



## Instructions of TT Kit (Coagulation)

### 【Product Name】

Generic Name: TT Test Kit (Coagulation)

English Name: Thrombin Time

### 【Specification】

Thrombin Reagent: 1mL、2mL、4mL、10mL

Solution: 6.5mL、10mL

Specifics please see the kit outer package and bottle label.

### 【Intend Use】

Suitable for in vitro quantitative determination of thrombin time of human plasma sample.

Prothrombin turning into thrombin, so it promotes fibrinogen changing into fibrin; abnormal fibrinogen, plasma containing heparin and heparin-like anticoagulants will cause thrombin time be extended.

### 【Principle of the Test】

Adding "standardized" thrombin solution into plasma, fibrinogen turns into fibrin, and coagulated time of plasma is called TT.

### 【Main Components】

Thrombin Reagent:

Bovine Thrombin

Solution:

stabilizer 1g/L

The different batches of thrombin kits and imidazole buffer cannot be interchangeable

### 【Storage Conditions and Validity】

Unopened kits should be stored at 2 °C ~ 8 °C, valid for 24 months and used within the validity period. Dissolved thrombin reagent should be closely stored at 2 °C ~ 8 °C, stable for seven days, not frozen; Solution after opening should be sealed stored at 2 °C ~ 8 °C.

### 【Applicable Instruments】

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

### 【Specimen Requirement】

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

2. Plasma should be assayed within four hours, otherwise keep it at low temperature (-20 °C to save two weeks, -70 °C to save a month), It

should be rapid melting at 37 °C before measuring and cannot be repeated freezing and thawing.

### 【Test Methods】

#### 1. Reagent Preparation

Each bottle of thrombin reagent should add the solution according to the marked amount of bottle label, shake softly and mix thoroughly, and then settling for 15 minutes at room temperature.

#### 2. Procedure

##### 2.1 Semi-automatic Coagulation analyzer Procedure

Warm the prepared thrombin reagent to room temperature, and then operate according to table below.

TT Determination Procedure

Addition	Addition Volume
Test Plasma	100uL
Mixing well, 37°C warm for 3 minutes	
TT Reagent	100uL
Add and Mix immediately, record clotting time	

##### 2.2 Automatic Coagulation Analyzer Procedure

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

#### 1. Quality Control Procedures

##### 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

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

#### 2. Display Results

The measurement result of TT 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	9~16seconds
XL3600p/XL3600t/XL3600c/XL3600i	9~15seconds

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. Fibrinogen concentration which is less than 0.6g / L will affect TT.
2. Hemolytic plasma can cause TT shortened because the components of red blood cell are responsible for procoagulant effect.

**【Limitations of Test Methods】**

TT depends on the concentration and type of thrombin, diluted thrombin solution will quickly lose their activity.

**【Performance Indicators】**

1. Accuracy: The results should be in the range of calibrated value  $\pm$  calibrated value  $\times$  20%.
2. Precision
  - 2.1 Vial to vial variations: coefficient of variation  $CV \leq 5\%$ .
  - 2.2 Inter Relative range: coefficient of variation  $CV \leq 10\%$ .
3. Stability: the end result should be in the range of calibrated value  $\pm$  calibrated value  $\times 20\%$ .

**【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 blood test is unavailable with EDTA-Na<sub>2</sub>, 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 possessed blood clot.
7. The blood should be mixed immediately with the anticoagulant after collection, to prevent some coagulation phenomenon. Action should be gentle, and avoid violently shaking.
8. If the hematocrit of tested blood  $<0.20$  or  $>0.55$ , it should be adjusted according to the ratio of blood and anticoagulant:

Anticoagulant dosage (mL) =  $0.185 \times \text{blood volume (mL)} \times (1 - \text{patient hematocrit})$

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 blood should be centrifuged at 2500 revolutions / minute for 10 minutes to 15 minutes at 2500 revolutions / minute, so as to obtain plasma with less platelet.

11. Before detection of thrombin reagent, make it to room temperature.

12. Since solution 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: 45.
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: 132.
4. Thomas L.(吕元, 朱汉民, 沈霞等译). Clinical Laboratory Diagnostics Use And Assessment of Clinical Laboratory Results【M】. 上海: 上海科学技术出版社, 2004: 571~572.

**【Description of Symbols】**

Classification Number



Reference Description



Storage temperature 2 °C ~ 8 °C



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



Beijing ZONCI Technology Development Co., Ltd

---

Production Address: No.1. Yanjiao Airport International Industrial Base,  
North Side of Gushan North Road, West Side of Yingbing North Road,  
Yanjiao Develop Zone, Sanhe City, Hebei Province Post Code: 102200  
Tel: 010-80843551/3552/3553  
Fax: 010-80843567  
Website: [Http://www.zonci.com](http://www.zonci.com)

【Medical Instrument Manufacturing License】

Producing Certificate No.20070099 of Jing Drug Instrument  
Administration

【Registration Certificate Number for Medical Device】

Permission No.20122400669 of Jing Drug Instrument Administration

【Product Standard No.】

YZB/Jing 0687—2012

【Instructions of Approval Date and Modified Date】

Instructions of Approval Date and Modified Date: 2012.07.04.