APTT

Partial Thromboplastin Time

REF. 1002 10x4 ml
REF. 1002/12 10x4 ml

CE IVD

DNV CERTIFIED COMPANY
UNI EN ISO 9001:2008
UN EN ISO 13485:2012

GIESSE DIAGNOSTICS

INTENDED USE

The Reagent is intended for use in performing the activated partial thromboplastin time (APTT) test, and for APTT based factor assays using ellagic acid activator.

PRINCIPLE

The APTT is useful as a screening tool, and as a quantitative test for the intrinsic coagulation factors. It is a simple and versatile test which is sensitive to deficiencies of all plasma clotting factors except Factor VII. However, it is mainly used to detect deficiencies in Factor VIII, IX, XI, XII and Prekallikrein.

The APTT is also commonly used to monitor heparin theraphy since APTT prolongation is directly proportional to increasing amounts of heparin.

The APTT test is performed by adding reagent containing a plasma activator and phospholipid to the test specimen. This mixture is incubated for 3 minutes at 37°C for optimum activation. Calcium chloride is added and clot formation is timed.

SAMPLE

Plasma in trisodium citrate 3.2 % (0.109 M).

Avoid hemolysis and contamination by tissue fluids. Centrifuge blood for 15 minutes at 1500 x g. Test within 2 hours if samples are held at 22-24°C.

KIT COMPONENTS

Reagent (10 x 4 ml)	Ellagic Acid 0.003 %; Bovine serum albumin (BSA) 0.005 %; phenol 0.30 %; buffers 2,6 %; salts and stabilizers.
$CaCl_2$ *	Calcium chloride

*** Calcium Chloride 0.02 M is available separately, (Ref. 1009 - 6x10 ml)**

Store unopened vials at 2-8°C. Do not freeze. Opened vials are stable for 30 days when stored at 2-8°C.

A yellow sediment may form after prolonged storage. Mix gently before use. Erratic values, quality control values outside established ranges, or product color variations could indicate deterioration. However, poor performance could also be due to other factors within the test system.

REAGENT PREPARATION

Liquid reagent, ready to use.

PRECAUTIONS AND WARNINGS

Reagent may contain some non-reactive and preservative components. It is suggested to handle carefully it, avoiding contact with skin and swallow.

Use the normal precautions required in the laboratory.

Dispose of waste according to local laws.

TEST PROCEDURE

Dispense the sample into a tube of plastic or siliconized glass as shown in the diagram:

plasma citrate (supernatant)	100 µl
Reagent (prewarm to 37°C)	100 µl
Mix, Incubate 4 – 5 minutes at 37°C. Add:	
Calcium chloride	100 µl
Time clot formation.	

EXPECTED VALUES

When APTT was evaluated on a normal population, the following results were obtained:

	Mean	± 2SD Range
	30.0	**20.0 - 40.0**

These values should only be used as a guideline.

Each laboratory should establish its own reference range.

LIMITATIONS

The biochemistry of coagulation involves a series of reactions that are influenced by many pre-test conditions. These variables must be controlled to obtain reproducible results.

- Plasma pH will increase if exposed to air. Store samples stoppered.
- APTT was designed to work at 37°C ± 0.5°C. Frequently check the temperature of all heating elements.
- All labware must be clean and free of trace amounts of detergents.
- Always follow instrument manufacturer's instructions for proper maintenance.
- Sodium oxalate, EDTA, and heparin are not suitable anticoagulants.
- Oral contraceptives, estrogen, pregnancy, coumarin type drugs, heparin, asparaginase, and naloxone have been reported to influence APTT results.

QUALITY CONTROL

Normal and abnormal plasmas should be tested in conjunction with patient plasmas for each use of the kit. For this purpose we recommend the use of control: CONTROL PLASMA N (Ref. 1007) and CONTROL PLASMA P (Ref. 1008).

PERFORMANCE

Heparin Sensitivity:

The anticoagulant action of heparin depends on many factors, including an adequate level of Antithrombin-III, platelet activation and subsequent Platelet Factor-4 release during specimen preparation, in vivo presence of other medications, rate of heparin metabolism, mode of heparin administration, and delayed specimen handling. While recognizing these variables, the laboratory can determine the relative sensitivity of a given reagent to heparin by adding known amounts of heparin to pooled normal plasma and performing an APTT. For example, the following results were obtained on a photo-optical instrument with one lot of APTT reagent:

Heparin conc. (units/ml)	APTT (seconds)
0.0	28.8
0.1	38.3
0.2	50.1
0.3	63.1
0.4	80.9
0.5	98.0

Each laboratory should establish its own heparin sensitivity curve using the same heparin source used for therapy in that institution. Variations can result from different brands of heparin, tissue origin, and salts forms.

Factor Sensitivity:

An APTT reagent with adequate sensitivity should demonstrate a prolonged clotting time in samples having ≤ 30-40% factor activity. APTT was evaluated on mildly and severely deficient plasmas with the following results:

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Factor	% activity	APTT (seconds)
VIII	< 1%	82.0
VIII	20 %	44.8
IX	< 1%	83.5
IX	20 %	40.9
XI	< 1%	134.2
XI	20 %	47.8
XII	< 1%	> 200
XII	20 %	36.2
Prekallikrein	< 1%	69.5

Furthermore, the sensitivity of APTT to factor VIII has been determined as follows:

% Factor VIII	APTT (seconds)
100 %	32.5
70 %	34.0
50 %	36.9
40 %	38.9
30 %	40.8
20 %	44.4
10 %	50.6
5 %	56.1
1 %	68.1
< 1 %	83.6

These values should only be used as guidelines. Each Laboratory should establish sensitivity to individual factors using instruments, reagents, and techniques used in their laboratory.

REFERENCES

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