CE
In Vitro
Diagnostic

Behnk Elektronik

BE Factor VIII Deficient plasma

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

REF 771608: DP (6 x1 mL)

PRINCIPLE [1] [3]

Measurement of clotting time in the presence of cephaline and activator and the deficient plasma FVIII in which all the factors are present in excess except of Factor VIII 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 [5] [6] [8] [9]

Pathological changes in the FVIII (antihemophilic factor A) may occur in the following cases:

- Haemophilia A:

The seriousness of haemophilia is assessed on the basis of the FVIII:C concentration.

Severe hemophilia	< 0.1% (0.01 IU/mL)
Moderate hemophilia	1-5% (0.01 - 0.05 IU mL)
Hemophilia attenuated	5-40% (0.05 - 0.40 IU/mL)

- Von Willebrand disease, more or less pronounced decrease in the rate of FVIII.

The elevation of the FVIII rate is a risk factor for thrombosis, including venous thrombosis. This elevation is observed in case of thromboembolitic complications, coronary atherosclerosis, renal failure, diabetes, inflammatory syndrome...

There is a decrease in FVIII in the presence of inhibitor of FVIII.

REAGENTS

DP **FVIII** Deficient Plasma FVIII

Human Origin

Freeze dried plasma free of Factor VIII 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 [10]

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

LIMITS [4] [7]

Heparins and Thrombin inhibitors (hirudin, argatroban …) present in the specimen to be tested may lead to under-estimation of the Factor VIII activity in the specimen.
The presence of Lupus anticoagulants may lead to an under-estimation of Factor VIII 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 [2] [5]

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

FVIII:C levels may be increased in case of use of birth control pills, during pregnancy, during Vit. K antagonist and corticoid therapies, physical exercises or stress.
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 with normal and abnormal plasma on Thrombolyzer Compact X:

Within Run N = 20	level 1	level 2
Mean %	127	52
S.D. %:	6.6	2.9
C.V. % :	5.2	5.6

Between Run N = 20	level 1	level 2
Mean %	100	43
S.D. %:	9.0	2.6
C.V. % :	9.0	6.2

Linearity Range: from 20% (QL) to 135 %

Detection limit: 6 %

Interferences (APTT SL)**:**

Lipids	No interference up to 731 mg/dL of triglycerides
Haemoglobin	No interference up to 261 µmol/L
Total Bilirubin	Negative interference from 124 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) *SOULIER J.P., LARRIEU M-J.: Sang.* ***24****, 3, 205-215, 1953*
(2) *CAEN J., LARRIEU M-J., SAMAMA M.: Paris, L'Exp. Scient., 181, 1975*
(3) *ZACHARSKIL.R. ROSENSTEIN R.: "Standardisation of the one stage assay for F.VIII (antihemolytic factor". Am. J. Clin. Pathol.,* ***70****, 280-286, 1978*
(4) *YOUNG D.S., Effect of Drugs on Clinical laboratory Tests, 4th Ed. (1995) p.3-254 à 3-257*
(5) *SAMPOL J., ARNOUX D., BOUTIERE B.: "manuel d'hemostase" Paris: Editions scientifiques et médicales ELSEVIER, 311-336, 379-381, 552-553, 608-609, 1995.*
(6) *KAMPHUINSEN P.W., EIKENBOOM J.C.J., BERTINA R.M.:"Elevated F.VIII levels and the risk of thrombosis". Artheioscl. Thromb. Vasc. Biol.,* ***21****, 731-738, 2001*
(7) *BRANDT J.T., TRIPLETT D.A., ROCK W.A., BOVILL E.G., ARKIN C.F.: "Effect of lupus anticoagulants in activated partial thromboplastin time". Arch. Pathol. Lab. Med.,* ***115****, 109-114, 1991*
(8) *WHITE G.C., ROSENDAAL F., ALEDORT L.M., LUSHER J.M., ROTSHILD C., INGERSLEV J.: "Definition in haemophilia-Recommendation of the Scientific Subcommittee on factor VIII and factor VIII of the Scientific and Standardization Committee of the international society on Thrombosis and haemostasis"Thromb. Haemostasis,* ***85****, 560, 2001*
(9) *FRESSINAUD E., MEYER D.: "La maladie de Willebrand: du diagnostic au traitement". Rev. Prat.,* ***55****, 2209-2218, 2005*
(10) *CLSI Document H21-A5: "Collection, transport, and processing of blood specimens for testing plasma-based coagulation assays and molecular haemostasis assys; approved guideline". Fifth edition,* ***28****, 5, 2008*

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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