

BE Factor XI Deficient Plasma FXI

Immuno-depleted plasma for the determination of Factor XI activity in human plasma

REF 771611: DP (6 x 1 mL)

INTENDED USE

This reagent is designated for professional use in laboratory (semi-automated or automated method). It allows the quantitative determination of Factor XI activity in citrated human plasma to assess the status of coagulation factors normally found in blood.

This test is realized with Behnk reagents as follows:

- REF 771200, REF 771201: BE APTT K Kaolin + CaCl
- REF 771250, REF 771251: BE APTT SL Silica + CaCl
- REF 771700: BE Owren Buffer (Plasma dilution buffer)

PRINCIPLE ⁽¹⁾



The test is based on the measurement of clotting time in the presence of cephalin and activator with a method in which all factors are present in excess (supplied by Factor XI Deficient Plasma) except Factor XI, which is derived from the sample to be tested.

GENERALITIES ⁽²⁾

Factor XI is involved in the process of endogenous coagulation. The deficit in Factor XI described by Rosenthal 1953, appears following tooth avulsion or surgery.

These can be seen by phenomenon of haemorrhagic syndrome of variable intensity.

REAGENTS

	FXI	Deficient Plasma FXI	
			Human Origin
Freeze dried citrated plasma without Factor XI, removed by selective immune adsorption.			
According to 1272/2008 regulation, this reagent is not classified as dangerous.			

SAFETY CAUTIONS ^{(9) (10)}

- Refer to current Material Safety Data Sheet available on request or on www.behnk.de
 - 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, no test method can offer complete assurance that infectious agents are absent. All specimens or reagents from biological origin should be handled as potentially infectious, in accordance with good laboratory practices using appropriate precautions.
 - Waste disposal: Respect legislation in force in the country.
- Any serious incident that has occurred in connection with the device is notified to the manufacturer and the competent authority of the Member State in which the user and/or patient is based.

PREPARATION OF REAGENTS

Open the vial carefully and add exactly the volume of demineralised water stated on the label.
Cap the vial and let stand for 15 minutes at room temperature.
Mix gently by swirling and inverting before use, to homogenise the content.

STABILITY AND STORAGE

Unopened vials, stored away from light at 2-8 °C are stable until the expiry date stated on the label.

Stability after reconstitution:

- 2-8 °C 8 hours
- On board Stability (OBS)* 4 hours
- 15-25 °C 4 hours

* 18-22 °C

Do not use any reagent after expiry date.

SAMPLES COLLECTION AND HANDLING ^{(4) (5)}

Plasma from careful venipuncture with anticoagulant ratio of 1/10 (sodium 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 for 10 minutes at 3000 g and extract supernatant.

Stability:

- 4 h at 2-25 °C
- 15 days at -20 °C, 1 month at -80 °C (if quickly frozen. Defrost at 37 °C until complete defrosting).

LIMITS ^{(5) (6)}

Heparins and Thrombin inhibitors (hirudin, argatroban, ...) present in the specimen may decrease Factor XI activity in the specimen.

The presence of Lupus anticoagulants may lead to an underestimation of Factor XI 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
Automated or semi-automated coagulation analyzer
Demineralised water

REFERENCE RANGE ^{(7) (8)}

Plasma (adult): Usually 60-150 %

In the new born, the Factor XI level is low (30 to 50% of adult values).

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

QUALITY CONTROL

REF 773100: BE Trol 1; 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.

PROCEDURE

Semi-automated systems

Pre-incubate CC reagent (CaCl₂ 0.025 M) of the APTT reagent 15 min to reach a temperature of 37 °C.

Dilute specimens and controls: 1/10 in BE Owren Buffer.

Calibrators: prepare dilutions as indicated in § Calibration.

- | | |
|--|--------|
| • Diluted specimen (calibrators, controls, plasmas): | 100 µL |
| • Deficient Plasma: | 100 µl |
| • APTT reagent (mXI before use) | 100 µl |

Incubate for 180 sec at 37 °C

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|-----------------------|--------|
| • CC reagent (37 °C): | 100 µL |
|-----------------------|--------|

The automatic countdown timer will start immediately after CC reagent addition and stop when the clot is formed.

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.
- Other validated applications or proposal applications are available on request.

CALIBRATION

Use **REF** 775100: BE Cal Ref
Reference plasma traceable to WHO SSC/ISTH Secondary Coagulation Standard NIBSC code: SSCLOT4.

Semi-automatized method:

Prepare a calibration curve with dilution 1/10, 1/20, 1/40 and 1/80 in BE Owren Buffer. Measure in triplicate the clotting time of each level.

Automated method on Behnk Thrombolyzer series:

Perform a calibration with BE Cal Ref using automatic dilutions indicated in the specific application.

CALCULATION

Results are expressed in % of Deficient Factor according to the calibration curve.

PERFORMANCES

The studies were performed on Thrombolyzer Compact X.

Precision:

Within run N = 20	Level 1	Level 2	Between run N = 20	Level 1	Level 2
Mean (%)	129	50	Mean (%)	125	59
S.D. (%)	5.1	1.9	S.D. (%)	7.8	3.7
C.V. %	4.0	3.7	C.V. %	6.3	6.3

Detection limit: equivalent to 8 % of Factor XI

Measuring Range: from 15 % (QL) to 240 %

Interferences (APTT Silica, sec):

Turbidity	No interference up to 731 mg/dL of Triglycerides
Bilirubin	Positive interference from 124 µmol/L
Hemoglobin	No interference up to 261 µmol/L

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) SAMPOL, J., ARNOUX D., BOUTIERE B. : « *Manuel d'Hémostase* » Paris : Editions scientifiques et médicales Elsevier, 48, 359-361, 1995
- (3) BRANDT J.T., TRIPLETT D.A., ROCK W.A., BOVILL E.G., ARKIN C.F. : « *Effect of lupus anticoagulant on the activated partial thromboplastin time* » Arch. Pathol. Lab. Med., 115, 109-114, 1991
- (4) WOODHAMS B., GIRARDOT O., BLANCO M.J., COLESSE G., GOURMELIN Y. : "Stability of coagulation proteins in frozen plasma" *Blood Coag. Fibrinolysis*, 12, 229-236, 2001
- (5) CLSI Document H21-A5: "Collection, transport, and processing of blood specimens for testing plasma-based coagulation assays and molecular haemostasis assays; approved guideline". Fifth edition, 28, 5, 2008
- (6) YOUNG D.S., *Effect of Drugs on Clinical laboratory Tests*, 4th Ed. (1995) p.3-254 à 3-257
- (7) CAEN J., LARRIEU M.J., SAMAMA M. : « *L'hémostase. Méthodes d'exploration et diagnostic pratique* ». Paris : L'expansion scientifique, 1975.
- (8) 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, 1, 165-172, 1987
- (9) Occupational Safety and Health Standards; Bloodborne pathogens (29CFR1910.1030) Federal Register July 1, (1998) ; 6, p.267-280
- (10) Directive du conseil de l'Europe (90/679/CEE) J. O. de la communauté européenne n°L374 du 31.12.1990, p.1-12

| = Significant modifications

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Manufacturer	Expiry date	In Vitro Diagnostic	Temperature limitation	Catalogue number	See insert	Batch number	Store away from light	Sufficient for	Dilute with	Demineralized water	Biological hazard

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