

BE Factor IX Deficient plasma

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

PRINCIPLE ⁽¹⁾

Measurement of clotting time in the presence of cephaline and activator and the deficient plasma FIX in which all the factors are present in excess except of Factor IX 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 ^{(2) (3) (4) (7) (8)}

Decrease of FIX activity is associated with:

- Hemophilia B

The severity of hemophilia depends on FIX:C level:

FIX Concentration	Type of hemophilia
< 1%	Severe
1 to 5%	Moderate
5 to 25%	Mild

- Hypovitaminosis K
 - AVK Treatment
 - Nutritional intake deficiency, disorders in absorption or metabolism of vitamin K (hemorrhagic disease of the newborn, cholestasis, treatments with antibiotics)
- Liver diseases: cirrhosis, hepatitis
- Decrease of the level of FIX in the presence of FIX inhibitor.

REAGENTS

DP FIX Deficient Plasma FIX



Human Origin

Freeze dried plasma free of Factor IX 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 ⁽⁹⁾

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 ^{(5) (6)}

Heparins and Thrombin inhibitors (hirudin, argatroban ...) present in the specimen to be tested may lead to under-estimation of the Factor IX activity in the specimen.

The presence of Lupus anticoagulants may lead to an under-estimation of Factor IX 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⁾

- Plasma (adult): Usually between 60 % and 150 %
Each laboratory should establish its own normal ranges for the population that it serves

REF 771609: DP (6 x1 mL)

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 IX 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	Between Run N = 20	level 1	level 2
Mean %	158	56	Mean %	132	47
S.D. %:	8,2	2,8	S.D. %:	9,4	3,3
C.V. % :	5,4	5,0	C.V. % :	7,1	7,0

Linearity Range: from 12 % (QL) to 200 %

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 114 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'Expansion scientifique, 181, 1975
- (3) ORSTAVIK K.H., LAAKE K.: "Factor IX in warfarin treated patients". Thromb. RES., **13**, 2, 207-218, 1978
- (4) PANICUCCI F., SAGRIPANTI A., CONTE B., PINORI E., VISPI M., LESCHINI L.: "Characterization of heterogeneity of haemophilia B for detection of carriers". Haemostasis, **9**, 310-318, 1980.
- (5) 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
- (6) YOUNG D.S., Effect of Drugs on Clinical laboratory Tests, 4th Ed. (1995) p.3-254 à 3-257
- (7) SAMPOL J., ARNOUX D., BOUTIERE B.: "manuel d'hemostase" Paris: Editions scientifiques et médicales ELSEVIER, 311-336, 379-381, 552-553, 608-609, 1995.
- (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 IX of the Scientific and Standardization Committee of the international society on Thrombosis and haemostasis" Thromb. Haemostasis, **85**, 560, 2001
- (9) CLSI Document H21-A5: 3Collection, transport, and processing of blood specimens for testing plasma-based coagulation assays and molecular haemostasis assays; approved guideline". Fifth edition, **28**, 5, 2008

