CE
In Vitro
Diagnostic

Behnk Elektronik

BE FIB Thrombin Kaolin + Buffer

Reagent for quantitative determination of Fibrinogen (FIB) in human plasma

REF 771300: RE (5 x 2 mL), BU (2 x 15 mL)
REF 771301: RE (10 x 5 mL), BU (8 x 15 mL)

PRINCIPLE [4][6]

Method according to Clauss
In the presence of an excess of thrombin, the time of formation of the fibrin clot in the plasma (pre-diluted) is reversely proportional to the amount of fibrinogen in the sample. The clotting time is measured at 37 °C.

CLINICAL SIGNIFICANCE [1] [2]

Fibrinogen is a glycoprotein (340 KDa) synthesised by liver.
The concentration of fibrinogen is increased in infections, estrogens ingestion, tissue necrosis, obesity, pregnancies and diabetes. An increase of fibrinogen is also involved as a risk factor for coronary artery disorders and cerebrovascular diseases.
A decrease of fibrinogen in plasma is associated with:

- Liver diseases (cirrhosis, jaundice)
- Fibrinolysis or disseminated intravascular coagulation (DIC)

REAGENTS

RE **FIB** Thrombin Reagent
Lyophilized Thrombin of animal origin

BU **FIB BU** Buffer for dilution of plasma
Hepes pH 7.35, stabilizer

SAFETY CAUTIONS

Behnk reagent kits are designated for professional in vitro diagnostic use.
Good Laboratory Practices must be applied during use of reagents, reference or control plasmas, and human samples and should be handled as potentially infectious.
For further information, Material Safety datasheet is available upon request.
Dispose of waste in accordance with the local regulations.

PREPARATION OF REAGENTS

RE: Reconstitute the lyophilisate with the amount of distilled water indicated on the label. Cap the vial and mix gently until complete dissolution.
BU: Ready for use.

STABILITY AND STORAGE

Unopened vials stored at 2-8 °C are stable until the expiry date stated on the label.
RE: After reconstitution the working reagent is stable at least 7 days at 2-8 °C or 24 hours at room temperature.
BU: Once opened, if stored at 2-8 °C and free from contamination, content is stable until the expiry date stated on the label.
Do not use any reagent after expiry date.

SAMPLES COLLECTION AND HANDLING [2] [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.
The specimen is stable 4 hours after collection, at room temperature (15-25 °C).
Collection on Citrate Hepes tube increases the sample stability to 8 hours.

LIMITS [2] [3] [8]

For a more comprehensive review of factors affecting this assay, refer to the publication of Young D.S.

MATERIAL REQUIRED BUT NOT PROVIDED

General laboratory equipment
Automatic coagulation analyzer or semi-automated analyzer
Distilled or demineralised water for reconstitution of reagent
REF 050813: Magnetic stirrers 8 x 1.5 mm, for Behnk Thrombolyzer series.
REF 771350: FIB BU (16 x 15 mL) Buffer for dilution of plasma (add. needed for Manual method and semi-automated method).

EXPECTED VALUES [1] [2]

The normal range for fibrinogen in adult plasma is usually 200-400 mg/dL.

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

Let stand the RE reagent reach room temperature (18-25 °C).

Manual method on semi-automated analyzer
Dilute samples and controls: 1/10 in BU Buffer.
Calibrators: prepare dilutions as indicated in § Calibration.

- Diluted Plasma (calibrators, controls, plasmas): 200 µL

Incubate for 2 minutes at 37 °C

- RE Reagent (mix before use): 200 µL

The automatic countdown timer will start immediately after RE 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 traceable to WHO International Standard NIBSC Code: 98/612
Manual method on semi-automated analyzer: Prepare a calibration curve with dilution 1/5, 1/10, 1/15 and 1/20 in BU 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

Manual method on semi-automated analyzer
Enter the mean of the clotting time found for each dilution of BE Cal Ref, and the corresponding Fibrinogen concentration (mg/dL) in the system. Fibrinogen concentration will be calculated automatically according to calibration curve.
Automated method on Behnk Thrombolyzer series: Fibrinogen concentration (mg/dL) will be calculated automatically according to calibration curve.

PERFORMANCES

The within run and between run studies were performed with normal and abnormal plasma on Thrombolyzer Compact X:

Within run ***N = 20***	Normal Plasma	High Plasma
Mean (mg/dL)	145	278
S.D. (mg/dL)	4.2	3.6
C.V. %	2.9	1.3

Between run ***N = 20***	Normal Plasma	High Plasma
Mean (mg/dL)	152	307
S.D. (mg/dL)	3.4	10.4
C.V. %	2.3	3.4

Linearity Range: between 99.5 and 871 mg/dL
Comparison with commercially available reagent, same method: 173 plasmas between 80 mg/dL and 1109 mg/dL were tested:
y = 1.0065 – 25.597 r= 0.9875
Interferences:

Turbidity	No interference up to 731 mg/dL triglycerides
Low Molecular weight heparin	No interference up to 2 IU anti Xa
Unfractionated heparin	Negative interference from 1.66 UI anti Xa
Bilirubin	No interference up to 496 µmo/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

(1) *TIETZ N.W. Text book of clinical chemistry, 3rd Ed. C.A. Curtis, E.R. Ashwood, W.B. Saunders (1999) p. 1133, 1145, 1740-41, 1813, 1846.*
(2) *Clinical Guide to Laboratory Test, 4th Ed., N.W. TIETZ (2006) p.404-405*
(3) *YOUNG D.S., Effect of Drugs on Clinical laboratory Tests, 4th Ed. (1995) p.3-260 à 3-261*
(4) *Von Clauss A. acta haematologica 1957. 17, 237-246.*
(5) *Destaing F-Duzer A. Pathologie et Biologie 1960, 8, 1615.*
(6) *Hurlet A.-Josso F: pathologie biologie 1972, 20, 3-4,165-173*
(7) *Caen-Larrieu-Samama : l'hemostase, 1968, expansion scientifique.*
(8) *Technique en hématologie, Flammarion médecine-sciences, 2nd éd . 1978, p.184-18*

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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