

Precision in Hemostasis



BE Factor XI Deficient Plasma EXI

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

| 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

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

REAGENTS



Deficient Plasma FXI



Freeze dried citrated plasma without Factor XI, removed by selective immune adsorption

Human Origin

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.

REF 771611: DP (6 x 1 mL)

| 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:

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

* 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

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

| 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.

OUALITY 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

I 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 μΙ Deficient Plasma: 100 µl APTT reagent (mXI before use) 100 µl

Incubate for 180 sec at 37 °C

CC reagent (37 °C):

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.



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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
Mean (%)	129	50
S.D. (%)	5.1	1.9
C.V. %	4.0	3.7

Between run N = 20	Level 1	Level 2
Mean (%)	125	59
S.D. (%)	7.8	3.7
C.V. %	6.3	6.3

Detection limit: equivalent to 8 % of Factor XI **Measuring Range**: from 15 % (OL) to 240 %

Interferences (APTT Silica, sec):

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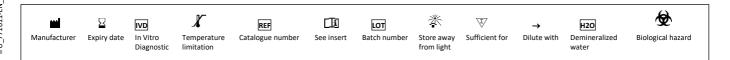
Other substances may interfere with the results (see § Limits)

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.

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I = Significant modifications



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