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TRI-APTT

Determination of Activated Partial Thromboplastin Time Clotting Assay

For professional in vitro diagnostic use only.

INTENDED USE

Determination of Activated Partial Thromboplastin Time. It is a phospholipid preparation derived from rabbit brain with ellagic acid as an activator.

GENERALITIES

The activated partial thromboplastin time (APTT) is used as a general screening test for the detection of coagulation abnormalities in the intrinsic pathway. The APTT is sensitive to deficiencies or abnormalities of factors VIII, IX, XI, XII, X, and II, prekallikrein, high molecular weight kininogen (HMWK), and fibrinogen. APTT is also sensitive to inhibitors of blood coagulation such as lupus inhibitor and fibrin/fibrinogen degradation products (1). The APTT is the most widely used method for monitoring intravenous heparin anticoagulation therapy.

TEST PRINCIPLE

The capacity of blood to form a fibrin clot by means of the intrinsic hemostatic pathway requires coagulation factors I, II, V, VIII, IX, X, XI and XII, platelet lipids and calcium. The assay is performed by the addition in the sample of a suspension of rabbit brain cephalin with a surface activator. The APTT has proven to be a simple and highly reliable measurement of the intrinsic coagulation mechanism.

REAGENT COMPOSITION

Reagent: Phospholipid cephaloplastin reagent derived from rabbit brain, Ellagic acid.
Activator (Optional): 0.025 M Calcium Chloride.

STORAGE AND SHELFLIFE

APTT liquid reagent in intact vial is stable until the expiration date given on the vial, when stored at 2-8°C. DO NOT FREEZE. Stability after opening in the original vial stable for 7 days.

SAMPLE COLLECTION AND PREPARATION

- The venipuncture must be a 'clean' one and, if there is any difficulty, take a new syringe and needle and try another vein.
- Immediately mix 9 parts of freshly collected blood with 1 part tri-sodium citrate (0.109mol/L, 3.2%).
- Centrifuge immediately for 15 minutes at approximately 2500 g
- Transfer the plasma into a clean test tube.
- Plasma must be tested within three hours of blood collection.
- For heparin determination, platelet deficient plasma should be used, hence higher centrifugation time is required.
- Fresh Normal Plasma pool collection: Prepare a plasma pool (FNP) of freshly collected blood from at least five normal healthy donors and process as above.
- Plasma must be tested within three hours of blood collection.

MATERIALS REQUIRED

Pipettes with disposable tips.
General laboratory equipment.

TEST PROCEDURE

- Before use, the reagent should be mixed well by gentle swirling. Do not shake. Aspirate enough reagent from the vial for immediate testing requirements into a thoroughly clean and dry test tube (Plastic tubes are preferred).
- Pre-warm Reagent and samples to 37°C.
- Pipette 100 µL samples / controls into test tubes/ cuvettes
- Pipette 100 µL and controls into test tubes/ cuvettes
- Shake tube briefly to mix the reagent and plasma; place the tube at 37°C for 3 minutes.
- Pipette 100 µL of Calcium Chloride (prewarmed)
- Simultaneously start a stopwatch and incubate for 20 seconds at 37°C. Following incubation, gently tilt back and forth until a gel clot forms. Stop the watch and record time in seconds.

QUALITY CONTROL

Normal and pathological controls should be tested in conjunction with patient samples for verified measuring. It is recommended that at least one Normal and one Abnormal Control Plasma be run at least each shift. A Control Range should be established by the laboratory to determine the allowable variation in day to day performance of each Control Plasma.

INTERPRETATION OF TEST RESULTS

- The result can be reported directly in terms of the double determination of the APTT of the test plasma clotting time. It is suggested that the results be reported to the clinicians in conjunction with the normal range.

EXPECTED VALUES

APTT results are influenced by the method of clot detection and can vary from laboratory to laboratory.
In general, an APTT test performed on a photo-optical coagulometer will give clotting time for normal plasma in the range of 24 to 35 seconds. Therapeutic ranges for monitoring oral anticoagulation therapy will vary from
laboratory to laboratory, therefore it is essential that each laboratory establish relevant APTT ranges for its respective patient population.

LIMITATIONS

Abnormal results obtained with a plasma from a patient not on anticoagulant therapy may indicate a factor deficiency or the presence on an inhibitor.
The result may also be due to the effects of certain drugs and medications. Additional procedures such as the PT test and mixing studies using factor deficient plasma are usually required.

LITERATURE

- Biggs, R. ed.: Human Blood Coagulation, Haemostasis and thrombosis, Blackwell, Scientific Publications Oxford, England, 1972

- Hoffmann, J.J.M.L.. and Neulendijk P. N.: Thrombos. Haemosta. (Stuttgart) 39, 640 (1978).
- CRC. Handbook Series in Clinical Laboratory, Science, Section 1: Haematology, Volume III, 1980. CRC Press, INC. Boca Raton, Florida.
- Journal Of Thrombosis and Haemostasis 10: 2338-2434, Original article: APTT reagent with ellagic acid as activator shows adequate lupus anticoagulant sensitivity in comparison to silica-based reagent.
- Triplett DA, Harms CS, Procedures for the Coagulation Laboratory, American Society of Clinical Pathologists Press, Chicago, p 7 (1981).

USED SYMBOLS

IVD	In Vitro Diagnostic Medical Device
	Manufacturer
	Date of Manufacture
REF	Catalogue Number
LOT	Batch Code
	Use by YYYY-MM (MM = end of month)
	Operator's Manual; Operating Instructions
	Keep away from Sunlight
	Keep away from Rain
	Temperature Limit
	Caution
	Do not use if Package is Damaged
	Do Not Re-Use
Σ	Contains Sufficient for <N> Tests