

GB CLOT – TT (THROMBIN TIME REAGENT)



| Kit contents | Pack size | Cat no. |
|---------------------|-----------|------------|
| GB CLOT- TT Reagent | 200T | GBCTT0200T |

[Intended Use]

Suitable for in vitro diagnostic of Thrombin Time (TT) of human plasma. Clinically, it is mainly used to reflect abnormal concentration or structure of plasma fibrinogen as well as the function of the fibrinolytic system. Prolonged TT can be seen in increase in heparin or the existence of heparinoid anticoagulant, increase in fibrin (fibrinogen) degradation product (FDP) and hypofibrinogenemia (afibrinogenemia). Shortened TT can be seen when small clots or calcium ions exist in the blood sample.

[Principle]

When the plasma under test is added with appropriate amount of thrombin, the fibrinogen is converted into insoluble fibrin. The time of coagulation measured on the instrument using the optical heterometry method is the TT of the plasma under test.

[Reagents Composition]

R1: TT Reagent: Bovine thrombin, stabilizer;

[Storage and Stability]

Store at 2~8°C in the dark. Do not freeze the reagents! The shelf life is 12 months.

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

[Instruments]

Semi-automated or automated coagulation analyzers. It is suggested that you verify test results according to the actual situation of the laboratory when using this Reagent.

[Specimen]

1. Add nine parts of freshly drawn venous blood to one part of anticoagulant and fully blend with 0.109mol/L trisodium citrate. Centrifuge at room temperature (15~25°C) at 3000rpm for 12 minutes. The light yellow liquid on top is the poor platelet plasma under test.

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

3. 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 testing.

Refer to CLSI H21 for further information on specimen collection and storage.

[Test Procedure]

1. Preparation of reagent

Gently shake and mix the liquid reagent well before using.

2. Test with the semi-automated coagulation analyzer.

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

Add 100µL TT Reagent balanced at room temperature (15~25°C) and record the coagulation time of the plasma.

3. 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.

4. Quality Control Procedure

Test the coagulation QC weekly and establish a QC curve.

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

[Reference Values]

14~21 sec. (n=202, 95% confidence limit).

Due to the normal and reasonable difference between regions and individuals as well as the different test methods adopted, the levels of TT measured may vary. It is suggested that each laboratory establish its own reference values for the population that it serves.

[Interpretation of Test Results]

TT may be reported in seconds (s). The results in the reference interval are usually regarded as normal. However, results may be affected by the diet, region, etc. Please conduct assessment by combining the medical history and other clinical test results. A professional should audit the test results.

[Limitations of the Procedure]

· The course of coagulation includes a series of reactions from activation of factor to fibrin formation. Therefore, test results may be affected by therapeutic drugs (interferent), test operations, test systems, etc., which should be considered.

· 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 20s.

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]

1. The product is only for in vitro diagnosis and operated by medical professionals or trained workers.
2. The test temperature should be within 37±0.5°C.
3. During the test, use plastic or siliconized test tubes, straws and syringes only. Do not use those made of common glass.
4. The plasma under test must not be EDTA, heparin or oxalate anticoagulate plasma.
5. For a coagulation analyzer using turbidimetry, hemolysis, obvious jaundice and lipidemia may affect test results, in which cases, a manual method or electromechanical coagulation analyzer is appropriate.
6. When the hematocrit value is out of the range of 20~55%, adjust the dose of anticoagulant.
7. QC plasma should be tested at the same time each working day to eliminate the interference caused by the instrument, reagents, abnormal operation, etc.
8. 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 samples test presents potential biohazard risk. Personal protections are necessary and dispose the liquid waste in accordance with the local regulations

[References]

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



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