CE
In Vitro
Diagnostic

Behnk Elektronik

BE Factor II Deficient plasma

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

REF 771602: DP (6 x1 mL)

PRINCIPLE [1]

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

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

CLINICAL SIGNIFICANCE [2] [4] [6]

Factor II (prothrombin) is a single chain polypeptide molecule consisting of 2 parts:
- C-terminal part (Thrombin)
- N-terminal part

A Factor II deficiency has been observed in case of:
- Isolated deficiency (Congenital deficiency, dysprothrombinemia, acquired deficiency associated to Factor II inhibitors)
- Acquired deficiency associated with deficiencies of other coagulation factors:
  - Vitamin K antagonist therapy, hypovitaminosis K by nutritional intake deficiency, disorders in absorption or metabolism of Vitamin K (hemorrhagic disease of newborn, cholestasis, treatments with antibiotics).
  - Liver diseases: cirrhosis, hepatitis (during hepatitis, comparison of Factor II and Factor V level is relevant for diagnosis and prognosis).
  - Disseminated intravascular coagulation (DIC).

REAGENTS

DP	**FII**	Deficient Plasma FII	Human Origin

Freeze dried plasma free of Factor II 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 [5]

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 20-25 °C, 8 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 [3]

Thrombin inhibitors (hirudin, argatroban, …) present in the specimen may decrease Factor II 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 [7]

- Plasma (adult) : Usually > 70 %

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 II 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 %	89	37
S.D. %:	3.0	1.0
C.V. % :	3.8	1.8

Between Run N = 20	level 1	level 2
Mean %	93	54
S.D. %:	5.5	2.9
C.V. % :	5.9	5.3

Linearity Range: from 10 % (QL) to 100 %

Interferences (Thromboplastin low ISI)**:**

Lipids	No interference up to 450 mg/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

(1) *SOULIER J.P., LARRIEU M-J.: Sang.* ***23****, 7, 549-559, 1952*
(2) *FAVRE-GILLY J., BELLEVILLE J., CROIZAT P., REVOL L.: Cah. Méd. Lyonnais,* ***43****, 28, 2611-2628, 1967*
(3) *YOUNG D.S., Effect of Drugs on Clinical laboratory Tests, 4th Ed. (1995) p.3-254 à 3-257*
(4) *CAEN J., LARRIEU M-J., SAMAMA M.: "L"hémostase, methodes d'exploration et diagnostic pratique" Paris, L'Expension scientifique,* ***153****, 347, 1975*
(5) *GJOANNES H., FAGERHOL M.K.: Acta Obstet. Gynecol. Scand.,* ***54****, 363-367, 1975*
(6) *BILAND L., DUCKERT F., PRISENDER S., NYMAN D.:Trhomb. Haemostasis,* ***39****, 646-656, 1978*
(7) *BEZEAUD A., GUILLIN M-C., OLMEDA F., QUINTANA M., GOMEZ N.: Thromb. Res.,* ***16****, 47-58, 1979*

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			→	H2O	

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