GB CLOT – PT
(PROTHROMBIN TIME REAGENT)

Kit contents	Pack size	Cat no.
GB CLOT- PT Reagent	200T	GBCPT0200T

GENUINE BIOSYSTEM

[Intended Use]
Suitable for in vitro diagnostic of Prothrombin Time (PT) of huma n plasma. Clinically, it is mainly used for screening of extrinsic coagulation system functional defect and for monitoring oral anticoagulant therapy. Prolonged PT can be seen in factor II, V, VII and X deficiencies and hypofib rinogenaemia (afibrinogenemia); acquired prolonged PT can be seen in DIC, primary fibrinolysis, vitamin k deficiency, anticoagulant (such as oral anticoagulant, heparin and FDP) in blood circulation. Shortened PT can be seen in congenital factor V increase disease, oral contraceptive taking, hyper coagulable state, thromboembolism, etc.

[Principle]
The plasma under test is added with excessive amount of tissue t hromboplastin and Ca^{2+} to activate the extrinsic coagulation pathway and finally convert fibrinogen into fibrin. The time of coagulation measured on t he instrument using the optical heterometry method is the PT of the plasma under test.

[Reagents Composition]
PT Reagent: Rabbit thromboplastin, stabilizer and buffer.

Note: For the ISI values of this lot of reagents see the label of the k it.

[Storage and Stability]
Store at 2-8˚C in the dark. Do not freeze the reagents! The sh elf life is 12 months.

Opened reagents are stable for 7 days when stored at 2~8˚C.

[Instruments]
Semi-automated or automated coagulation analyzers produced b y Rayto Life and Analytical Sciences Co., Ltd.. It is suggested that you veri fy test results according to the actual situation of the laboratory when using this reagent.

[Specimen]
• Nine parts of freshly drawn venous blood are added to one part of anticoagulant and 0.109mol/L trisodium citrate. Fully blend. Centr ifuge at room temperature (15~25˚C) at 3000rpm for 12 minutes. The light yellow liquid on top is the poor platelet plasma under test.

• Store the plasma at room temperature (15~25˚C) and test it within 2 hours.

• If the plasma can't be tested timely, separate with a plastic straw and it is stable for 2 weeks at -20˚C. Melt rapidly at 37˚C and gently shake immediately before test.

Refer to CLSI H21 for further information on specimen collection and disposal

[Test Procedure]
Gently shake and mix the liquid reagent well before use!

· Test with the semi-automated coagulation analyzer.

Take 50μL plasma under test and incubate at 37˚C for 3 min.→

Add 100μL PT Reagent pre-warmed to 37˚C and record the coagulation time of the plasma.

· Test with the automated coagulation analyzer.

Conduct the test according to the operation steps of the automated coagulation analyzer. For the doses of plasma and reagent, refer to the above conditions.

· Calculation

4.1 Prothrombin Time Ratio *(PTR)*

$$PTR = \frac{\text{PT of plasma for test (sec.)}}{\text{PT of normal Contrast (sec.)}}$$

4.2 International Normalized Ratio (*INR*)

$$INR = PTR^{ISI}$$

In which, ISI is International Sensitivity Index. The ISI values of different batches of reagent vary. For the specific value, see the package label of the respective reagent.

5. Quality Control Procedure

Test the coagulation QC weekly and establish a QC c urve.

If the test results exceed the range, check the QC , reagent, instrument, etc. Conduct a retest to find the causes.

[Reference Values]
PT: 11~15 sec. (n=202, 95% confidence limit).

Due to the normal and reasonable difference betwee n regions and individuals as well as the different test methods adopted, the va lues of PT may vary. It is suggested that each laboratory establish its own reference values for the population that it serves.

[Interpretation of Test Results]
PT may be reported in seconds (s) or INR. The results in the reference interval are usually regarded as normal. However, results m ay be affected by the diet, region, etc. Please conduct assessment by combing the medical history and other clinical test results. A professional should audit the test results.

[Limitations of the Procedure]
1 The course of coagulation includes a series of reactions from activation of factor to fibrin formation. Therefore, test results ma y be affected by therapeutic drugs (interferent), test operations, test systems , etc., which should be considered.

2 Reagent contamination or contamination of sample cups, straws, etc. by blood coagulation reagent may cause blood coagulation disorders, so strict control is required.

[Performance Characteristics]
1. Normal Plasma Measurement: Use normal plasma to do the test and the average of the results should not be greater than 14s.

2. Repeatability: The coefficient of variation (CV) of the results of repeated tests with QC plasma should not exceed 5.0%.

3 Lot Tolerance: Use the QC plasma to test different lots of reagents repeatedly and the coefficient of variation (CV) of the results should not exceed 10%.

[Notes]
• The product is only for in vitro diagnosis and operated by medical professionals or trained workers.

• The test temperature should be within 37±0.5˚C.

• During the test, use plastic or siliconized test tubes, straws and syringes only. Do not use those made of common glass.

• The plasma under test must not be EDTA, heparin or oxalate anti-coagulate plasma.

• When the hematocrit value is out of the range of 20~55%, adjust the dose of anticoagulant.

• For a coagulation analyzer using turbidimetry, hemolysis, obvious jaundice and lipoidemia may affect test results, in which cases, a manual method or electromechanical coagulation analyzer is appropriate.

• QC plasma should be tested at the same time each working day to eliminate the interference caused by the instrument, reagents, abnormal operation, etc.

The reagents contain chemicals. Do not eat them mistakenly or expose your skin or mucous membrane to them. In case of eye, mouth or skin contact, flush with plenty of clear water, go to the doctor if necessary. The liquid waste from the sample test presents potential biohazard risk. Personal protections are necessary and dispose the liquid waste in accordance with the local regulations.

[References]

1. The 3rd edition of National Clinical Laboratory Procedure. Southeast University press.2006
2. ICSH/ICTH. J Clin Pathol. 1985, 38(2):133-134.
3. Quick AJ. Science. 1940, 92(2379):113-114.

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Genuine Biosystem Private Limited
Plot 97 & 98, Kattabomman street, Parvathy nagar Extn,
Old Perungalatur, Chennai-600063.TN.India
Ph:044-48681845 , Email:info@gb-group.co.in,
Web: www.genuinebiosystem.com