Instructions of PT Test Kit (Coauglation)

【Product Name】

Generic Name：PT Test Kit(Coagulation)

English Name：Prothrombin Time

【Specification】

PT 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 human plasma PT of the sample.

Shortened PT is common happening on hypercoagulable state (such as early DIC); Prolonged PT is common deficiency of Ⅱ, Ⅴ, Ⅶ, Ⅹ.It is a way of detection for exogenic coagulation, the lack of one or more coagulation factors causes PT prolonged.

【Principle of the Test】

By the excess addition of leaching solution and Ca2+ of tissue thromboplastin in test plasma(rabbit brain, the human brain, placenta, lung, etc.),turns thrombin into thrombin, which makes fibrinogen into fibrin, and plasma coagulation time is called PT.

【Main Components】

PT Reagent：

extractive of rabbit brain powder

solution：

calcium chloride

stabilize 1g/L

The different batches of PT kit and solution cannot be interchangeable

【Storage Conditions and Validity】

Unopened kits should be stored at 2 ℃ ~ 8 ℃, valid for 24 months and used within the validity period. Dissolved PT reagent should be confined stored at 2 ℃ ~ 8 ℃, stable for seven days, not frozen;

【Applicable Instruments】

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

【Specimen Requirement】

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 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

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

Take the right amount of prepared PT reagent and warm to 37℃, and then operate according to table below.

PT Determination Procedure

Addition	Addition Volume
Test Plasma	50uL
Mixing，37℃ warm for 3 minutes	
PTreagent	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.

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3. Quality Control Procedure

3.1 Internal Quality Control

When each measurement, should use normal and abnormal quality control materials 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. Results of Calculation

4.1 Prothrombin Time Ration（PTR）：

$$PTR = \frac{Test\,Plasma\,\text{PT（秒）}}{Natural\,Comparison\,\text{PT（秒）}}$$

4.2 International Normalized Ratio （ international normalized ratio,INR）：$INR=PTR^{ISI}$

ISI：International Sensitivity Index（international sensitivity index,ISI）It Shows the relationship between PT reagent and 67/40. WHO proposed to use human brain thromboplastin 67/40 as the original reference product, set ISI at 1.0. Different values of ISI for each batch reagent, specifics see the instructions.

【Normal Reference Value（reference range）】

Applicable Models	Reference Range
XL1000/XL1000i/XL1000P/XL1000C/XL1800/XL 1600	9 秒～14 秒
XL3600p/XL3600t/XL3600c/XL3600i	9 秒～14 秒

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

【Explanation for Test Results】

Factors that may affect the test results:

1. The plasma containing heparin can prolong PT.
2. Degradation products of plasma fibrinogen > 50mg / L, PT extended.
3. Using central venous catheter to collect blood samples will extend PT because it contains hypertonic solution. If add 7.5% NaCl solution and hypertonic saline solution of blood samples is over 10%, PT will extend.
4. Penicillin will shorten PT, particularly apparent for children.
5. The hemolytic plasma can lead to PT shortened because the components of red blood cell have an effect on procoagulation.

【Limitations of Test Methods】

1. In time format to report PT, the internal and external result cannot be comparable because the different ISI value of PT reagent.
2. In INR format to report PT, does not apply to those patients of PT prolonged who are oral anticoagulant drugs early, deficient in liver coagulant factors and non-anticoagulant therapy.

【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 range: coefficient of variation CV≤10%.
3. Stability: the end result should be in the range of calibrated value ± calibrated value×15%.
4. International Sensitivity Index（ISI）: The ISI value of each batch of PT reagent should be in the range of 1.0 to 2.0.

【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 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 × 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 blood should be centrifuged at 2500 revolutions / minute lasting 10 minutes to 15 minutes, so as to obtain plasma with poor platelet.
11. It should complete the test within two hours when the room temperature is 22 ℃ ~ 24 ℃,; if it is 4 ℃ ~ 8 ℃, the prothrombin time may be shortened.
12. The reagent must be warmed to 37 ℃ when detect prothrombin time, and avoid warm time too long(over 30 minutes) or repeating warm.
13. 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，1997：31.
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：

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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，2004：567～569.

【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

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【Medical Instrument Manufacturing License】

Producing Certificate No.20070099 of Jing Drug Instrument Administration

【Medical Device Registration Certificate No.】

Permition No.20122400669 of Jing Drug Instrument Administration

【Product Standard No.】

YZB/Jing 0689—2012

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