CE
In Vitro
Diagnostic

Behnk Elektronik

BE APTT K APTT Kaolin + CaCl2

Reagent for determination of activated partial thromboplastin time (APTT) in human plasma

REF 771200: AC (5 x 3 mL), CC (2 x 10 mL)
REF 771201: AC (8 x 10 mL), CC (8 x 10 mL)

PRINCIPLE [3] [4]

In presence of standardized amount of phospholipids (Cephalin), calcium chloride, and activator (kaolin), the factors of intrinsic coagulation system in citrated plasma are activated. The clotting time is measured.

CLINICAL SIGNIFICANCE [6] [7] [9]

The APTT is a screening coagulation test used for investigation of intrinsic coagulation pathway (factors XII, XI, IX, VIII, V, X, II and fibrinogen).
Except in the case of monitoring heparin therapy, APTT should not be made as a single test. It should be completed by clinical signs study and complementary tests
An abnormally prolonged APTT may be en countered in congenital or acquired deficiencies or other abnormal conditions. If associated with normal PT (Prothrombin Time), congenital deficiencies of coagulation factors (XII, XI, IX, VIII) should be explored. Acquired deficiencies or abnormal conditions which may lead to an increased APTT are: liver diseases, consumptive coagulopathy, circulating anticoagulants, heparin or oral anticoagulant therapy, treatment with thrombin inhibitors (hirudin, argatroban...)

REAGENTS

AC **APTT K** Reagent
Cephalin (rabbit cerebral tissues)
Activator (Kaolin)
CC **CaCl** Calcium chloride Solution

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

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

STABILITY AND STORAGE

Unopened vials stored at 2-8 °C are stable until the expiry date stated on the label.
AC: After reconstitution the working reagent is stable 21 days at 2-8 °C.
CC: Once opened, if stored at 2-8 °C and free from contamination, CC content is stable until the expiry date stated on the label. Discard any cloudy reagent.
Do not use any reagent after expiry date.

SAMPLES COLLECTION AND HANDLING [1] [8]

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 3 hours after collection, at room temperature (15-25 °C).
Patients under heparin anticoagulant therapy: run the assay within 1 hour following blood collection.

LIMITS [2] [4] [5]

Heparin, depending on its origin and composition (calcium or sodium salt) has a different influence on the sensitivity of the reagent.
Mishrahi et al. indicate an easy procedure to determine the sensitivity of the method used in each laboratory and to inform the clinician to optimize the dose.
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 or semi-automated analyzer
Distilled or demineralized water for reconstitution of reagent.
REF 050813: Magnetic stirrers 8 x 1.5 mm, for Behnk Thrombolyzer series.

PROCEDURE

Manual method on semi-automated systems:

- Plasma: 100 µL
- AC Reagent (mix before use): 100 µL

Mix and incubate for 180 sec at 37 °C.

- CC Reagent (37°C): 100 µL

The automatic Countdown timer will start immediately after CC 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

Results are expressed in seconds or ratio. The validity of the result depends on the accuracy of the time counting, the respect of reagent/specimen ratio and temperature.

CALCULATION [5]

Results may be expressed as follows:

- In seconds (Patient time and Reference normal plasma time)
- In ratio Patient time/Reference normal plasma time

Each laboratory should determine its Reference normal plasma time using a pool of normal patient specimens.

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.

EXPECTED VALUES [1]

Normal values (usually < 35 sec) may vary with local conditions.

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 (sec)	34.8	65.7
S.D. (sec)	0.44	0.77
C.V. %	1.25	1.18

Between run N = 20	Normal Plasma	High Plasma
Mean (sec)	36.6	62.4
S.D. (sec)	0.92	2.00
C.V. %	2.50	3.21

Comparison with commercially available reagent (same method):
192 plasmas located between 21.6 sec and 68.6 sec were tested:
y = 0.8515 x + 3.498 r= 0.9424

Interferences:

Total bilirubin	Positive interference from 133 µmol/L
Turbidity	No interference up to 731 mg/dL of triglycerides
Hemoglobin	No interference up to 261 µmol/L

Other substances may interfere with the results (see § Limits)

REFERENCES

(1) *Clinical Guide to Laboratory Test, 4th Ed., N.W. TIETZ (2006) p.46-47*
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(4) *Struver G.P., Bittner D.L. Am. J. Clin. Path. 1962, **38**, 473-481).*
(5) *Misrahi N., Manet L., Conard J., Samama M., Act. Pharm. Biol. Clin. 1981, **1**, 81-85.*
(6) *Langdell R.D., WAGNER R.H., BRINKHOUS K.M.: "Effects of antihemophilic factor on one-stage clotting tests". J. Lab. Clin. Med., **41**, 637-647(1953)*
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(8) *"Etude des différents paramètres intervenant dans les variables préanalytiques (revue de littérature) ». Sang Thromb. Vaiss., **10**, p.5-18 (1998)*
(9) *Samama M ., Conard J., Horellou M.H., Lecompte T. : « Physiologie et exploraion de l'hémostase » in « Manuel d'hémostase », J. Sampol, D. Arnoux, B. Boutière, Paris : Elsevier, 359-377,1995*

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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