ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT)

CAT NO	DESCRIPTION	PACK SIZE
COAAPT1	APTT REAGENT ONLY	1x3ml
COAAPT2	APTT REAGENT ONLY	5x3ml
COAAPC3	APTT REAGENT WITH CALCIUM CHLORIDE	6x3ml / 2x10ml
COAAPC4	APTT REAGENT WITH CALCIUM CHLORIDE	6x6ml / 4x10ml
COACCL1	CALCIUM CHLORIDE	1x10ml
COACCL2	CALCIUM CHLORIDE	5x10ml

Intended Use:

APTT Reagent is an in vitro diagnostics assay for the determination of activated Partial Thromboplastin time using Ellagic acid as an activator and aPTT based factor assays. This reagent is for In vitro Diagnostic use only.

Summary and Principle:

The APTT is a screening tool for evaluation of coagulation abnormalities in the intrinsic pathway. The kit also is helpful in detecting severe functional deficiencies in factor II, V, X or fibrinogen. The APTT reagent has also been widely advocated as a means to monitor the effectiveness of heparin therapy where the clotting time is prolonged in proportion to the level of heparin.

Reagent Composition:

APTT REAGENT	Ellagic Acid 0.034%
	Cephalin 0.40%
	Tris Buffer
	Preservatives (0.09%)
CALCIUM CHLORIDE	Calcium Chloride (25 mmol/l)
	Preservatives (0.09%)

Materials required but not provided:

Control Material, Pipettes, Coagulation Analyser, Plastic tubes

Reagent Preparation and Stability:

The APTT Reagent and CaCl2 are supplied ready to use. Mix reagents gently before use.
Unopened reagents are stable up to expiry when stored at 2-8°C.
Once opened the reagents are stable for a period of 30 days when stored tightly capped and stored at 2-8°C.

Specimen Collection:

Mix nine parts of freshly collected patient blood with 1 part of 3.2% sodium citrate. Avoid haemolysis. Centrifuge anti-coagulated blood for 15 minutes at 3000 rpm. Test immediately.
If tests cannot be conducted immediately, store at 2-8°C and test within 3 hours. Clotting time prolongs with storage time.

Procedure:

Manual Method:

1. Remove the required volume of Calcium Chloride Reagent and incubate for at least 10 minutes at 37°C.
2. Remove the required volume of APTT reagent from the vial and ensure that the reagent is at room temperature before use.
3. To a cuvette add 0.1ml (100ul) of APTT reagent and 0.1ml (100ul) of test plasma and mix.
4. Incubate at 37°C for 3 minutes.
5. Add 0.1ml (100ul) of the pre-incubated Calcium Chloride reagent rapidly and start the timer.
6. Record the clotting time.

For automated assays, refer to the instrument operator manual and follow instructions.
Clotting times are reported within the nearest 0.1 seconds.

Performance Characteristics:

Sensitivity: 3 seconds with 99.7% confidence limit.
Linearity: 3seconds to 25 seconds.
Interferences: Criterion: +/- 10% of initial value.
Lipaemia: No significant interference up to a level of 2000 mg/dl
Icteremia: No significant interference up to a bilirubin level of 30 mg/dl
Haemolysis: No significant interference up to a haemoglobin concentration of 500 mg/dl.

INTRA ASSAY PRECISION (WITHIN RUN PRECISION)

LEVEL	MEAN (SEC)	CV%
Plasma Control L1	33.1	1.31%
Plasma Control L 2	82.5	1.1%

INTER ASSAY PRECISION (BETWEEN RUN PRECISION

LEVEL	MEAN (SEC)	CV%
Plasma Control L1	33.1	2.27%
Plasma Control L 2	82.5	1.30%

Reproducibility of the control plasma of CV </= 5%
Repeatability of the reagent: within 5%

Quality Controls:

We recommend the use of AMS UK Quality controls with this kit.
QCCPCL1 – Plasma Control Level 1 – 5x1ml
QCCPCL2 – Plasma Control Level 2 – 5x1ml

Limitations:

APTT results are affected by the commonly administered drugs and further studies must be made to determine the source of unexpected abnormal results.
Ratio of Anticoagulants to the patient blood, while collecting specimen, is a crucial factor in the determination of APTT. Follow the recommended technique.

Warning and Precautions:

- For Invitro diagnostics use only
- All precautions necessary for laboratory reagents must be taken with this reagent also.
- Contains Preservatives. Do Not swallow. Avoid contact with skin and mucous membranes.
- Disposal of all waste material should be in accordance with the local guidelines.
- MSDS available upon request.

References:

1. Biggs, Rosemary Ed., Human Blood Coagulation, Haemostasis and Thrombosis, 2nd Ed, Blackwell Scientific Publications, London.
2. Young D.S.et al., Effect of Drugs on Clinical Laboratory Tests, 3rd ed., AACC Press Washington DC 1990.

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by
	Manufacturer		

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