CE IVD

Precision in Hemostasis

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)

| INTENDED USE

This reagent is designated for professional use in laboratory (semi-automated or automated method). It allows the quantitative determination of fibrinogen in human plasma.

PRINCIPLE [5] [6]

| Method based on von Clauss et al. studies, validated by Destaing F. et al.
When an excess of thrombin is present, the fibrinogen is transformed into fibrin with the formation of a detectable clot.

GENERALITIES [1] [2]

Fibrinogen is the principal plasma protein affecting the sedimentation rate. Fibrinogen concentration raises several folds during inflammation or tissue necrosis. Oestrogen ingestion, diabetes, obesity or pregnancy may also induce increased levels. Evidence as shown that plasma levels above the reference range constitute a significant independent risk factor for both coronary artery and cerebrovascular diseases.
A decreased fibrinogen level in plasma is generally associated with a disturbance of liver metabolism (cirrhosis, icterus...) or with fibrinolysis and DIC (disseminated intravascular coagulation).

REAGENTS

RE **FIB** Lyophilized Reagent
Calcium Thrombin from animal origin
Kaolin (in slight quantity to optimize optical detection)

BU **FIB BU** Dilution buffer for plasmas
HEPES 0.02 M, pH 7.35
Anticoagulant (citrate)
Heparin inhibitor
According to 1272/2008 regulation, these reagents are not classified as dangerous.

SAFETY CAUTIONS

- Refer to current Material Safety Data Sheet available on request or on www.behnk.de
- Verify the integrity of the contents before use.
- Waste disposal: Respect legislation in force in the country.
- All specimens or reagents of biological origin should be handled as potentially infectious. 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

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 away from light at 2-8 °C are stable until the expiry date stated on the label.

RE: Stability after reconstitution:

- 2-8 °C 7 days
- On board Stability (OBS)* 24 hours
- Laboratory mode** 5 days
- 15-25 °C 24 hours

* 18-22 °C, stirred
** Laboratory mode = 8 hours on board; 16 hours well capped in the original vial at 2-8 °C.

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 (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 10 minutes at 2500 g.
Fibrinogen is stable in plasma for:

- 4 hours at room temperature, 18 months at -70°C

LIMITS [1] [2] [3] [8]

Fibrinogen degradation products (FDP) may lead to under-estimations. Then re-assay at a higher dilution level.
A specific heparin inhibitor present in diluting buffer allows the test of fibrinogen in heparinised plasmas.
For a more comprehensive review of factors affecting this assay, refer to the publication of Young D.S. and Norbert W. Tietz.

MATERIAL REQUIRED BUT NOT PROVIDED

General laboratory equipment
Automated or semi-automated coagulation 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).

REFERENCE RANGE [1] [2]

Clauss Method Fibrinogen (mg/dL) 150 - 400
Reference range may depend on the reagent-instrument combination.
Each laboratory should establish its own reference 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

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
Reference plasma traceable to WHO SSC/ISTH Secondary Coagulation Standard NIBSC code: SSCLOT4.

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.

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CALCULATION [6]

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 on Thrombolyzer Compact X.

Precision:

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

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(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.*

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(8) *Technique en hématologie, Flammarion médecine-sciences, 2nd éd . 1978, p.184-18*

| = Significant modifications

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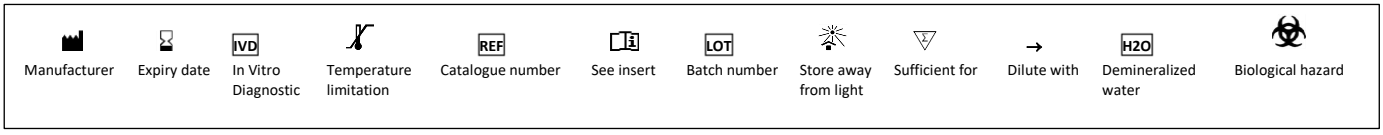

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