CE IVD

Precision in Hemostasis

Behnk Elektronik

BE APTT K APTT Kaolin + CaCl2

Reagent for chronometric determination of Activated Partial Thromboplastin Time in human citrated 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

Reagent (Kaolin activator) and Calcium Chloride 0.025M solution for *in vitro* chronometric determination of Activated Partial Thromboplastin Time (APTT) in human citrated plasma.
Suitable for use with manual procedure on semi automated coagulation analyzer, or automated coagulation analyzer.
This device is intended for the evaluation of the function of the intrinsic pathway of the coagulation cascade (except platelets, Factor VII) and the monitoring of patients with heparin therapy.
It can also be used in conjunction with the relevant deficient plasmas, for the determination of the activity of coagulation Factors VIII, IX, XI and XII.
For clinical laboratory use by healthcare professionals.

PRINCIPLE [2] [3] [4]

BE APTT K reagent contains a standardized amount of cephalin (platelet substitute) and a Factor XII activator (Kaolin). The reaction medium in contact with the $CaCl_2$ solution recalcifies the plasma and triggers the coagulation reaction. Kaolin offers the dual advantage of easy reading and shorter reading time.

GENERALITIES [11]

A prolongation of the APTT happens in the following cases:
- Congenital Deficiencies
  - ✓ If the prothrombin time (PT) is normal, Factor VIII, IX, XI, XII may be Deficient.
  - ✓ If all these factors are normal, a deficiency in the following should be considered: prekallikrein (Fletcher factor) or HMW kininogen (Fitzgerald factor).
- Acquired Deficiencies and Abnormal Conditions
  - ✓ Liver diseases
  - ✓ Consumptive coagulopathy
  - ✓ Fibrinolysis
  - ✓ Circulating anticoagulants (LA type or circulating anticoagulant against a factor)
  - ✓ During heparin or oral anticoagulant therapy
  - ✓ Treatments with thrombin inhibitors (e.g., hirudin, argatroban, ...)

| REAGENTS

AC	**APTT K**	Reagent (freeze dried)
Cephalin (rabbit cerebral tissues)		2.5%
Kaolin		11.8%
Excipients (non active ingredients)		qsp 100%
CC	**APTT K**	$CaCl_2$
Calcium chloride in aqueous solution		0.025M

According to (EC) 1272/2008 regulation, these reagents are not classified as dangerous.

SAFETY CAUTIONS

- Refer to Safety Data Sheet (SDS) 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 lyophilizate with the amount of demineralized 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

* 16-22 °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] [8] [9] [10]

Careful venipuncture in conformity with recommendations for Haemostasis tests.
Citrated plasma:
Collect blood (9 parts) in 0.109 M (*i.e.,* 3.2 %) trisodium citrate anticoagulant (1 part).
Use collection tubes made of plastic or siliconized glass.
When monitoring heparin therapy, use preferably CTAD tubes to prevent heparin inactivation. Follow instructions of tube manufacturer.
Centrifuge within 1 hour after collection for 10 minutes at 2500 g.
Stability in plasmas:
- ✓ For 4 hours at 15-25°C

If, on heparin therapy:
- ✓ For 2 hours at 15-25°C (with Citrate anticoagulant)
- ✓ For 4 hours at 15-25°C (with CTAD tubes)

LIMITS [3] [5] [12-18]

Traumatic venipuncture may contaminate the specimen with tissue thromboplastin and shorten the APTT.
When monitoring heparin therapy, any release of platelet factor 4 (PF4) which is a potent inhibitor of heparin, represents a major source of error.
When using APTT assay to monitor unfractionated heparin therapy (UFH), it needs to consider factors and pre-analytical variables which may affect results. For more details refer to Performances file available on request.
Drugs: No interference was found at therapeutic concentrations using common drug panels.
CRP binds to phospholipids. High levels can result in a prolongation of the clotting time.
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] [7]

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 plasmas.
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 babies and shortened in older populations

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.

CALIBRATION

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. 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.

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.
- Performances and stability data have been validated on Thrombolyzer Compact X (available on request). These data's are valid for all instruments in the Thrombolyzer series
- With manual procedure and on other automated coagulation analyzer, performances and stability data must be validated by user.

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CALCULATION

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

On the automated Thrombolyzer Compact X analyzer:

Precision: Repeatability (Within run) and Reproducibility (Between run):

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: 192 plasmas located between 21.6 sec and 68.6 sec were tested:

y = 0.8515 x + 3.5 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)

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| = Significant modifications

IFU_771200-771201-EN_V04_20260703

Table of symbols

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
									→		

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