Instructions of FIB Test Kit (CLAUSS Method)

【Product Name】

Generic Name： Instructions of FIB Test Kit（**CLAUSS** Method）

English Name：Fibrinogen

【Specification】

Thrombin Reagent：1mL、2mL、4mL、10mL

Imidazole Buffer：6.5mL、10mL、100mL

Specifics please see the kit outer package and bottle label

【Intend Use】

Suitable for in vitro quantitative determination of fibrinogen content of human plasma sample.

Congenital fibrinogen deficiency, dysfibrinogenemia and malnutrition, liver disease will decrease fibrinogen content; hyperfibrinogenemia is a high risk factor for causing brain stroke and coronary heart, and has very important significance to detect it.

【Principle of the Test】

According to the principle of fibrinogen reaction with thrombin to generate fibrin ultimately, should use the standard substance to calibrate plasma and make a standard curve, and employ thrombin to test clotting time which is negatively correlated to fibrinogen concentration, so as to obtain FIB content.

【Main Components】

Thrombin Reagent：

Bovine Thrombin

Imidazole Buffer：

Imidazole Buffer pH7.35±0.1

The different batches of thrombin kits and imidazole buffer 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 thrombin reagent should be confined stored at 2 ℃ ~ 8 ℃, stable for seven days, not frozen; Imidazole buffer after opening should be sealed stored at 2 ℃ ~ 8 ℃.

【Applicable Instruments】

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

【Specimen Requirement】

1. 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.

2. 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

Add the distilled water into each bottle of thrombin reagent according to the marked amount of bottle label, shake softly and mix thoroughly, and then set for 15 minutes at room temperature.

2. Procedure

2.1 Semi-automatic Coagulation Analyzer Procedure

Dilute the plasma for 10 times with imidazole buffer, and set the prepared reagent at room temperature and then operate according to table below.

FIB Determination Procedures

Addition	Addition Volume
Diluted Plasma	200ul
37℃ warm for 3 minutes	
Reagent	100ul

According to plasma coagulation time, find out the corresponding fibrinogen content on the standard curve. If the clotting time is not within the range of standard curve, in order to reduce errors, propose to re-test after dilution test plasma again. If the coagulation time is longer than thirtyfold dilution point, test after fivefold dilution, and then calculate the figure and multiply 0.5 to obtain the actual FIB content; If the coagulation time is shorter than fivefold dilution point, test after thirtyfold dilution, and then calculate the figure and multiply 3 to obtain the actual FIB content

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.

1. Calibration Procedure

3.1 Standard Procedure of Semi-automatic Coagulation Analyzer

⑴According to the table below, with the effect of imidazole buffer, make the calibration plasma of marked FIB content into different dilutions.

	Dilution Method of Calibration Plasma		
Dilutablity	Imidazole Buffer（ul）	Plasma （ul）	Content of FIB （g/L）
Five-fold dilution	200	50	indicated value×2
ten-fold dilution	450	50	indicated value
twenty-fold dilution	950	50	indicated value×1/2
thirty-fold dilution	1450	50	indicated value×1/3

⑵Assay different dilutions of plasma according to Table 1, and record their clotting time.

⑶According to using 10-fold dilution as the indicated value, taking double logarithmic chart as a standard curve, and making correct plasma levels as Y axis, the corresponding clotting time as X axis, four points draw a straight line.

2. Quality Control Procedure

4.1 Internal Quality Control

When each measurement, should use normal and abnormal control material 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.

4.2 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.

3. Results of Calculation

According to plasma coagulation time, find out the corresponding fibrinogen content on the standard curve.

【Normal Reference Value（reference range）】

Applicable Models	Reference Range
XL1000/XL1000i/XL1000P/XL1000C/XL1800/XL 1600	2～4g/L
XL3600p/XL3600t/XL3600c/XL3600i	2～4g/L

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. If the FDP content in test plasma is more than 100mg / L, or heparin content exceeds 0.6U / Ml, will affect the measurement results of fibrinogen.
2. Hemolytic plasma can cause fibrinogen levels rising, because red blood cells have procoagulant effect.

【Limitations of Test Methods】

1. Thrombin method is not suitable sample of anticoagulant heparin.
2. Fragment of fibrin degradation can restrain fibrin aggregation, therefore extend the coagulation time to generate low level of pseudo fibrinogen.

【Performance Indicators】

1. Accuracy: The results should be in the range of calibrated value ± calibrated value × 25%.
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×25%.

【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 lasting 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 thrombin reagent and imidazole buffer contain 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. 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.
2. 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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3. 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，2004：575～578.

【Description of Symbols 使用符号的说明】

 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

【Registration Certificate Number for Medical Device】

Permition No.20122400669 of Jing Drug Instrument Administration

【Product Standard No.】

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