TEClot APTT-S

TECO

CE IVD REF **A0300-025, A0300-050, A0320-050, A0320-100**

Intended Use

This product is intended for determination of Activated Partial Thromboplastin Time (APTT) using silicate as activator. The determination of the APTT is used for the global evaluation of the intrinsic pathway and detecting deficiencies of the intrinsic coagulation factors VIII, IX, XI, XII, and Fletcher Factor as well as for monitoring heparin anticoagulant therapy or other coagulation methods where an APTT reagent is required[1,2]. The APTT reagent in the kit contains phospholipids and silica to ensure a highly consistent and stable product[3]. The APTT reagent is lupus anticoagulant insensitive. Lupus anticoagulant insensitive reagents yield more reliable factor assay results than reagents, which are sensitive to lupus inhibitors[4]. Prolonged clotting times maybe observed in the following situations: deficiency of intrinsic coagulation factors, presence of heparin, in liver diseases, vitamin K Deficiency or other anticoagulants, which affect the intrinsic pathway.

Contents & Determinations

Product	TEClot APTT-S Kit-25	TEClot APTT-S Kit-50	TEClot APTT-S	TEClot APTT-S
Cat.No.	A0300-025	A0300-050	A0320-050	A0320-100
APTT-S Reagent*	5x5 mL	5x10 mL	10x5 mL	10x10 mL
$CaCl_2$ 0.025M**	5x5 mL	5x10 mL	-	-

Determinations

Coatron M***	1000 Det.	2000 Det.	2000 Det.	4000 Det.
Coatron A4	500 Det.	1000 Det.	1000 Det.	2000 Det.
Coatron A6	1000 Det.	2000 Det.	2000 Det.	4000 Det.

*APTT-S Reagent contains colloidal silicate with phospholipids, buffer and preservatives.
**$CaCl_2$ contains sodium azide.
***Micro method (75µL in total)

Preparation

Components of kit are ready to use. Allow $CaCl_2$ to prewarm 15 min at 37 °C and mix APTT reagent gently prior usage

Storage & Stability

Unopened reagents are stable until the expiration date shown on the label stored at 2°-8°C. Opened reagent:

	2-8 °C	20-25 °C	37 °C
APTT-S Reagent	30 days	8 days	8 hours

Precautions

Avoid contact with skin and eyes. Wear suitable protective clothing. Dispose components in compliance with local regulations for infectious material. All components are checked for HIV, HBV, HCV. However products from human blood should be considered as potentially infectious.

Specimen collection and storage[5]

1. Obtain venous blood by clean vein puncture.
2. Immediately mix 9 parts blood with 1 part 3.2% sodium citrate (0.105M) and mix well
3. Centrifuge the specimen at 1500g for 10 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.

Stability of plasma: 4h at 18-26°C 8h at 2-8° 14d at -20°C 6m at -70°C

Procedure

A. Automated Method: Coatron A

APTT-S		A4		A6	
PAT	Patient	50µl	CP1	25µl	CP1
BUF	-	0µl	P00	0µl	P00
CLR	-	0µl	-	0µl	-
DP	-	0µl	P00	0µl	P00
R0	-	0µl	P00	0µl	P00
R1	APTT-S	50µl	P31	25µl	P60
R2	CaCl 25mM	50µl	P26	25µl	P47

	A4	A6
Incubation	180s	
Maxtime	180s	
Unit	17	
Method	Coag	
Math	-	
CT-Mech	No	
Deadtime	17s	

	A4	A6
SENS	1	
POINTS	0	
MIX	No	
Clean	0	0
Multi	1	3
S-Corr	0%	
T-Corr	15% - 6s	

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B. Manual Method: Coatron M

1. Prewarm **$CaCl_2$** (0.025M) at 37°C for at least 10 min
2. Pipette **25 µl of sample** into a test cuvette. Prewarm at 37°C for 1-2 minutes.
3. Add **25 µl APTT-S reagent** and incubate exactly for **3 min** at 37°C.
4. Add **25 µl of $CaCl_2$** (0.025M) and simultaneously start test.
5. Record the clotting time in seconds.

Expected Results

Typical normal results are 27-42 sec. However results are influenced by the method of clot detection and can vary from laboratory to laboratory. Each laboratory is recommended to establish its own normal range on the specific instrument used.

Quality Control

TEControl or other commercial control plasma should be used for reliable quality control of performance at a frequency in accordance with good laboratory practice (GLP). TEControl can be frozen one time after reconstitution. 120-150 µl stored in closed polypropylen tubes at -20°C is stable for 30 days

Limitations

A. Specimen Collection. AVOID:
   1. Use only plastic tubes or siliconised glass.
   2. Delayed mixing of blood with anticoagulant.
   3. Contamination with tissue thromboplastin.
   4. Improper ratio of anticoagulant with blood.
   5. Hemolyzed, icteric or lipemic samples may interfere optical systems

B. Laboratory Techniques
   1. Perform tests at 37°C.
   2. Use only high purity water.
   3. Optimum pH is 7.0-7.5.

Performance Characteristics

Typical performance on instrument Coatron M4

Precision:	CV% (within run)	CV% (inter-runs)
QC control	< 3,0	< 5,0

Factor & Heparin sensitivity:

	APTT Clotting time (s)		
Factor (%)	F VIII	F IX	F XI
< 1%	100	80	103
10%	53	52	58
40%	40	39	41
100%	35	35	358

Heparin (U/mL)	0 U/mL	0,2 U/mL	0,4 U/mL
APTT clotting time (s)	35	70	180

These values should be used as guidelines only. Each laboratory should establish factor or heparin sensitivity using its own instruments and techniques.

Warranty

This product is warranted to perform in accordance with its labelling and literature. TECO disclaims any implied warranty of merchantability or fitness for any other purpose, and in no event will TECO be liable for any consequential damages arising out of aforesaid express warranty.

References

1. Proctor RR, Rapaport SI. The partial thromboplastin time with kaolin. A simple screening test for first stage plasma clotting factor deficiencies. *Am J Clin Pathol 36, 212-219 (1961).*
2. Triplett DA, Harms CS, Koepke JA. The effect of heparin on the activated partial thromboplastin time. *Am J Clin Pathol 70, 556-569 (1978).*
3. Stevenson KJ, Easton AC, Thomson JM, Poller L. The reliability of activated partial thromboplastin time methods and the relationship to lipid composition and ultrastructure. *Thromb Haemost 55, 250-258 (1986).*
4. Denis-Magdelaine A, Flahault A, Verdy E. Sensitivity of sixteen APTT reagents for the presence of lupus anticoagulants. *Haemostasis 25, 98-105 (1995).*
5. NCCLS: Guidelines for the Standardized Collection, Transport and Preparation of Blood Specimens for Coagulation Testing and Performance of Coagulation Assays

Symbols key:

	Expiry date	IVD	In Vitro Diagnostica		Biological hazard	REF	Catalogue Number		Consult accompanying documents
	Store at 2-8°C	CE	EU conformity		Manufacturer	LOT	Lot. Number	EC REP	Authorized Representative