere congelati una sola volta. Lo scongelamento deve essere eseguito rapidamente a bagnomaria a 37 °C.