



GENESIS

Instructions For Use

PARTIAL THROMBOPLASTIN TIME (GENOCELLINE-E) (Agglutination Method)

Cat no.	size
2103 101	6*3
2103 102	6*5

INTENDED USE

Liquicelin - E ready to use liquid stable, Cephaloplastin reagent, for the Activated partial thrombin time (APTT) determination in plasma for monitoring of heparin therapy and assessment of Intrinsic pathway. The reagent is derived from rabbit brain.

DIAGNOSTIC CHARACTERISTICS

The activated partial thromboplastin time (APTT) is used to detect disorders in the intrinsic coagulation system, which involves coagulation factors II, V, VIII IX, XI, and XII. APTT is often used in assay systems that quantitate these factors. The APTT is commonly used for pre-surgical screening for intrinsic factor deficiencies (1), for monitoring heparin therapy (2), and in the detection of LupusAnticoagulants (3).

In the basic screening test, the activated partial thromboplastin time indirectly measures the formation of thrombin by its action on fibrinogen resulting in a fibrin clot.

PRINCIPLE OF THE METHOD

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.

COMPOSITION

The reagent contains 0.1mM ellagic acid with phospholipids derived from soybean lecithin. Buffers, stabilizers, and preservatives have been added.

STORAGE

The reagent is stable until expiration date stated on the vial label when stored refrigerated at 2 - 8°C

REAGENT PREPARATION

- 1-Single reagent ready for use .
- 2-CaCl₂ 0.025mole/L

ADDITIONAL EQUIPMENT

12 x 75 mm test tubes (plastic tubes are preferred), pipettes, Stop watch and Water bath or heating block at 37°C.

SPECIMEN.

1. Obtain venous blood by clean vein puncture.
2. Immediately mix 9 parts blood with 1 part sodium citrate (3.2% or 3.8%) and mix well.
3. Centrifuge the specimen at 1500 r.p.m for 15 min (platelet<10000/μL).
4. Separate plasma after centrifugation and store in plastic or siliconised glass tube.
5. Use plasma within 4 hours, otherwise store frozen and thaw just prior to use.

Symbols in Product Labeling	
	Authorized Representative
	For in-vitro diagnostic use
	Catalogue number
	Lot number
	Consult instructions for use
	Expiration date
	CAUTION, consult instructions for use
	Manufactured by
	Temperature Limit

MANUAL METHODS

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 Genocelline E. 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).

CALCULATIONS

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

REFERENCE VALUES

Normal values using Genocelline E are between 25-40 seconds.

QUALITY CONTROL

It is recommended to use the Control Plasma level Iand II to verify the performance of the measurement procedure.

Each laboratory should establish its own internal Quality Control

BIBLIOGRAPHY

1. Dahlback B, Carlsson M, Svensson PJ. Familial thrombophilia due to a previously unrecognized mechanism characterised by a poor anticoagulant response to activated Protein C. Proc Natl Sci 1993;90:1104-08.
2. Denson KWE, Reed SV, Haddon ME, Davidson S, Littlewood TJ. A more discriminating test for APC resistance and a possible screening test to include Protein S. Thromb Res 1996;81:151-156.
3. Jorquera JL, Montoro JM, Fernandez MA, Aznar J. Modified test for activated Protein C resistance. Lancet 1994;334:1162-3.
4. Denson KWE, Reed SV, Haddon ME. The modified APC resistance test. Thomb Haemost 1995;74:995..

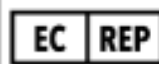
GENESIS LAB FOR DIAGNOSTIC REAGENTS

1st industrial area, Obour City, Cairo, Egypt

(+202) 44891632 Fax : (+202) 44891632

www.genesis-egy.com

info@genesis-egy.com



CMC Medical device, C/ Horacio
Lengo n18 C.P 29006, Málaga-Spain

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