Instructions of APTT Test Kit（Coagulation Method）

【Product Name】

Generic Name：APTT Test Kit（Coagulation Method）

English Name：Activated Parial thromboplastin Time

【Specification】

APTT Reagent：1mL、2mL、4mL、10mL

Calcium Chloride Solution：6.5mL、10mL

Specifics please see the kit outer package and bottle label

【Intend Use】

Suitable for in vitro quantitative diagnostic APTT of human plasma samples.

APTT shortened by the commonly increased activity of Ⅷ and Ⅴ, such as DIC hypercoagulable status; thrombotic diseases, such as pulmonary embolism, deep vein thrombosis and thrombocytosis; APTT prolonged by the deficiency of Ⅷ, Ⅸ, Ⅺ, Ⅻ;and severe shortage of Ⅹ、Ⅴ、prothrombin and fibrinogen; blood contains anticoagulant substances, such as lupus anticoagulant etc., are the pathway of detected intrinsic coagulation, the deficiency of one or more endogenous clotting factors will make APTT prolonged.

【Principle of the Test】

At 37 ℃ to activate the reagent activating factor Ⅻ and Ⅺ, with activated partial thromboplastin cephalin suspension instead of catalytic surfaces of coagulation provided by platelet, participation with Ca^{2+}, the clotting time of poor platelet and plasma, namely called APTT.

【Main Components】

APTT Reagent：

Ellagic acid

Rabbit brain phospholipids

Calcium chloride solution:

Calcium chloride 0.025mol/L

【Storage Conditions and Validity】

Unopened kits should be stored at 2 ℃ ~ 8 ℃, valid for 24 months and used within the validity period. APTT reagents after dissolving or opening should be sealed stored at 2 ℃ ~ 8 ℃ and not frozen, stable period for seven days; combination solution after opening bottle should be sealed stored at 2 ℃ ~ 8 ℃.

【Applicable Instruments】

It applies to full-automatic coagulation analyzer which is produced by Beijing ZONCI Technology Development Co.,Ltd.

【Specimen Requirements】

To collect venous blood, mix immediately and thoroughly with 0.109mol / L sodium citrate solution by 9: 1 ratio. Separate the upper layer of poor platelet from plasma, by 2500 rpm/minute centrifugation 10 to 15 minutes.

Plasma should be assayed within four hours, otherwise keep it at low temperature (-20 ℃ to save two weeks, -70 ℃ to save a month), It should be rapid melting at 37 ℃ before testing and cannot be repeated freezing and thawing.

【Test Methods】

1. Reagent preparation

Dried frozen aquatic APTT reagent adds the distilled or deionized water for dissolution according to the marks of bottle label, shake softly and mix thoroughly, and then settling for 15 minutes at room temperature.

CaCl2 liquid reagent can be used immediately when open its bottle.

2. Procedure

2.1 Semi-automatic Coagulation Analyzer Procedure

Set APTT at room temperature, and warm the calcium chloride solution to 37 ℃, then operate according to the table below.

APTT Determination Procedure

Addition	addition volume
Test Plasma	50uL
APTT Reagnet	50uL
Mixing well，37℃ warm for 3 minutes	
Calcium chloride solution	50uL
Add and Mix immediately, record clotting time	

2.2 Automatic Coagulation Analyzer Procedure

According to the operating steps of automatic coagulation analyzer to assay, plasma and reagent consumption can refer to the table above.

3. Quality Control Procedure

3.1 Internal Quality Control

When each measurement, should use normal and abnormal control plasma to evaluate the operation technique, instruments and reagents. If the result of control material is not within the allowable range, the batch measurements of the patients will be considered ineffectively and not be reported.

3.2 External Quality Control

By external quality assessment or called external quality assurance (external Quality assurance, EQA) to achieve, EQA is a method of providing degree of result exactitude, which reflect laboratory accuracy and precision.

4. Display Results

The test result of APTT shows in seconds, and should be evaluated in accordance with the range of normal value of each laboratory.

【Normal Reference Value（reference range）】

Applicable Models	Reference Range
XL1000/XL1000i/XL1000P/XL1000C/XL1800/ XL1600	25seconds ～ 38seconds
XL3600p/XL3600t/XL3600c/XL3600i	24seconds ～ 36seconds

Above data is for reference only, because the differences are likely to exist between instruments, laboratories and local crowd, recommend that each laboratory establish its own reference range.

【Explanation for Test Results】

Factors that may affect the test results:

1. penicillin can prolong APTT.
2. Hemolytic plasma can make APTT shortened, because red blood cell is responsible for procoagulant effect.

【Limitations of Test Methods】

The sensitivity of APTT measurement depends on which reagent can be used.

【Performance Indicators】

1. Accuracy: The results should be in the range of calibrated value ± calibrated value × 15%.
2. Precision

2.1 Vial to vial variations: coefficient of variation CV≤5%.

2.2 Inter Relative variations: coefficient of variation CV≤10%.

3. Stability: the end result should be in the range of calibrated value ± calibrated value×15%.

【Notes】

1. This product is only used for in vitro diagnosis
2. Diagnosis and treatment cannot rely on the test results only, and should consider clinical history and other laboratory test results.
3. In the detection process, the use of test tubes, pipettes, syringes should be plastic.
4. The test blood is unavailable with EDTA-Na2, heparin, oxalate as an anticoagulant, it should be used with 0.109mol / L sodium citrate solution.
5. The ratio of anticoagulant and blood is 1: 9, 1 part anticoagulant, 9 parts of blood.
6. Smoothly drawing blood, fully prepared anticoagulation, never appearing blood clot.
7. The blood should be mixed immediately with the anticoagulant after collection, to prevent part of coagulation phenomenon. Action should be gentle, and avoid violently shaking.
8. If the hematocrit of test blood <0.20 or> 0.55, it should be adjusted according to the ratio of blood and anticoagulant:

Anticoagulant dosage (mL) = 0.185 × blood volume (mL) × (1- patient hematocrit)

9. The PH value will rise if blood samples expose in air for a long time, so it should be saved with a stopper if it cannot be detected immediately.
10. The test blood should be centrifuged at 2500 revolutions / minute for 10 minutes to 15 minutes, so as to obtain plasma with poor platelet.
11. It should establish a standard curve before using a new batch of kits.
12. Before detection of thrombin reagent, make it to room temperature.
13. Since the APTT reagent contains sodium azide, it will form the explosive metal compounds of sodium azide if touches cooper and plumbum of pipes. Therefore, when such substances discharged into the sewer, use plenty of water, to minimize this risk.

【References】

1. 中华人民共和国卫生部医正司编，全国临床检验操作规程【M】。第二版，南京：东南大学出版社，1997：30.
2. 王学锋，王鸿利主编。血栓与止血的检测及应用。上海：上海世界图书出版公司，2002：28～31.
3. 丁振若等主编，现代检验医学，北京：人民军医出版社，2007：131.
4. Thomas L.(吕元，朱汉民，沈霞等译).Clinical Laboratory Diagnostics Use And Assessment of Clinical Laboratory Resurlts【M】.上海：上海科学技术出版社，2004：569～571.

【Description of Symbols】

Classification Number


Reference Description

Storage Temperature 2 ℃ ～8 ℃

Only for in Vitro Diagnosis

Batch Number


Validity

【Manufacturer】

Company Name：Beijing ZONCI Technology Development Co.,Ltd

Registered Address：No.23, Torch Street, Science and Technology Park, Changping District,Beijing

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【Medical Instrument Manufacturing License】

Producing Certificate No.20070099 of Jing Drug Instrument Administration

【Registration Certificate Number for Medical Device】

Permition No.20122400669 of Jing Drug Instrument Administration

【Product Standard No.】

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