GB CLOT - aPTT

(ACTIVATED PARTIAL THROMBOPLASTIN TIME)

Coagulmetric Assay

Kit contents	Pack size	Cat no.
GB CLOT- aPTT Reagent	400T	GBCAPTT400T

[Intended Use]
It is intended for in vitro determination of Activated Partial Thromboplastin Time (APTT) of human plasma.

[Principle]
When the plasma for test is added with activator (ellagic acid) and brain cephalin, which is called partial thromboplastin, it is incubated at 37℃ for a specific period of time to activate factors XII and XI of the intrinsic pathway of coagulation, and then in the presence of calcium ions, the fibrinogen is converted into insoluble fibrin finally. The time of plasma coagulation after adding calcium chloride measured on the instrument using the optical nephelometry method is the APTT of the plasma.

[Reagents Composition]
Kit consists of Reagent 1 (R1) and Reagent 2 (R2).
R1: APTT Reagent: Ellagic acid, rabbit brain cephalin
R2: CaCl2 Solution: 25mmol/L calcium chloride.

[Storage and Stability]
The reagents store at 2-8℃. Do not freeze! The shelf life is 12 months. Opened vial reagents are stable for 30 days at 2~8℃.

[Instruments]
Semi-automated or automated coagulation analyzers

[Specimen]
1. Nine parts of freshly drawn venous blood are collected into one part of anticoagulant and 0.109mol/L trisodium citrate. Centrifuge at room temperature at 3000rpm for 12 minutes. The light yellow liquid on top is the poor platelet plasma for test.
2. Store the plasma at room temperature 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℃. Melt rapidly at 37℃ and gently mix immediately before test.
Refer to CLSI H21 for further instructions on specimen collection and preparation.

[Test Procedure]
1. Preparation of Reagent
Before use, gently mix the APTT liquid reagent and balance it at room temperature.
2. Assay with the semi-automated coagulation analyzer.
Take 50uL plasma and incubate at 37℃for 1 min.→
Add 50uL APTT Reagent and incubate at 37℃ for 4 min. →
Add 50uL CaCl2 pre-warmed to 37℃, and record the coagulation time of the plasma.
3. Assay 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.

[Expected Values]
24~36 sec.
Each laboratory should establish its own reference ranges.

[Interpretation of Test Results]
1. APTT results can be reported in seconds and/ or ratios. Test results are associated with the reference ranges of the individual laboratory.
2. heparin and coumarin therapy may prolong APTT.

[Limitations of the Procedure]
1. The course of coagulation includes a series of reactions from activation of factors to fibrin formation. Therefore, test results may be affected by therapeutic drugs (interferent), test operations, test systems, etc., which should be considered.
2. Reagent contamination or contamination of sample containers, straws, etc. by coagulant/anticoagulant may cause blood coagulation disorders, so strict control is required.

[Performance Characteristics]
Repeatability: The coefficient of variation (CV) of the results of repeated tests with QC plasma should not exceed 3.8%.

[Notes]
1. The product is for in vitro diagnosis and used by persons with major in medical laboratory or trained persons only.
2. The time of incubation at 37℃ after the plasma mixed with APTT Reagent can be 3 to 5 minutes. APTT values may be affected if the time is too short or too long.
3. The test temperature should be within 37±0.5℃.
4. To measure APTT, poor platelet plasma is required.
5. During the test, use plastic or siliconized test tubes, straws and syringes only. Do not use those made of common glass.
6. The plasma for test must not be anticoagulated by EDTA, heparin or oxalate.
7. Hemolyzed or lipemic plasma may affect test results.
8. When the HCT of blood is out of the range of 20~55%, adjust the dose of anticoagulant.
9. QC plasma should be tested at the same time each working day to eliminate the interference of the instrument, reagents, abnormal operation, etc.

[References]
1. National Guide to Clinical Laboratory Procedures (Third Edition). Southeast University Publishing House, 2006.
2. Charles Eby. Clin Chem. 1997, 43(7):1105-1107.
3. Tetrault G. Am J Clin Pathol. 2000, 113(5):741-742.

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