TAIZHOU STEELLEX BIOTECH CO., LTD

Certificated ISO 13485

Lot Number: See vial body

File No:IFU-PT; Ver.:A/0

PT Kit

Prothrombin Time (PT) Liquid Kit

REAGENT KIT

10×2ml、10×5ml、10×10ml ISI Marked in vial label

Intended Use

The product is used for quantitative measurement of human plasma prothrombin time (PT) in vitro.

PT prolongation was found in congenital factor Ⅱ, Ⅴ, Ⅶ, Ⅹ deficiency and hypoproteinemia; acquired in DIC (disseminated intravascular coagulation), primary fibrinolysis, vitamin K deficiency, anticoagulants in blood circulation such as oral anticoagulant, heparin and FDP. PT shortens in congenital factor Ⅴ, oral contraceptives, hypercoagulable state and thrombopathy, and so on.

PRINCIPLE

Tissue thromboplastin, in the presence of calcium ions and Factor VII, activates the extrinsic pathway of coagulation. When a mixture of tissue thromboplastin and calcium ions is added to normal anticoagulant plasma, the clotting mechanism is initiated and a clot will form within a specified time period. If a deficiency exists within the external pathway, the time required for clot formation will be prolonged. The degree of prolongation is proportional to the severity of single factor deficiency, or in a cumulative deficiency of all the factors involved.

COMPOSITION FOR PT

1.4% calcium chloride, 0.1% Sodium benzoate, 2.5% aminoacetic acid, 0.15% sodium chloride, 2.5% rabbit brain powder

STORAGE CONDITIONS AND VALIDITY

1. Under the condition of 2 ℃ ~ 8 ℃, the shelf life is 24 months.
2. Bottle opening stability: sealed at 2 ℃ - 8 ℃ for 30 days after bottle opening

SAMPLE REQUIREMENTS

1. Sample collection: Plasma obtained from whole blood anticoagulant with 109mmol/L, nine parts of fleshly collected whole blood should be immediately added to one part anticoagulant.
2. Sample preparation: Centrifuge the whole blood specimen at 3000xg for 10 minutes, using a plastic pipette and placing it in a plastic test tube.
3. Plasma samples must be tested at room temperature within 2 hours to ensure their stability. If the test is delayed for more than 2 hours, the plasma samples must be stored at - 20 ℃ (2 weeks). When retested, frozen plasma samples should be thawed rapidly at 37 ℃ and tested immediately.
4. During blood collection, hemolysis and the use of hyperlipidemia and jaundice samples should be avoided.

TEST METHOD

1. Preparation before test

   Required instruments and materials: coagulation analyzer (if the instrument itself does not have pre temperature timing function, it also needs to be equipped with 37 ℃ water bath and timer), centrifuge, test cup or test tube, distilled water (or purified water, deionized water), quality control plasma.
2. Put Pt reagent in the 37 ℃ reagent preheating hole of the instrument, the reagent preheating time must be greater than 10min, and it must be shaken evenly before use.
3. Take SC 40 coagulation analyzer as an example, the specific operation steps are as follows

(a) The test plasma (the control plasma, the normal control plasma, the abnormal control plasma)----------50μl

(b) Pre-warm for 3minutes at 37℃

(c) PT reagent (pre-warm for 20 minutes at 37℃)---100μl

(d) Record the time required for clot formation.

REFERENCE VALUE

1. The reference value of normal population in 95% confidence interval of normal distribution was determined to be 9-14 seconds through clinical trials on 130 normal population
2. INR: 0.8-1.24
3. The normal reference range shall be determined according to the specific conditions of the laboratory and shall be within ± 2sd of the laboratory test value of the normal person

INTERPRETATION OF TEST RESULTS

1. The test result of prothrombin time should be reported as Pt, and the unit of test result can be seconds (s), INR, percentage activity (%)
2. INR Value

   The World Health Organization (who) recommends using the international standardized ratio (INR value) instead of directly reporting prothrombin time when monitoring patients taking oral anticoagulant therapy.

   These values should only serve as guidelines. Because differences may exist between instruments, laboratories, and local populations, it is recommended that each laboratory establish its own reference range of expected Prothrombin time results. INR was calculated by the international sensitivity index (ISI) power of the ratio of Pt value to the mean of normal reference plasma.INR = (patient Pt / normal reference plasma mean) ^{ISI}
3. Prolongation of Pt time: it can be seen in congenital or acquired coagulation factor Ⅱ, Ⅴ, Ⅶ, Ⅹ deficiency, hypoproteinemia and anticoagulant drugs.
4. Shortening of Pt time: it can be seen in congenital factor Ⅴ, hypercoagulable state of blood, oral contraceptive and thrombopathy, etc.
5. Each laboratory must have a set of quality control procedures, which include the use of normal and abnormal controls to

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evaluate instruments, reagents and technical operations to determine the mean and standard deviation of daily plasma. If the data obtained by quality control plasma is not within the reference range.

6. For some special groups (such as newborn, infant) or other types of automatic or semi-automatic instruments, the normal reference range should be re established, which is often within ± 2sd of the normal laboratory test value.
7. It is suggested to use the control plasma Pt produced by our company as the quality control material to ensure the matching between the kit and the quality control plasma.

LIMITATIONS OF TEST METHODS

1. Due to the existence of multiple variables and the different proficiency and operation methods of laboratory inspectors, the test value of Pt will vary with the laboratory. Clotting test method, preheat time, type of anticoagulant (this test method is not applicable to plasma with anticoagulant effect of sodium citrate), sample storage method and time will affect the test results. Therefore, each laboratory should establish its own reference range and establish its own performance standards for quality control plasma.
2. In addition to oral anticoagulants, the use of other drugs may also affect the test results of Pt. Obtaining accurate patient history and paying attention to specific drug treatment can help to correctly understand and analyze the potential influencing factors of test results.

PRODUCT PERFORMANCE INDEX

1. Appearance: the appearance of the reagent box shall be clean and clear with text symbols; Pt reagent liquid reagent shall be uniform milky white suspension.
2. Normal plasma measurement:
   The results of normal plasma test should be no more than 14 seconds
3. ISI value: ISI value shall be indicated on the label of the kit.
4. Repeatability
   Repeat the test with quality control plasma, the CV of the result should not exceed 5%.
5. Batch difference
   The coefficient of variation (CV) of the results obtained from repeated testing of different batches of reagents with quality control plasma should not exceed 10%.Throughout testing all test tubes, syringes and pipettes should be plastic.
6. Stability
   The shelf life of the kit is 24 months under the condition of 2 ℃ ~ 8 ℃. The appearance, normal plasma measurement value, ISI value and repeatability of the sample within one month after the shelf life should meet the requirements of 1 ~ 4.

ATTENTION

1. All test tubes, syringes and pipettes shall be plastic products during the whole blood collection and test process.

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2. The room temperature mentioned in this manual is 10 ℃ - 30 ℃.
3. Heparin and EDTA should not be used for anticoagulation of the plasma to be tested. 109mmol / L sodium citrate should be used for anticoagulation.
4. If hematocrit is less than 20% or more than 55%, adjust the proportion of blood sample and anticoagulant according to the following formula: anticoagulant dosage = 0.00185 × blood volume (ML) × (100 patient hematocrit).
5. Hemolytic samples shall not be used and must be resampled.
6. In order to prevent the loss of V factor in the measurement process, the pre temperature time should be accurate to 180 seconds, and the pre temperature should be kept at 36.5 ℃ ~ 37.5 ℃.
7. The reagent and buffer shall not be frozen. The reagent shall be stored at 2 ℃ ~ 8 ℃ in time after use.
8. Warning: since Pt kits contain animal derived raw materials, although the inactivation steps of virus and bacteria have been completed in the preparation process, there is no experimental method to ensure that the animal derived ingredients in the kits are not likely to spread diseases, so users may be infected by diseases or transmitted to others during the use process and waste disposal

BASIC INFORMATION

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INTERPRETATION OF SYMBOLS

CE	CONFORMITE EUROPEENNE	IVD	IN VITRO DIAGNOSTIC MEDICAL DEVICE
	CAUTION		USE-BY DATE
	CONSULT INSTRUCTIONS FOR USE	LOT	BATCH CODE
	DO NOT REUSE	Σ	SUFFICIENT FOR
	TEMPERATURE LIMITE		DATEOF MANUFACTURE
	MANUFACTURER	EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY

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