aPTT-s

Activated Partial Thromboplastin Time



Product information

24aPTT01 Coax aPTT-S

10 x 4 mL

Purpose

In vitro assay with reduced lupus sensitivity for the determination of activated partial thromboplastin time (aPTT) in citrated plasma on fully automated or semi-automated analyzers. aPTT is used to evaluate the intrinsic coagulation pathway

Summary

The capacity of the blood to form a fibrin clot through the intrinsic hemostatic pathway requires coagulation factors I, II, V, VIII, IX, X, XI and XII, platelet lipids and calcium. The test is performed by adding rabbit brain cephalin suspension to the sample with a surface activator.

Test principle

The plasma is pre-incubated with aPTT reagent containing a mixture of purified phospholipids and contact activators that stimulate the formation of factor XIIa. Next, calcium chloride is added, which activates the onset of the intrinsic coagulation cascade. The time from the addition of calcium chloride to the formation of clots is measured.

Reagents and working solutions

Buffered ellagic acid activator. Stabilizers and preservatives.

Precautions and warnings

It is intended for in vitro diagnostic use by healthcare professionals. Follow the normal precautions necessary in handling all laboratory reagents.

Infectious or microbial waste:

Warning: handle waste as potentially biohazardous. Dispose of waste according to accepted laboratory instructions and procedures.

Environmental hazards: Follow all relevant local disposal regulations to determine that it has been disposed of safely. If requested, a safety data sheet can be provided to professional users. Inhibit foam formation in all reagents and sample types (sample, calibrator and control).

Use of reagents

The Coax aPTT Reagent is boxed ready to use.

Storage and stability

2 Store at 8°C. The reagent can be stored until the expiration date indicated on the label. Once the lid is opened, the aPTT reagent can be used for 2 days when stored in its original container at 8°C for 14°C. Do not freeze.

Sample collection and preparation

Only the samples listed below have been tested and found acceptable:

Human plasma with 3.2% citrate.

Use standard sampling tubes made of plastic or siliconized glass. Be absolutely sure of the ratio of sodium citrate solution $0.11\,\mathrm{M}$ (1 part) with blood (9 parts).

The listed sample types were tested with a fraction of the commercially available sample collection tubes at the time of testing; In other words, not all existing tubes from all manufacturers have been tested. Sample collection systems from various manufacturers may contain different materials that may affect test results in some cases. Follow the tube manufacturer's instructions when handling samples in primary tubes (sample collection systems).

Centrifuge at 2500 g for 15 min or until platelet count is <10000 platelets/ μ L and test specimens during certain stability period. Centrifuge within 1 hour after blood collection Platelet factor 4 (PF4) binds to heparin with high affinity. It is released during platelet aggregation and from ruptured platelets. When heparin treatment is monitored, PF4 is released due to improper sampling, which may lead to false results.

Stability:

2 hours at $^{15-25}$ OC

11 months at $^{-80}$ OC

The frozen plasma portions should be defrosted in a water bath at 37 °C within 5 minutes, homogeneous by stirring carefully without forming foam. Test defrosted samples within 2 hours. Do not refreeze samples.

Materials required but not provided in the box

- 1. Cat# 24CC01 Coax Calcium Chloride 25mM
- 2. Cat# 24PC01 Coax Plasma Control L1
- 3. Cat# 24PC02 Coax Plasma Control L2
- 4. Cat# 24RC01 Coax Reaction Cuvette
- Cat# 24FT4001 Coax FT40 Semi-Auto Coagulation Analyser
- 6. 100 μL adjustable automatic pipette
- 7. General laboratory equipment
- 8. Distilled or deionized water

Working Procedure

This procedure applies to manual or semi-automatic coagulation systems. For best results, double sampling is recommended.

- 1. Pre-incubate calcium chloride 0.02 mol/L at 37 0C for at least 10 minutes.
- 2. Pipette 50 μ L of sample or control plasma into a test cuvette. Incubate at 37 OC for 3 min.
- 3. Add 50 μL of aPTT reagent to the cuvette containing plasma.
- 4. Incubate the mixture at 37 $^{\rm 0C\,for\,3\,min.}$
- 5. Add 50 μL of the pre-incubated Calcium Chloride at a speed and start the timer at the same time.
- 6. Record coagulation time in seconds.

Refer to your device's manual for other fully automatic and semiautomatic devices.

Limitations – interaction

Delay in testing, difficulty in specimens, or venous structure above the heparin lock site may inadvertently prolong aPTT results aPTT may also be affected by certain medications and treatments. aPTT results may vary with anticoagulant therapy depending on the

EN-IFU.0824.aPTT v.01

aPTT-s

Activated Partial Thromboplastin Time

type and dosage of the anticoagulant, the route of administration, and the time of administration of the last dose.

Expected results

25-43 seconds

aPTT results are affected by the clot detection method and may vary from laboratory to laboratory. In general, an aPTT test on a photo-optical coagulometer will give clotting time in the range of 25 to 43 seconds for normal plasma. Therapeutic intervals for monitoring oral anticoagulation therapy will vary from laboratory to laboratory, so it is important for each laboratory to determine the relevant aPTT intervals for its patient population.

Abnormal results obtained with plasma from a patient not receiving anticoagulant therapy may indicate a factor deficiency or the presence of an inhibitor. The result may also depend on the effects of certain drugs and medications. Additional procedures, such as PT testing and mixing studies using factor-deficient plasma, are often required.

Specific performance data

Representative performance data of the analyzers are given below. Results from individual laboratories may vary

A- Precision

Optics		Reproducibility	Intermediate Sensitivity
Coax L1	n	20	60
	Mean	29.4	29.8
	SD	0.47	1.29
	CV%	1.6	4.8
Coax L2	n 20 Mean 47.4	20	60
		47.2	
	SD	0.53	2.7
	CV%	1.1	5.8

B- Comparison

Optics				
N = 120		r2 = 0.99	Y = 1.065X - 0.1245	

Y = Coax Liquid aPTT Reagent

X = Reference aPTT reagent



Resources

- Human Blood Coagulation, Hemostasisand Thrombosis, 3rded. RBiggs, CRRizza, Editors, Blackwell Scientific Publications, London (1984).
- ColeE, HallER, WuKK, Principles of Antithromboltic Therapy. InWuKK, Thomboembolic Disorders, PSG Publishing Co.Inc., Litteton, p91 (1984).
- TriplettDA, Heparin Clinicaluseand Laboratory Monitoring In Triplett DA, Laboratory Evaluation of Coagulation, American Society of Clinical Pathologists Press, Chicagop272(1982).
- HougieC, The Biochemistry of Blood Coagulation, In Laboratory Evaluation of Coagulation, American Society of Clinical Pathologists Press, Chicagop2(1982).
- OwenCA, BowieEJW, ThomsonJH, The Diagnosis of Bleeding Disorders, Little Brown and Company, Bostonp110(1975).
- HarkerLA, HemostasisManual, FADavisCo, Philadelphiap62(1974).
- TriplettDA, HarmsCS, Procedures for the Coagulation Laboratory, American Society of Clinical Pathologists Press, Chicago,p7(1981).
- 8. YoungDS, PestanerLC, GibbermanV, Effects of Drugs on Clinical Laboratory Tests, ClinChem21; 1D(1975).





Medios Medical Informatics Consultancy Trade Ltd. Sti.











EN-IFU.0824.aPTT v.01 2