ACCUCARE

Activated- Partial Thromboplastin Reagent

activated - Partial Thromboplastin Time

INTENDED USE

Activated Partial Thromboplastin Time (aPTT) quantitative coagulometric assay on citrated plasma, activated by ellagic acid, with ACL (I.L.)

ORDER INFORMATION

REF	Cont.
aPTT 03	1 X 3 ml
aPTT 12	4 X 3 ml

SUMMARY

The Activated Partial Thromboplastin Time (aPTT) is the most important method for monitoring the "intrinsic" pathway of coagulation of the blood and anticoagulant therapy with heparin. The ability of blood to form a fibrin clot by means of the intrinsic pathway requires phospholipids, calcium and a contact activator negatively charged, ellagic acid. So aPTT is sensitive to the decrease in the concentration of coagulation factors of the intrinsic and common, of the contact phase and of the anticoagulant effects of heparin. A prolongation of aPTT is generally related to the decrease of one or more Factors (deficiency of XII, XI, X, IX, V, II and fibrinogen); by functional deficits(deficiency of vitamin K, liver disease); the effect of an anticoagulant such as heparin; by the presence of an inhibitor.

PRINCIPLE

The **aPTT liquid** Reagent is constituted by phospholipids from rabbit brain stabilized and optimized as a platelet substitute and a soluble plasmatic activator, ellagic acid, for an optimal activation of the contact phase of coagulation. The plasma sample is placed in contact with the Reagent containing an optimized amount of phospholipids and a contact activator negatively charged (R1); an incubation at 37°C for a defined time allows the activation of the intrinsic coagulation pathway. The addition of calcium ions (R2) to the reaction mixture starts the coagulation and it is determined the time required for the formation of the fibrin clot.

PRECAUTIONS FOR USE

1. This product has been formulated for in vitro diagnostic use.
2. A proportional variation of the reaction volumes does not change the result.
3. DO NOT mix Reagents from different Production lots.
4. In addition to the possible risk indications, the Reagent can contain preservatives, which total concentration is lower than the limits mentioned in Dir. 67/548/CEE e 88/379/CEE and following modifications regarding classification, labelling and packaging of dangerous preparations (Reagents). However it is recommended to handle the reagents carefully, avoiding ingestion and contact with eyes, mucous membranes and skin; to use reagents according to good laboratory practice. On the material safety data sheet are detailed the operating procedures for the manipulation of this product. Material safety data sheet should be supplied on request.

ATTENTION

A) The Reagent can be used with manual, mechanical, photometric and nephelometric clot detection systems. The automated determinations must be performed according to specific instructions attached to the instrument used.
B) Very deep attention must be given to interfering substances: certain drugs and other substances may influence levels of aPTT or aPTT assay.
C) The Reagent must be used ONLY for the intended destinations, by expert and trained people and in according to good laboratory practice.
D) The clinical diagnosis cannot be done correctly using the result of only one test, but have to be done integrating critically the results of different laboratory tests and clinical data.
E)A series of factors, such as ambient temperature, the temperature of the working reagents, the accuracy of the washings, the type of coagulo-meter and the distilled water characteristics, can affect the performances of the test.
F)For the handling of Reagents, observe the precautions normally taken in the laboratory.

REAGENTS

R1-aPTT reagent	1 x 3ml	Rabbit Brain phospholipids, Kaolin, Ellagic acid, Excipients and stabilizers

STABILITY: the Reagents are stable up to the expiry date mentioned on the labels, stored at 2-8°C, if closed and kept in their intact primary container; if not exposed to heat sources and/or pressure variations.
After opening the Reagents are stable for 30days at 2-8°Cin the original vial.

PREPARATION OF THE WORKING REAGENT

R1 -aPTT Reagent - ready for use.
Before to use the container must be mixed by inversion several times to as sure homogeneity of the Reagent.
A lipid/ ellagic acid sediment might form upon prolonged standing of the containers.
R2 -CaCl2 - (Not in Kit)
NEVER FREEZE the Reagents.
Close immediately after handling. The Reagents have to be used correctly, to avoid contamination.
An incompetent handling relieves us from any responsibility.

MATERIAL REQUIRED BUT NOT PROVIDED

Standard laboratory equipment.
Micropipettes to deliver from 3 to 1000 µL.
Disposable micropipettes tips .
Plastic test tubes for sample dilution.
Coagulation tubes.
Stopwatch or timer. Water bath 37°C.
Saline solution, distilled water, Calibrators and Controls.
Coagulometers.
R2 -CaCl2 CaCl2 >0.1 g/L

SAMPLES

Plasma (citrated plasma) can be used. Do not use plasma with anticoagulants other than citrate.

ANALYTICAL PROCEDURE with MANUAL METHOD

• Preheat **R2 –$CaCl_2$** at 37°C.
• Pipette into coagulation tube as follows:

Reagent	Dose
Citrated Plasma (sample)	100µl
R1 -aPTT reagent	100µl
Incubate for 5 minutes at 37°C.	
R2 - $CaCl_2$	100µl

Start the stopwatch at the same time the addition of the**R2 -CaCl2**. Determine the time of formation of the blood clot (seconds).

REFERENCE VALUES

Normal Range -19 to 31 seconds
However, each laboratory must establish its own normal range by testing individuals representative of the population.

Interferences:

Interference test criterion: recovery ± 10% of initial value.
No interference found on samples with:
-total bilirubin up to 40 mg/dL;
-haemoglobin up to 600 mg/dL;
-lipemia fino a 2000 mg/dL;
-ascorbic acid up to 50 mg/dL.

REFERENCES

1.Tietz Textbook of Clinical Chemistry, Ed. by C.A. Burtis, Elsevier Saunders Co., St. Louis-MO (2012).
2.Young D.S., Effect of drugs on Clinical Lab. Test, 5th Ed. AACC Press (2000).
3.CLSI(NCCLS) H21-A5: Collection, Handling, Transport and Storage for Hemostasis. Quick Guide.
4. CLSI(NCCLS) H47-A2: One-Stage PT Test and aPTT Test.
5. Hirsh, J. et al., Chest108, 258S (1995).
6. Brill-Edwards P. et al., Ann. Int. Med. 119, 104 (1993).
7. Tripodi A. et al., Blood 104, 3631 (2004).

LAB-CARE DIAGNOSTICS (INDIA) PVT. LTD.
C1 Type, Shed No. 3225, Chemical Zone, GIDC Sarigam,
SARIGAM - 396 155 (Dist. Valsad). INDIA
Tel : 91-22-2554 2109 / 2554 1558 • Fax : 2554 3541
Email : accucare@labcarediagnostics.com
Website : www.labcarediagnostics.com