PTT Liquid + CaCl2

IVD

CE

ACTIVATED PARTIAL THROMBOPLASTIN TIME

REF CO1050 10x4 mL + 1x40 mL

For In Vitro Diagnostic Use

PRINCIPLE

PTT Liquid is a rabbit brain cephalin for the determination of the Activated Partial Thromboplastin Time, a qualitative and quantitative screening test for the exploration of the intrinsic coagulation pathway (Factors XII, XI, X, IX, VIII, V, II, I). It is based on the recalcification of the plasma in the presence of a standardized activator (Ellagic Acid) with measurement of the time of formation of the clot.

CLINICAL SIGNIFICANCE

Activated Partial Thromboplastin Time (aPTT) is performed to determine the possible cause of a haemorrhagic or coagulation disorder (thrombotic episode), to monitor the effect of anticoagulant therapy with heparin (which leads to an increase in coagulation times), to screen before surgery or an invasive medical procedure. The test is recommended if the patient has had hemorrhagic episodes, inappropriate blood clot formation, recurrent miscarriages.

Activated Partial Tromblopastine Time (aPTT), together with the determination of Prothrombin Time (PT), is an indicative test to evaluate haemostasis. This allows to have a more complete picture on blood coagulation, in the presence of excess disorders (thrombosis) or in the defect (loss of nosebleeds, bleeding gums, chronic anemia, tendency to bruising and bruising, abundant menstrual flow etc. .). Particularly, aPTT is useful for evaluating the following coagulation factors: XII, XI, IX, VIII, X, V, II (Prothrombin) and I (Fibrinogen).

REAGENT COMPOSITION

Reagent: Rabbit brain cephalin and Ellagic Acid.

$CaCl_2$: Buffered Solution of Calcium Chloride 0,025 M

REAGENT PREPARATION AND STABILITY

Liquid and ready to use, stable until the expiration date shown, if stored as indicated on the label and avoid contamination, evaporation and prolonged exposure to direct light.

Do not freeze the reagents. After opening the Reagent bottle, the stability is 14 days at 2-8 ° C. Shake gently and avoid foaming before use.

After opening the bottles, it is advisable to withdraw the necessary volume, to immediately close the bottles and store them in the fridge in order to avoid contamination, degradation from direct light and evaporation. Discard reagent if signs of deterioration appear as failure to recover certified control plasmas

SPECIMENS

Fresh and decalcified plasma. Take 9 parts of whole blood from a vein and mix with 1 part of trisodium citrate (3.2% - 109 mmol / L). Trisodium Citrate 3.8% - 129 mmol is not recommended. Gently mix, centrifuge (1500 x g for 15 minutes) before performing the test (within 2 hours of sampling) on the supernatant plasma. For further details on withdrawal methods, refer to NCCLS document H3-A3 and H21-A3.

PROCEDURE

For use on automatic systems, refer to the user manual of the instrument used. For use on manual or semi-automatic systems, proceed as follows (it is always advisable to make the determinations in duplicate).

1. Bring a volume of PTT Liquid Reagent and $CaCl_2$ to 37° C, sufficient to perform scheduled tests (≈ 15 minutes).
2. Add 100 µL of control plasma or patient plasma to each reaction cuvette.
3. Add 100 µL of PTT Liquid Reagent and mix gently.
4. Incubate the reaction cuvettes for at least 3 minutes at 37 ° C.
5. Bring a reaction cuvette into the reading cell, zero the stopwatch, add 100 µL of $CaCl_2$ (reaction starter) and simultaneously start the stopwatch. It is recommended to use only the Calcium Chloride ($CaCl_2$) present in the package and not one of another origin.
6. Measure the coagulation time.

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RESULTS

The results can be reported in 2 following units:

- **Seconds:** Record the observed clotting time.
- **Ratio**: It is the ratio between the time obtained by the patient plasma and the time obtained by the Normal Control Plasma or by a pool of plasma taken from normal or considered normal persons, belonging to both sexes and not taking any medication (MNPTT = Medium Normal Partial Thromboplastin Time).

Ratio = Patient Time / MNPTT

QUALITY CONTROL

For Internal Quality Control (Precision Verification, Repeatability), use Control Plasmas at the normal (I) and pathological (II) levels:

MTD PLASMA CONT I-II 7 + 7 x 1 mL REF: CO1110

For the evaluation of the Accuracy of the method (Reproducibility) it is necessary to adhere to a program of External Quality Assessment (EQA) managed by certified bodies.

EXPECTED VALUES

The normal values depend on the population of the area in which it operates and on the instrumentation used. The factors that can influence the MNPTT are local population, sex, race, type of sample, the type of tube, the instrumentation used, the skill of the operator. As suggested by the CLSI, each laboratory should determine the average time related to its users using a pool of plasmas of subjects considered healthy and of the two sexes in equal number. Alternatively, a normal control plasma can be used.

Only as an indication or guideline, they can be considered normal:

- **Seconds: 28 (23 – 33)**
- **Ratio: 1 (0.82 – 1.18)**

PERFORMANCES

PRECISION

Precision depends from many factor, such as instrument, reagent and manual skill. Twenty normal samples and twenty abnormal samples were tested and the following CV% were obtained:
Normal Level: Samples= 20; CV = 2.3%
Abnormal Level: Samples= 20; CV = 1.3%

ACCURACY (CORRELATION)

The comparison between this method (x) and another commercial product (y) gave the following results on 20 different samples:

- Time correlation: r = 0.98 y = 1.126x +1.9
- RATIO correlation: r = 0.98 y = 0.89x + 0.05

SPECIFICITY / INTERFERENCES

- Sodium oxalate, EDTA and Heparin can not be used as anticoagulants.
- Triglycerides > 700 mg/dL, Bilirubin > 15 mg/dL, Hemoglobin > 0.68 g/dL may interefere
- Times may be lengthened if the patient uses Cefepime, Cefmetazol, Heparin, Antihistamines, Ascorbic Acid, Chlorpromazine, Salicylates (aspirin).
- The product has been designed to operate at 37° C±0.5 ° C. Make sure that all heating elements are therefore constantly at this temperature.
- Do not delay mixing blood with the anticoagulant during collection. Avoid foam in the samples.
- Turbid, icteric, lipemic or hemolyzed samples may give erroneous results.
- Freezing and thawing of plasma can compromise the results
- Acute inflammatory reactions may reduce the value of APTT due to the increased amount of fibrinogen
- Plasma samples with a hematocrit not between 20 and 55% may not respond correctly to the test.

PRECAUTIONS

The Reagent does not contain dangerous substances or mixtures, according to the EC Regulation n ° 1272/2008 or their concentrations are such as not to be considered persistent, bioaccumulative or toxic (PBT). The product is classified and labeled in accordance with EC directives or respective national laws. Sodium azide, less than 0.1%.
$CaCl_2$ can cause irreversible effects if is wallowed and may cause damage to organs - R 68-22 (H371).
However, in compliance with the normal prudential rules that everyone has to keep managing any chemical or laboratory reagent, in case of contact of reagents with the operator, you must apply the following first aid:
S26 (P305 – P351 – P338): In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S28 (P302 – P352): After contact with skin, wash immediately with plenty of water.
S36/37/39 (P280): Wear suitable protective clothing, gloves and eye/face protection.
S46 (P301 – P310): If swallowed, seek medical advice immediately and show container or label. If victim is conscious and alert, wash out mouth with water.
S56 (P273): Dispose of this material and its container at hazardous or special waste collection point.
S63 (P304 – P340): In case of accident by inhalation: remove casualty to fresh air and keep at rest. If breathing is difficult, give oxygen and get medical aid.

All samples, calibrators and controls should be treated as potentially infectious material capable of transmitting HIV and hepatitis

FOR MORE INFORMATION, REQUEST SAFETY DATA SHEET FOR REAGENT (MSDS) AT THE MANUFACTURER.

SIMBOLOGY

CE	CE Mark (EC Directive 98/79)		
IVD	In Vitro Diagnostic		Temperature Limitation
	Consult instructions for use		Contains sufficient for <n> test
REF	Catalog Number		Use By
LOT	Batch Code		Manufacturer

BIBLIOGRAFY

1. Angell RD, Wagner RH, Brinkhous KM: Effect ofantihemophilic factor on one stage hemophilic test. J Lab Clin Med; 41:637; 1953.
2. Bell W, Alton HG: A brain extract is the substitute for platelet suspensions in the thromboplastin generation test. Nature; 174:880; 1954.