CE
In Vitro
Diagnostic

Behnk Elektronik

# BE Factor XII Deficient plasma

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

REF 771612: DP (6 x1 mL)

## PRINCIPLE [1]

Measurement of clotting time in the presence of cephaline and activator and the deficient plasma FXII in which all the factors are present in excess except of Factor XII which is derived from the sample being tested.
This test is determined with BE 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)

## CLINICAL SIGNIFICANCE [2] [3] [4] [5]

Factor XII is involved at different stages:

- In the endogenous coagulation pathway
- In relation with Kallikrein in case of inflammation
- In fibrinolysis

There are pathological changes in the FXII in the following cases:

- In congenital deficits (autosomal recessive), the rate of Factor XII varies from 15 % to 80 % in heterozygotes and less than 1 % in Homozygotes.

Factor XII deficiency is not accompanied by hemorrhagic syndromes, which suggests that there is another mechanism substituting to the activation of Factor XII. It has not been demonstrated that this deficit increases risks of thrombosis.

## REAGENTS

DP **FXII** Deficient Plasma FXII

Human Origin

Freeze dried plasma free of Factor XII 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 [6]

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

## LIMITS [7] [8]

Anticoagulants present in the specimen may interfere with Factor XII measured activity.
The presence of Lupus anticoagulants may lead to an under-estimation of Factor XII 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 [9][10][11]

- Plasma (adult): Usually between 60 % and 150 %

Factor XII is lower in newborn (50% less of the adult values).
Factor XII values may be twice to three times higher than normal (200 to 300 %) after strenuous physical exercises.
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
This Standard is traceable to SSC/ISTH Secondary Coagulation Standard NIBSC code: SSCLOT4.
Follow the Factor VIII 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 on normal and abnormal plasma on Thrombolyzer Compact X:

| Within Run N = 20 | level 1 | level 2 |
|---|---|---|
| Mean % | 143 | 84 |
| S.D. %: | 5.7 | 5.0 |
| C.V. % : | 4.0 | 5.9 |

| Between Run N = 20 | level 1 | level 2 |
|---|---|---|
| Mean % | 104 | 54 |
| S.D. %: | 7.2 | 6.4 |
| C.V. % : | 7.0 | 11.7 |

**Linearity Range:** from 25% (QL) to 100%

**Interferences** (APTT K)**:**

| | |
|---|---|
| Lipids | No interference up to 731 mg/dL of triglycerides |
| Haemoglobin | No interference up to 261 µmol/L |
| Total Bilirubin | No interference up to 133 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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| Manufacturer | Use by | In Vitro Diagnostic | Temperature limitation | Catalogue number | See insert | Batch number | Store away from light | Sufficient for | Dilute with | Demineralized water | Biological hazard |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | IVD | | REF | | LOT | | Σ | → | H2O | |


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