MISPA clot+ AGAPPE

APTT 'New' 200 Tests 12602003

Intended Use

The **APTT** reagent is an *in vitro* diagnostic assay intended for use in determining activated partial thromboplastin time (APTT) on the Mispa Clog Plus Analyzer.

Summary

The activated partial thromboplastin time (APTT) is used as a general screening test for the detection of coagulation abnormalities in the intrinsic pathway. The APTT is sensitive to deficiencies or abnormalities of factors VIII, IX, XI, XII, X, and II, prekallikrein, high molecular weight kininogen (HMWK), and fibrinogen. APTT is also sensitive to inhibitors of blood coagulation such as lupus inhibitor and fibrin/fibrinogen degradation products (1).

Principle

The APTT is the most widely used method for monitoring intravenous heparin anticoagulation therapy (2, 3).The capacity of blood to form a fibrin clot by way of the intrinsic hemostatic pathway requires coagulation factors I, II, V, VIII, IX, X, XI and XII, platelet lipids and calcium(4). The assay is performed by the addition of a suspension of rabbit brain cephalin with a surface activator(1). The APTT
has proven to be a simple and highly reliable measurement of the intrinsic coagulation mechanism(5).

Kit Components

Reagent/ Component	Product Code 12602003	Description
APTT Reagent	5 x 4 mL	Rabbit brain cephalin, ellagic acid
Calcium chloride	5 x 4 mL	Calcium chloride (0.02 M)
Accessory Kit (provided in separate box)	200 nos	Coagulation Cuvette with Steel Beads
	1 pc	Forceps

Risk & Safety

Material Safety data sheets (MSDS) will be provided on request

Reagent

The **APTT** reagent is a preparation of rabbit brain cephalin and ellagic acid activator with buffer, stabilizers and preservatives. The reagent is provided ready to use.

Precautions

Do not ingest. Avoid contact with skin, eyes or clothing.

Waste Management

Reagents must be disposed off in accordance with local regulations.

Storage and Stability

The **APTT** reagent is stable to the expiry date shown on the label when stored in the original container at 2 to 8°C.

Specimen Collection and Preparation

Test plasma should be prepared from citrated whole blood **without** heparin, EDTA or oxalate.

1. **Blood Collection using Syringe Method:** Draw venous blood into a plastic or siliconized syringe. Immediately transfer 9.0 mL of blood into a tube containing 1.0 mL of 3.2% or 3.8% sodium citrate solution.
2. **Blood Collection using an Evacuated Blood Collection Tube:** Draw venous blood into a commercial vacuum tube containing 3.2% or 3.8% sodium citrate solution. Insure that a full draw has been obtained since the ratio of 9 parts blood to 1 part citrate is critical. A heparinized lock or transfer line should not be used. It is generally recommended that the second or third tube draw be used for coagulation tests.
3. **Plasma Preparation:** Mix well by inversion and centrifuge at 2,500 x g for 15 minutes soon after blood collection. Unless samples are to be processed immediately, transfer the plasma into a plastic tube. Plasma that is clearly hemolyzed or contains > 10,000 platelets per cubic milliliter or red cells is not suitable for coagulation testing.
4. **Plasma Storage:** Plasma samples should be transferred to a plastic tube as soon as possible and stored refrigerated (2 to 8°C). Plasma samples should be tested within 4 hours and should not be incubated at 37°C for more than 5 minutes to avoid loss of factors V and VII.

Procedure

This procedure pertains to the Mispa Clog Plus coagulation system:

1. Pre-incubate the Calcium Chloride (0.02M) to 37°C for at least 10 minutes.
2. Pipette 100 µL of sample or control plasma into a coagulation microcuvette and pre-incubate in channel from 1 to 4 at 37°C for 1 to 2 minutes.
3. Add 100 µL of the **APTT** reagent to the microcuvette containing the plasma. Maintain the suspension of the reagent by magnetic stirring or mixing by inversion immediately prior to use.
4. Incubate the mixture at 37°C for 3 minutes.
5. Add a magnetic stirrer to the microcuvette.
6. Transfer the microcuvette into the reading channel (**Filter A**).
7. When requested on the display, rapidly add 100 µL of the preincubated Calcium Chloride (0.02M).
8. Record the clotting time which will appear automatically on the display once the clot is formed.

Quality Control

Reliability of test results should be monitored within each run using **Coagulation Control Plasmas**. Each laboratory should establish a control range to determine the allowable variation in day to day performance of each control plasma. Agappe Coagulation Control (Bi-Level) (Product Code: 11624003) is available.

Calculation of Results

For best results, duplicate samples are recommended. APTT results should be reported as clotting time in seconds. Calculate the mean clotting time of duplicate samples and controls. Differences between duplicate results should be less than 5%. Repeat the test if necessary.

Limitations

To prevent discrepant results ensure the blood to anticoagulant ratio is 9:1. Grossly lipemic or hemolysed samples may produce erroneous APTT values(6). Delay in testing, difficulty in specimen collection, or venipucture above the site of a heparin lock may result in falsely prolonged APTT results(7). The APTT may also be influenced by certain drugs and medications(8). APTT results can vary with anticoagulation therapy depending upon the type and dosage of anticoagulant, the route of administration and the time of administration of the last dose.

Expected Values

APTT results are influenced by the method of clot detection and can vary from laboratory to laboratory. In general an APTT test performed on a photo-optical coagulometer will give clotting time for normal plasma in the range of 24 to 39 seconds. Therapeutic ranges for monitoring oral anticoagulation therapy will vary from laboratory to laboratory, therefore it is essential that each laboratory establish relevant APTT ranges for its respective patient population.

Abnormal results obtained with a plasma from a patient not on anticoagulant therapy may indicate a factor deficiency or the presence on an inhibitor. The result may also be due to the effects of certain drugs and medications. Additional procedures such as the PT test and mixing studies using factor deficient plasma are usually required.

Performance Characteristics

Precision:

Within-run precision was assessed using normal and abnormal plasma controls.

Sample	Mean	SD	CV%
Control 1	22.5	1.32	5.85
Control 2	55.62	2.11	6.34

Comparison

A comparison study has been performed between Agappe reagent and another internationally available reagent yielded a correlation coefficient of r^2= 0.8902 and a regression equation of y = 0.9383x + 0.9387.

SYMBOLS USED ON THE LABELS

IVD IN VITRO DIAGNOSTIC USE | SEE PACKAGE INSERT FOR PROCEDURE | LOT LOT NUMBER | MANUFACTURER'S ADDRESS | MANUFACTURING DATE | EXPIRY DATE | TEMPERATURE LIMIT

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REV. NO.: ADL/IFU/APTT/CLG/R03

CE ISO 9001:2015
EN ISO 13485:2016

References

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