This package insert follows the Pharmaceuticals, Medical devices and Other Therapeutic Products Act of Japan.

In Vitro Diagnostics
Certification No. 222ADAMX00008000

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*Revised: April 2011 (3rd edition)

This package insert must be read carefully prior to use.

Activated partial thromboplastin time assay kit
(Classification No.: 38553000)

Coagpia APTT-N

General Precautions

1. This product is for in vitro diagnostic use, and must not be used for any other purposes.
2. Clinicians should make a comprehensive clinical decision based on assay results in conjunction with clinical symptoms and other examination results.
3. For the effects of an administered drug on the measured value, carefully read the Precautions for Use in the package insert of the drug, especially the section about the effects on laboratory test results.
4. This product should be used only as directed in this package insert. Reliability of results cannot be guaranteed if there are any deviations from the instructions in this package insert.
5. If the reagent accidentally comes in contact with eyes and/or mouth, rinse immediately with ample water as first aid, and consult the doctor if required.
6. Carefully read the operating instructions for each type of blood coagulation analyzer prior to using this product. Parameters for each type of analyzers are available, and can be requested from SEKISUI MEDICAL CO., LTD. if required.
7. Perform a quality control test prior to assay to ensure accuracy.

Description (Kit Components)

Component	Ingredients
APTT Reagent:	Phospholipid (derived from rabbit brain)
	Ellagic acid
Calcium Chloride Solution:	
	Calcium Chloride

Intended Use

Measurement of activated partial thromboplastin time (APTT) using plasma

APTT assay is widely used as a screening test for intrinsic coagulation factors, for monitoring patients on heparin therapy, or for measuring coagulation factor inhibitors.[1)]

Assay Principle

To the plasma sample, add sufficient phospholipid and ellagic acid to activate contact factors (Factor XII, prekallikrein, high molecular weight kininogen). Then add the Calcium Chloride Solution, and measure the APTT as the time (coagulation time) in seconds from addition of the solution until fibrin production.

Procedural Precautions **

1. Properties of Samples and Sampling Methods

1) Samples
Plasma (citrated plasma) can be used as the sample. Do not use plasma treated with an anti-coagulant other than sodium citrate.
2) Sampling method
(1) Promptly mix the collected blood with 3.2% sodium citrate at a volume ratio of 9:1, centrifuge the mixture (1500G for at least 15 minutes or 2000G for at least 10 minutes) at 18–25°C within 1 hour, and store the resulting plasma sample.[2] (It is particularly important to perform centrifugation so that the platelet count of the plasma sample is < 10000/μL.)
(2) At the time of blood collection, avoid contamination with tissue fluid and mixing with too much or too little sodium citrate, or accurate results may not be obtained.
3) Storage of samples
Perform the test immediately after separation of plasma. Store the plasma sample at room temperature (18–25°C), and perform the test within 1 hour of separation.[2)]

2. Interfering substances

1) Assay results are not affected by free bilirubin (up to 20 mg/dL), conjugated bilirubin (up to 20 mg/dL), hemoglobin (up to 500 mg/dL), or formazin turbidity (up to 3000 FTU).
2) The clotting time may be prolonged by heparin.
3) It may also be prolonged by aminoglycoside antibiotics.

Dosage/Administration (Assay Procedure) **

1. Preparation of reagents
APTT Reagent is ready to use.
Calcium Chloride Solution is ready to use.

2. Assay Procedure
This product is compatible with various types of blood coagulation analyzer. An example of the assay procedure is indicated below.

Plasma sample 50 μL → (37°C) → APTT Reagent 50 μL → (37°C) → Calcium Chloride Solution 50 μL → (37°C) → Measurement of clotting time

3. Precautions for testing

1) Before use, gently mix the APTT Reagent and Calcium Chloride Solution by inversion. At this time, avoid vigorous mixing.
2) After completion of measurement, tightly close the container, and store at 2–10°C.

Assessment of Assay Results **

1. Reference standard range[3)]
24–39 seconds Because the standard range of APTT varies between instruments, please

determine it at each laboratory.

2. Precautions for Assessment

There may be reactions or interfering reactions with non-target substances. If assay results appear to be unreliable, repeat the measurement or try another analytical methods.

Performance **

1. Sensitivity

The APTT is 25–35 seconds with normal plasma and 72–119 seconds with 1:4 diluted normal plasma.

2. Accuracy: 80–120 % of the expected assay value

3. Within-run Reproducibility:

Coefficient of variation ≤ 10 %

(Test methods used for 1.–3. are in-house methods.)

4. Measurement Range[3]: (Coapresta 2000)

20–200 seconds

5. Correlation[3]

1) N=95 r=0.969 y=0.97x–0.9

Control method: Approved in vitro diagnostic (clotting time method)

2) N=92 r=0.955 y=0.98x+0.1

Control method: Approved in vitro diagnostic (clotting time method)

Precautions for Use or Handling **

1. Precautions for Handling (to Ensure Safety)

1) All samples used in the test should be handled as a material possibly infected with HIV, HBV, HCV, or other viruses. To prevent infection, use disposable gloves and avoid mouth pipetting during the test.

2) Sodium azide is added as an antiseptic agent in the Calcium Chloride Solution. Therefore, if the reagent comes in accidentally contact with eyes, mouth or skin, rinse immediately with ample water as first aid, and consult the doctor if required.

2. Precautions for use

1) This product should be stored as directed, avoid freezing. Freezing can cause deterioration of the reagents, leading to inaccurate results. Therefore, do not use the product if it has been previously frozen.

2) Do not use expired reagents. Use of such reagents cannot guarantee the reliability of measurement values.

3) Do not replenish the reagents.

4) Do not mix materials from different kit lot numbers.

5) Do not perform the assay under direct sunlight

3. Precautions for Disposal

1) Before disposal, used samples and their containers must be immersed in sodium hypochlorite solution at a concentration of greater than 0.1% for longer than 1 hour or autoclaved at 121ºC for 20 minutes.

2) To prevent infections from spilled samples or solutions containing samples, wipe the spilled area thoroughly with disinfectants such as sodium hypochlorite solution at a concentration of greater than 0.1%.

3) The reagents and treated samples should be discarded as medical waste or industrial waste according to the waste disposal regulations.

4) The reagents should be disposed of in accordance with the Water Pollution Control act or related regulations.

5) Sodium azide has been added as an antiseptic agent in the Calcium Chloride Solution. It can react with lead or copper pipes to produce the highly explosive metal azide. Therefore, the reagent should be flushed with large amounts of water during disposal.

4. Other precautions

Do not use the containers for other purposes.

Storage and Shelf Life * * *

1. Storage temperature: 2–10°C

2. Shelf life: 2 years from the date of manufacture

(The expiration date is printed on the outer package.)

Packaging

Name		Package
Coagpia APTT-N	APTT Reagent	10 × 4 mL
	Calcium Chloride Solution	10 × 4 mL

Constituent reagents are available in other configurations. For further details please contact SEKISUI MEDICAL CO., LTD.

References **

1) Kanai M. (supervising editor): Kanai's manual of clinical laboratory medicine. 34th ed. 393, Kanehara Shuppan, 2015.

2) Edited by the Japanese Society for Laboratory Hematology: J Jpn Soc Lab Hematol, 17(2), 149–157, 2016.

3) In house data, SEKISUI MEDICAL CO., LTD.

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Manufacturer **

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