CE IVD

Precision in Hemostasis

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)

| INTENDED USE

This reagent is designated for professional use in laboratory (semi-automated or automated method). It is used for the chronometric determination of the activated partial thromboplastin time in human plasma to investigate the intrinsic coagulation pathway and for monitoring patients on heparin therapy.

| PRINCIPLE [4]

BE APTT K reagent contains a standardised amount of cephalin (platelet substitute) and a Factor XII activator (Kaolin). The reaction medium in contact with the CaCl solution recalcifies the plasma and triggers the coagulation reaction. Kaolin offers the dual advantage of easy reading and shorter reading time.

| GENERALITIES [1]

Activated partial thromboplastin time (aPTT) is used to investigate the intrinsic coagulation pathway (factors XII, XI, IX, VIII, V, X, II and fibrinogen) with the exception of platelets.
The aPTT is mainly used for monitoring heparin therapy.
APTT is also used to detect congenital or acquired abnormalities related to one of the factors mentioned above.
A prolonged aPTT may require further investigation to relate it to a congenital or acquired abnormality.

REAGENTS

AC **APTT K** Reagent
Cephalin (rabbit cerebral tissues)
Activator (Kaolin)

CC **CaCl** Calcium chloride Solution

According to 1272/2008/CE 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

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 away from light at 2-8 °C are stable until the expiry date stated on the label.
AC: Stability after reconstitution:

- 2-8 °C 30 days
- On board Stability (OBS)* 10 days
- Laboratory mode** 30 days
- 15-25 °C 10 days

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

Do not use any reagent after expiry date.

| SAMPLES COLLECTION AND HANDLING [1] [7]

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 within 3 hours of sampling.
The specimen is stable 4 hours after collection, at room temperature (15-25 °C).
For patients on heparin, perform the test within one hour of blood collection.

LIMITS [1] [2] [4] [5]

| Traumatic venipuncture can contaminate the specimen with tissue thromboplastin and shorten the partial thromboplastin time.
A difficult draw may also interfere with the partial thromboplastin time used to monitor patients on heparin therapy by neutralising the effect of the heparin in the sample due to the release of platelet factor 4 (PF4).
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
Automated or semi-automated coagulation analyzer
Distilled or demineralized water for reconstitution of reagent.
REF 050813: Magnetic stirrers 8 x 1.5 mm, for Behnk Thrombolyzer series.

| REFERENCE RANGE [1] [5] [6]

The reference values vary according to the reagent-instrument combinations and local conditions (population, etc.).
In general, the low limit value is 20-25 sec and the high limit value < 35 sec.
Therefore, it is necessary for each laboratory to establish its own reference intervals on a panel of normal plasma.
In this case, the reference interval is equivalent to the mean +/- 2 standard deviations (+/-2 SD).
For example, on 58 normal plasmas tested, the average observed is 31.1 sec with a standard deviation of 1.6 sec.
The aPTT is normally prolonged in newborns, gradually decreases until it reaches adult values at about 6 months of age.

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

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 [4]

Results depend on the method used. The validity of the results depends on the correct timing, the correct reagent volume/specimen volume ratio and temperature.
Reference plasma: use normal human plasma from healthy individuals, men or women aged between 18 and 55, who are not taking any medication and blood donors.

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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
- Reference plasma, see § Calibration.

PERFORMANCES

The within run and between run studies were performed on Thrombolyzer Compact X.
Precision:

Within run N = 20	Level 1	Level 2	Level 3
Mean (sec.)	34.8	50.2	65.7
S.D. (sec.)	0.44	1.48	0.77
C.V. %	1.3	2.9	1.2

Between run N = 20	Level 1	Level 2	Level 3
Mean (sec.)	36.6	55.8	62.4
S.D. (sec.)	0.92	2.42	2.00
C.V. %	2.5	4.3	3.2

Comparison with commercially available reagent, same method: 193 plasmas located between 21.6 sec and 68.6 sec were tested:
y = 0.9852 x – 0.6654 r= 0.9827

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*
(2) *YOUNG D,S,, Effect of Drugs on Clinical laboratory Tests, 4th Ed, (1995) p,3-447 à 3-448*
(3) *Bell W,N,, Alton H,G,, Nature, 1954, **174**, 880-881,*
(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) *LEVIN HILLMAN C.R., LUSHER J.M.: "Determining the sensitivity of coagulation screening reagents: a simplified method". Lab. Med., 13, 3, 162-165, 1982*
(7) *"Etude des différents paramètres intervenant dans les variables préanalytiques (revue de littérature) ». Sang Thromb. Vaiss., 10, p.5-18 (1998)*

| = Significant modifications

IFU_771200-771201-EN_V03_20230601

Manufacturer	Expiry date	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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