CE
In Vitro Diagnostic

Behnk Elektronik

BE Factor X Deficient plasma

Depleted plasma for quantitative determination of Factor X activity in human plasma

REF 771610: DP (6 x1 mL)

PRINCIPLE [2]

Measurement of clotting time in presence of tissular thromboplastin, calcium and the deficient plasma FX in which all the factors are present in excess except of Factor X which is derived from the specimen to be tested.
This test is determined with BE reagents as follows:

REF 771150, REF 771151: Thromboplastin high ISI
REF 771100, REF 771101: Thromboplastin low ISI
REF 771700: BE Owren Buffer (Plasma dilution buffer)

CLINICAL SIGNIFICANCE [1] [2] [7] [8]

Pathological variations may be observed in following cases:

- Congenital deficiency of FX
- Acquired deficiency of Factor X associated with deficiencies of factors II, VII and IX:
  - Oral anticoagulant therapy (using Vitamin K)
  - Intake or absorption deficiency of vitamin K (hemorrhagic disease of the newborn, obstructive icterus, antibiotic therapy)
- Acquired deficiency of Factor X associated with deficiencies of factors II, V and VII:
  - Hepatic disorders (cirrhosis, hepatitis)
  - Fibrinolysis
  - Disseminated intravascular coagulation (DIC)
- Acquired deficiency of Factor X during amyloidosis

Coagulation and Hepatics Disorders:
In the presence of vitamin K, liver cells synthesize Factors II, VII, IX and X. Any hepatic disorders may lead to variable decrease of the level of these factors. Liver damage therefore can lead to hemorrhagic disorders.

Evolution of Factors II, V, VII, and X level in the course of hepatitis.

Hepatitis	Diagnosis				Prognosis	
	Factors VII et X		Factor II		Factor V	
benign	↘ < 50%	N	↘	N	N	N
Prolonged	↘	↘	↘	↘	N	N
Severe	↘↘	↘↘↘	↘	↘↘	N	↘
N= Normal	1st day	10th day	1st day	10th day	1st day	10th day

REAGENTS

DP **FX** Deficient Plasma FX

Human Origin

Freeze dried plasma free of Factor X by selective immune-adsorption
According to 1272/2008 regulation, these reagents are not classified as dangerous.

SAFETY CAUTIONS

Behnk reagents are designated for professional in vitro diagnostic use.

- Refer to current Material Safety datasheet (MSDS) is available upon request.
- Use adequate protections (overall, gloves, glasses).
- Each donor unit used to manufacture this product was tested and found non-reactive for HBsAg, antibody to hepatitis C and antibody to HIV-1/HIV-2.
- However, as absence of infectious agents can never be proven, this plasma and all specimens should be handled as potentially infectious, in accordance with good laboratory practices using appropriate precautions.
- In the event of exposure, the directive of the responsible health authorities should be followed.
- Dispose of waste in accordance with the local regulations.

PREPARATION OF REAGENTS

DP: Open the vial carefully and add 1 mL of demineralised water without delay. Recap the vial and let stand for 15 min at room temperature. Mix gently by swirling before use.

STABILITY AND STORAGE

Unopened vials stored at 2-8 °C are stable until the expiry date stated on the label.
Once opened and reconstituted, plasma is stable:

- 10 hours at 2-25 °C

SAMPLES COLLECTION AND HANDLING [3] [9]

Plasma from careful venipuncture with anticoagulant ratio of 1/10 (trisodium citrate solution 0.109 M). Mix immediately the blood with anticoagulant.
Avoid drawing with a syringe that could result in the formation of micro-clots.
Centrifuge 10 minutes at 2500 g.

Stability: 4 h at 15-25 °C, 6 h at 2-8 °C

Caution: If testing also Factor VII, do not store sample at 2-8 °C, because the Factor VII may be activated by the Kallikrein system in this temperature range

LIMITS [4]

Thrombin inhibitors (hirudin, argatroban …) present in the specimen may decrease Factor X activity in the specimen.
For a more comprehensive review of factors affecting this assay refer to the publication of Young D.S

MATERIAL REQUIRED BUT NOT PROVIDED

Basic medical analysis laboratory equipment
Coagulation analyzer
Demineralised water

EXPECTED VALUES [5] [6]

- Plasma (adult) : Usually > 70 %
- New Born (30 to 50 % lower than adult value)

Each laboratory should establish its own normal ranges for the population that it serves.

PROCEDURE

Automated method on Behnk Thrombolyzer series
Refer to the full detailed application specific to the automated system.
Note:

- Performances and stability data have been validated on Thrombolyzer Compact X (available on request).
- With manual procedure and on other automated coagulation analyzer, performances and stability data must be validated by user.

CALIBRATION

REF 775100: **BE Cal Ref** Reference Plasma for calibration of coagulation tests
Traceable to SSC/ISTH Secondary Coagulation Standard NIBSC code: SSCLOT4.
Follow the Factor X calibration procedure of the analyzer

CALCULATION

Results are expressed in % according to the calibration curve by the analyzer.

QUALITY CONTROL

REF 773100 BE Trol 1 and REF 773101 BE Trol 2
Controls are required for checking the accuracy and reproducibility of the results.
The control intervals should be adapted to each laboratory's individual requirements.
Values obtained should fall within the defined limits.
Follow the applicable government regulations and local guidelines for quality control.

PERFORMANCES

The within run and between run studies were performed with normal and abnormal plasma on Thrombolyzer Compact X:

Within Run N = 20	level 1	level 2
Mean %	93	33
S.D. %:	2.4	1.9
C.V. % :	2.6	5.7

Between Run N = 20	level 1	level 2
Mean%	97	57
S.D. %:	5.5	3.4
C.V. % :	5.7	6.0

Linearity Range: from 10 % (QL) to 110%

Interferences (Thromboplastin low ISI)**:**

Lipids	No interference up to 731mg/dL of triglycerides
Haemoglobin	No interference up to 258 µmol/L
Total Bilirubin	Negative interference from 228 µmol/L
Low molecular weight Heparin	No interference up to 0.114 IU anti Xa
Non-fractioned Heparin	No interference up to 0.038 IU anti Xa

Other substances may interfere with the results (see § Limits)

Calibration Stability:
Make a new calibration when changing reagent batch, if quality control results are found out of the established range and after maintenance operations.

REFERENCES

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(2) *CAEN J., LARRIEU M-J., SAMAMA M.: "L'hémostase, methods d'exploration et diagnostic pratique" Paris, L'Expension scientifique, **153**, 347, 1975*
(3) *GJOANNES H., FAGERHOL M.K.: "Studies on coagulation and fibrinolysis in pregnancy" Acta Obstet. Gynecol. Scand., **54**, 363-367, 1975*
(4) *YOUNG D.S., Effect of Drugs on Clinical laboratory Tests, 4th Ed. (1995) p.3-254 à 3-257*
(5) *BEZEAUD A., GUILLIN M-C., OLMEDA F., QUINTANA M., GOMEZ N.: "Prothrombin Madrid: a new family of abnormality of prothrombin" Thromb. Res., **16**, 47-58, 1979*
(6) *ANDREW M., PAES B., MILNER R., JOHNSTON M., MITCHELL L.? TOLLEFSEN D.M., POWERS P.: "Development of the human coagulation system in the full-term infant" Blood, 70, 165-172, 1987*
(7) *SAMAMA M., CONARD J., HORELLOU M.H., LECOMPTE T.: "Physiologie et exploration de l'hémostase". PARIS: DOIN, 81-82, 112-118, 1990*
(8) *SAMPOL J., ARNOUX D., BOUTIERE B.:"Manuel d'Hémostase" Paris: Editions scientifiques et médicales Elsevier,46-48, 364-366, 395-405, 1995*
(9) *NCCLS Document H21-3: "Collection, transport and processing of blood specimen…" 3rd ed.**18**, 20, 1998*

Manufacturer	Use by	IVD	Temperature limitation	Catalogue number	See insert	Batch number	Store away from light	Sufficient for	Dilute with	Demineralized water	Biological hazard
		In Vitro Diagnostic		REF		LOT			→	H2O	

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