



For information use only.
Do not use for performing the assay.
Refer to the insert in the package.

TriniCLOT™ aPTT HS

REF	T1203	10 x 10 ml
REF	T1204	10 x 3 ml

Pour d'autres langues
Für andere Sprachen
Para otras lenguas
Per le altre lingue
Dla innych języków

Para outras línguas
Για τις άλλεςλώσεις
For andre språk



www.tcoag.com

INTENDED USE

TriniCLOT aPTT HS is a phospholipid reagent with particulate activator for the determination of Activated Partial Thromboplastin Time (APTT).

SUMMARY AND PRINCIPLE

The Activated Partial Thromboplastin Time (APTT) assay is a universally accepted screening procedure used to detect abnormalities in the intrinsic coagulation system.¹ It can be used to detect deficiencies of Factors II, V, VIII, IX, X, XI, and XII but is insensitive to platelet factor 3.²⁻⁵ In addition, it can be used to detect the Lupus anticoagulant⁶ and is recommended when monitoring heparin therapy since it is sensitive to the presence of heparin.^{3,7-10} The APTT assay is not recommended for monitoring oral anticoagulant therapy nor is it sensitive to platelet dysfunction. These conditions are better monitored by a prothrombin time test or a bleeding time test,² respectively.

TriniCLOT aPTT HS is mixed with plasma to provide optimal uniform activation of the sample. After incubation at 37°C for a specified time period, the reaction is initiated by the addition of calcium. The time, in seconds required for clot formation is measured.

REAGENT

For *in vitro* diagnostic use.

REAGENT DESCRIPTION

TriniCLOT aPTT HS, 10 x 10 ml, T1203A

TriniCLOT aPTT HS, 10 x 3 ml, T1204A

Purified phospholipids (porcine and chicken); contains micronized silica (activator), buffer, stabilizer and preservative.

REAGENT PREPARATION

Some settling of the activator may occur during storage; therefore, repeatedly invert TriniCLOT aPTT HS reagent gently just before use to ensure homogeneity. Continuous stirring is not required during use.

Caution: This product contains sodium azide (NaN₃) as a preservative. When discarding into plumbing, always flush with copious quantities of water. This helps prevent formation of metallic azides which, when highly concentrated in metal plumbing, may be potentially explosive.

ADDITIONAL MATERIALS REQUIRED

Calcium Chloride, 0.025 M

Disposable tip micropipette, 0.1 ml

MATERIALS AVAILABLE

- Calcium Chloride, 0.025 M
- Control reagents
- Coagulation instrumentation

INSTRUMENTS

Applications/method adaptations for individual analyzers are available upon request; please contact your local representative.

STORAGE AND STABILITY

Store TriniCLOT aPTT HS at 2-8°C when not in use. Do not freeze. The expiration date printed on the vial indicates the limit of stability of the unopened vial. When kept covered, the stability of the opened vial is eight hours at 37°C and 30 days at 2-8°C. Signs of deterioration are reflected by quality control results outside the established laboratory range.

SPECIMEN COLLECTION AND STORAGE

Nine volumes of blood are to be collected in one volume of 3.2% (0.109 M) sodium citrate. Immediately after blood collection, samples are centrifuged at 1500 x g for 15 minutes. Please refer to the most recent version of the CLSI document H21 for further instructions regarding specimen collection and storage.¹¹

PROCEDURE

WARNINGS AND PRECAUTIONS

1. Do not pipette any of the materials by mouth. Do not smoke, eat, or drink in areas in which specimens or reagents are handled.
2. Use disposable gloves and handle all blood specimens used in the test cautiously as though capable of transmitting infectious agents. Consult a physician immediately in the event that blood materials are ingested or come in contact with open lacerations, lesions, or other breaks in the skin.
3. Immediately clean up any spillage of specimens with a 1:10 dilution of 5% sodium hypochlorite. Dispose of the cleaning material by an acceptable method.

4. Treatment of blood products prior to disposal:
 - a. Autoclave for 60 minutes at 121°C.
 - b. Incinerate disposable materials.
 - c. Mix liquid waste with 5% sodium hypochlorite solution so that the final concentration is approximately 1% sodium hypochlorite. Allow 30 minutes before disposal.

TEST PROCEDURE

1. Prewarm a sufficient volume of calcium chloride to 37°C.
2. Label a test tube for each sample (patient and control) to be tested. Duplicate samples are recommended to ensure accuracy.
3. Pipette 0.1 ml of sample or control into the appropriate tube; then pipette 0.1 ml of TriniCLOT aPTT HS into each tube.
4. Activate each sample and control at 37°C for five minutes.
5. After activation, immediately pipette 0.1 ml of prewarmed calcium chloride into each tube and simultaneously begin timing for clot detection.
6. Record the time, in seconds, required for clot detection.

PROCEDURAL NOTES AND PRECAUTIONS

1. Use of clean glassware (or plasticware) is important. Container surface and surface area may affect activation of samples. Consistent technique is recommended for all coagulation procedures. Duplicate determinations are recommended.
2. A series of control materials (TriniCHECK Level 1, 2, 3 or TriniCHECK Control 1, 2, 3) is recommended for monitoring coagulation tests.
3. The test procedure listed is suitable for manual techniques; instrumental determinations should be performed according to the specific instructions accompanying the instrument use.

RESULTS

INTERPRETATION OF RESULTS

Although most manual or instrumental methods for clot detection may be used with TriniCLOT aPTT HS, different methods may detect slightly different endpoints. Caution must be used when comparing results from different methods.

EXPECTED RESULTS

Clotting times are dependent on numerous factors including temperature, water quality, pH, ionic strength, test system, anticoagulant, specimen collection, specimen preservation, and patient population. Specific normal ranges for each test should be established by each laboratory. As a guide for the user, Activated Partial Thromboplastin Time tests were performed on frozen plasma from 42 normal adults. The normal range was determined to be between 22.6 and 35.0 seconds.

PERFORMANCE CHARACTERISTICS

Precision:

In representative studies, replicate determinations were performed with TriniCLOT aPTT HS to determine the clotting time of normal and abnormal pooled plasma. The clotting times were determined using photo-optical instrumentation. The average clotting time for normal pooled plasma was 28.6 seconds with a coefficient of variation (CV) of 0.9%. The average clotting time for abnormal pooled plasma was 39.6 seconds with a CV of 1.2%.

In representative studies using photo-optical instruments and TriniCLOT aPTT HS, TriniCHECK Level 1 had an average clotting time of 32 seconds with a CV of <2.0%. The average clotting time for TriniCHECK Level 2 was 62 seconds with a CV of <2.0%. TriniCHECK Level 3 controls had an average clotting time of 83 seconds with a CV of <2.0%.

The results presented above should be used only as a guide. Each laboratory should establish its own control and precision values based on the endpoint detection method employed and test conditions within that laboratory.

Sensitivity:

When used in quantitative factor assays, TriniCLOT aPTT HS showed excellent sensitivity to Factors II, V, VIII, IX, X, XI, and XII.

For technical assistance in the U.S.A., contact Tcoag Customer Service at 888 291 0415. Outside the U.S.A., contact your local Tcoag Representative.

REFERENCES

1. Brinkhouse KM, Dombrose FA: Partial thromboplastin time, in Seligson D (ed): *Clinical Laboratory Science, CRC Handbook Series* Boca Raton, CRC Press Inc., 1980, pp 221-246.
2. Bloom, AL *Inherited disorders of blood coagulation*, in Bloom AL, Thomas DP (eds): Hemostasis and Thrombosis, London, Churchill Livingstone, 1981, pp 321-370.
3. Miale JB: *Laboratory Medicine: Hematology*, 6th ed, CV Mosby Co., 1982.
4. Koepke, JA (ed): *Laboratory Hematology*, London, Churchill Livingstone, 1984, chap 42, pp 1113-1140.
5. Thompson JM, Poller L: *Blood Coagulation and Hemostasis*, London, Churchill Livingstone, 1985, pp 301-339.
6. Shapiro SS, Thiagarajan P: *Lupus anticoagulants*. Progress in Hemostasis and Thrombosis 1982; 6: 263-285.
7. Banez EJ, Triplett DA, Koepke J: *Laboratory monitoring of heparin therapy - the effect of different salts of heparin on the activated partial thromboplastin time*. Am J Clin Pathol 1980; 74: 569.
8. Brandt JT, Triplett DA: *Laboratory monitoring of heparin—effect of reagents and instruments on the activated partial thromboplastin time*. Am J Clin Pathol 1981; 76 (suppl): 530.
9. Hirsch J, Hull RD: *Venous Thromboembolism: Natural History, Diagnosis, and Management*, Boca Raton, CRC Press, 1987.
10. Shapiro GA, Huntzinger SW, Wilson JE: *Variation among commercial activated partial thromboplastin time reagents in response to heparin*. Am J Clin Pathol 1977; 67(5): 477.
11. Clinical and Laboratory Standards Institute (CLSI). *Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assays; Approved Guideline - Fifth Edition*. CLSI document H21-A5 Vol. 28, No. 5, 2008.

ORDERING INFORMATION

KIT		TriniCLOT aPTT HS
Kit Content	Item	Quantity
T1203	TriniCLOT aPTT HS	10 x 10 ml
T1204	TriniCLOT aPTT HS	10 x 3 ml

ADDITIONAL REAGENTS AVAILABLE		
Catalogue No.	Item	Quantity
T1902	TriniCLOT Calcium Chloride (0.025 M)	10 x 10 ml
T4111	TriniCHECK Level 1 (un-assayed)	10 x 1 ml
T4112	TriniCHECK Level 2 (un-assayed)	10 x 1 ml
T4113	TriniCHECK Level 3 (un-assayed)	10 x 1 ml
T4101	TriniCHECK Control 1 (assayed)	10 x 1 ml
T4102	TriniCHECK Control 2 (assayed)	10 x 1 ml
T4103	TriniCHECK Control 3 (assayed)	10 x 1 ml



Tcoag Ireland Limited,
IDA Business Park,
Southern Cross Road,
Bray, Co. Wicklow,
Ireland.
Tel. + 353 1 2743200
Fax +.353 1 2746678
www.tcoag.com
info@tcoag.com



T1203-T1204 -29 Rev B
03/2011



t NL +31 (0)71 - 523 10 50

t B +32 (0)2 - 426 85 12

t F +33 (0)9 - 65 37 05 75

e kordia@kordia.com

i www.kordia.com