BioCELIN
(**APTT REAGENT**)

REF . APTT-0503 (5 X 3 ml)

Intended Use

NSBioTec BioCelin reagent is intended for partial Thromboplastin **(APTT)** determination using ellagic acid , as an activator.

BACKGROUND

The arrest of bleeding depends upon primary platelet plug formed along with the formation of a stable fibrin clot . Formation of this clot involves the sequential interaction of a series of plasma proteins in a highly ordered and complex manner and also in the interaction of these complexes with blood platelets and materials released from the tissues .
Activated Partial Thromboplastin Time (**APTT**) is prolonged with a deficiency of coagulation factors of the intrinsic pathway of the human coagulation mechanism such as factor XII , XI , IX , VIII, X , V , II , and Fibrinogen .
Determination of APTT helps in estimating abnormality in most of the clotting factors of the intrinsic pathway and is also a sensitive procedure for generating heparin response curves for monitoring heparin therapy .

ASSAY PRINCIPLE

Cephaloplastin activates the coagulation factors of the intrinsic pathway of the coagulation mechanism in the presence of calcium ions. APTT is prolonged by deficiency of one or more of these clotting factors of the intrinsic pathway and in the presence of coagulation inhibitors like heparin .

REAGENT

BioCelin is a liquid ready to use activated cephaloplastin reagent for the determination of APTT. It is phospholipids preparation derived from rabbit brain with ellagic acid as an activator .

REAGENT STORAGE AND STABILITY

Store the reagent at 2 – 8 °C . **Never freez the reagent** . The reagent is stable up to the expiry date given on label when stored at 2 – 8 °C , **1 week** at 18 – 25 °C , **2 days** at 37 °C .

NOTE

1- Avoid exposure of the reagent to elevated temperature and contamination.
2- Immediately replace cap after use and store at recommended temperature.
3- Reagent contain 0.01 g/dl Thimerosal as a preservative .

SPECIMEN COLLECTION AND PREPARATION

No special prepartion of the patient is required prior to sample collection .Withdraw blood without doing venous stasis and avoid haemolysis . The veinpuncture must be a clean one and , if there is any difficulty , take a new syringe and needle and try another vein .
Mix exactly nine parts of freshly collected blood with one part of trisodium citrate (0.11mol/L, 3.2 %) . Centrifuge immediately for 15 minutes at 3000 rpm and transfer the plasma into a clean test tube .
Plasma must be tested within 3 hours of blood collection.

POOLED PLASMA

Prepare a fresh normal plasma pool (**FNP**) from at least five normal healthy donors and process as above . **Plasma must be tested within 3 hours of blood collection.**

ADDITIONAL REGENT

0.025 mol/L calcium chloride (available from NS BioTec)

PROCEDURE

1-Before use , the reagent should be mixed well by gentle swirling do not shake.
2- Aspirate from the reagent vial enough reagent for the immediate test requirement in extremely clean and dry test tube . Bring this reagent to room temperature before prewarming at 37 °C for testing procedure . The calcium chloride solution should be brought to 37 °C before use .
3-To 12 x 75 mm test tube , add 0.1 ml test plasma and 0.1 ml **BioCelin** Shake tube briefly to mix the reagent and plasma, place tube at 37 °C for 3 minutes .
4- Add forcibly o.1 ml prewarmed calcium chloride and simultaneously start stop watch . Shake tube briefly to mix contents , keep at 37 °C for 20 seconds.
5- Following 20 seconds incubation , remove the tube , gently tilt back and forth until a gel clot forms , stop the watch and ,record the time.
6- Repeat for a duplicate test using the same test plasma .
7- Find the average from the duplicate test values . This is the Activated Partial Thromboplastin Time (APTT of patient plasma)
8- Similarly repeat the steps 2-4 twice , and record values using **FNP** in place of test plasma (APTT of FNP) .

Calculation and reporting of results

a) The result may be reported directly in terms of the mean of the double determination of the APTT of the test plasma

OR

b) **as a ratio R as follows:**

$$R = \frac{\text{APTT of patient plasma (in seconds)}}{\text{APTT of FNP (in seconds)}}$$

Expected Values

Normal values are between 22-34 seconds .

Remarks

1- Each laboratory must establish his own normal population range as well as normal and abnormal range.
2- Clotting time of patients on anticoagulant therapy depends upon the type and dosage of anticoagulant and also the time lag between the specimen collection and the dose
3- Abnormalities of coagulation factor VII , factor XIII , and platelets are not detected by this method .
4- Platelet factor IV, a heparine-nutralising factor can be released due to platelet aggregation or damage. In order to prevent this phenomenon in vitro the specimen should be collected with a minimum of trauma.
5- Decrease in APTT time is observed in males under estrogen therapy and oral contraceptive administration in females.

REFERENCES

1-Biggs, R.ed.: Human Blood Coagulation , Haemostasis and Thrombosis , Blackwell Scientific Publications , Oxford , England , 1972.

2- Hoffmann , J.J.M.L and Neulendijk P.N.: Thrombos . Haemosta.(Stuttgard) 39 , 640 (1978)

	Consult Instruction for Use
	Caution Consult Accompanying Documents
IVD	In Vitro Diagnostic Medical Device
	Temperature Limitation
	Manufacturer
EC REP	Authorized Representative In The European Community
REF	Catalogue Number
LOT	Batch Code
	Use By

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