CE XXXX IVD

Precision in Hemostasis

Behnk Elektronik

BE Factor II Deficient Plasma FII

Auxiliary reagent (human citrated plasma) for the quantitative determination of Factor II activity in human citrated plasma

REF 771602: DP (6 x 1 mL)

| INTENDED USE

Freeze dried citrated human plasma from which Factor II has been removed by selective immuno-adsorption.
Suitable for use with manual procedure on semi automated coagulometer, or on automated coagulation analyzer, it is an auxiliary reagent for the *in vitro* quantitative determination of Factor II in human citrated plasma using BEHNK reagents for Prothrombin Time (PT) measurements as follows:
REF 775100: BE Cal Ref (Reference plasma for calibration)
REF 771100, REF 771101: BE PT LI Thromboplastin low ISI
REF 771150, REF 771151: BE PT HI Thromboplastin high ISI
REF 771700: BE Owren Buffer (Plasma dilution buffer)
The assay is intended as an aid in the laboratory investigation of coagulation abnormalities and for characterization of coagulation factor activity. Results must be interpreted in conjunction with clinical findings and other laboratory tests. For clinical laboratory use by healthcare professionals.

| PRINCIPLE [1][4]

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

| GENERALITIES [2] [4] [6] [8] [9] [10] [11] [16]

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 the following cases:
- Isolated deficiency:
  - Congenital deficiency (very rare) and dysprothrombinemia
  - Acquired deficiency associated to Factor II inhibitors
- Acquired deficiency associated with deficiencies of other coagulation Factors:
  - Vitamin K antagonist therapy
  - Hypovitaminosis K: 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

Freeze dried human citrated plasma

According to (EC) 1272/2008 regulation, this reagent is not classified as dangerous.

SAFETY CAUTIONS

- Refer to current Safety Data Sheet (SDS) 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.
Add exactly the volume of demineralized 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 homogenize 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:
- 18-25°C 4 hours
- On board Stability (OBS)* 4 hours

* 16-22°C,
Do not use any reagent after expiry date.

SAMPLES COLLECTION AND HANDLING [5] [13-15]

Plasma from careful venipuncture with anticoagulant ratio of 1/10 (trisodium citrate anticoagulant solution 0.109 M, *i.e.* 3,2%). Mix immediately the blood with anticoagulant.
Avoid drawing with a syringe that could result in the formation of micro-clots.
Centrifuge for 15 minutes at 2000-2500 g and extract supernatant.
Storage in plastic tube: 4 h at 15-25°C, 8 h at 2-8°C, 15 days at -20°C*, 1 month at -80°C*.
*If quickly frozen; thaw plasmas at 37°C until complete thawing.

Caution: if the same plasma is used for testing Factor VII, do not store 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
Automated or semi-automated coagulation analyzer
Demineralized water

| REFERENCE RANGE [7]

Plasma (adult): Usually > 70 %

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

Manual method on semi-automated systems
Pre-incubate PT reagent (Thromboplastin) 15 min to reach a temperature of 37 °C and mix gently before use.
Dilute samples and controls: 1/10 in BE Owren Buffer.
Calibrators: prepare dilutions as indicated in § Calibration
- Diluted Plasma (calibrators, controls, plasmas): 100 µL
- Deficient Plasma: 100 µl

Incubate for 120 sec at 37 °C
- Thromboplastin (37 °C): 200 µL

The automatic countdown timer will start immediately after Thromboplastin 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). These data are valid for all instruments in the Thrombolyzer series.
- With manual procedure and on other automated coagulation analyzer, performances and stability data must be validated by user.

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CALIBRATION [12]

Use REF 775100: BE Cal Ref

Reference plasma traceable to SSCLOT5, non WHO SSC/ISTH Secondary Coagulation Standard from NIBSC.

Manual method on semi-automated analyzer: 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: Repeatability (Within run) and Reproducibility (Between run)

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

Detection limit: equivalent to 6 % of Factor II

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

Interferences (PT LI, sec):

Turbidity	No interference up to 450 mg/dL of Triglycerides
Low Molecular weight heparin	No interference up to 0.114 IU anti Xa
Unfractionated heparin	No interference up to 0.038 IU anti Xa
Total Bilirubin	Negative interference from 228 µmol/L
Hemoglobin	No interference up to 258 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.

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(15) *CLSI Document H21-A5: "Collection, transport, and processing of blood specimens for coagulation test and general performance of coagulation assays; approved guideline". Fifth Edition, 20, 5, 2008.*

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| = Significant modifications

IFU_771602-EN_V03_20260810

Table of symbols

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
		IVD		REF		LOT		Σ	→	H_2O	

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