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
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	Colloidal Silicates 0.52%
	Phospholipids 0.45%
	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 4 hours, frozen at -20°C for up to 2 weeks or at -70°C for up to 6 months.

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 100 µl of the sample and incubate at 37°C for 1 – 2 minutes.
4. Add 100 µl of the APTT reagent that is at room temperature and incubate the mix for 5 minutes at 37°C.
5. Add 100 µl 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:

Interferences: Criterion: +/- 10% of initial value.
Icterus: No significant interference up to a bilirubin level of 0.50 mg/ml
Haemolysis: No significant interference up to a haemoglobin concentration of 10 mg/ml.

Heparin Sensitivity:
Clotting time of 30 seconds without any heparin in the sample.
Clotting time of 70 seconds with 0.2 U/ml of Heparin in the sample.
Clotting time of 174 seconds with 0.4 U/ml of Heparin in the sample.

Factor Sensitivity:
Normal Clotting time: 26.7 – 34.9 seconds

	APTT Clotting time in Seconds		
Factor %	**Factor VIII**	**Factor IX**	**Factor XI**
100 %	28.8 Seconds	28.8 Seconds	28.8 Seconds
40%	34.2 Seconds	33.9 Seconds	34.4 Seconds
10%	45.9 Seconds	44.4 Seconds	50.7 Seconds
1%	85.7 Seconds	70.9 Seconds	92.4 Seconds

Intra Assay Precision

LEVEL	CV%
Plasma Control L1	1.0
Plasma Control L2	1.0

Inter Assay Precision

LEVEL	CV%
Plasma Control L1	1.5
Plasma Control L2	1.5

Quality Controls:

We recommend the use of Prestige Diagnostics 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.
The result from this test should not be used as the sole criteria for the diagnosis of clotting disorders, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated

Warning and Precautions:

- For In-vitro diagnostic use by trained professionals 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.
- Delay in testing prolongs APTT values.
- MSDS available upon request.

References:

1. Proctor RR and Rapaport SI. The partial thromboplastin time with kaolin. A simple screening test for first stage plasma clotting factor deficiencies. Am J Clin Pathol, 1961; 36: 212-219
2. Triplett DA, Harms CS and Koepke JA. The effect of heparin on the activated partial thromboplastin time. Am J Clin Pathol, 1978; 70: 556-569.
3. Barrowcliffe TW and Gray E. Studies of phospholipid reagents used in coagulation. II: Factors influencing their sensitivity to heparin. Thromb Haemost, 1981; 46: 634-637.

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

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