

This package insert must be read carefully prior to use.

Fibrinogen assay kit
(Classification No.: 30541000)

fibrinogen level (mg/dL) from the calibration curve plotted by using plasma samples with known fibrinogen levels.

Coagpia Fbg

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
Sample Dilution Solution	
Thrombin Reagent:	Thrombin

Intended Use

Measurement of fibrinogen in plasma

Fibrinogen is one of the acute phase reactant proteins produced by hepatocytes. Its plasma level is increased by acute infection, malignancy, and thrombotic diseases, while it is decreased by reduced production due to parenchymal liver disease or enhanced consumption due to disseminated intravascular coagulation (DIC).¹ Measurement of fibrinogen is performed to assess the pathologic effects of these diseases and assist with diagnosis.

Assay Principle

1. Assay Principle

Coagpia Fbg is a reagent for determination of plasma fibrinogen based on the thrombin time assay. Add a fixed amount of thrombin to the diluted plasma sample, and measure the time (coagulation time) in seconds from addition of thrombin until production of fibrin from fibrinogen. Since the coagulation time depends on the fibrinogen level, determine the plasma

Procedural Precautions **

1. Properties of Samples and Sampling Methods

- 1) Samples
Plasma (citrate plasma) can be used as the sample. Do not use plasma treated with an anti-coagulant other than sodium citrate.
- 2) Sampling method
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.
- 3) Storage of samples
 - (1) After separation of plasma, store the plasma sample at room temperature (18–25°C), and perform the test within 4 hours of separation.²⁾ Test the plasma sample within 3 days of separation if it is stored at 2–10°C and within 4 days if it is stored at -28°C or lower.⁴⁾
Bring samples to room temperature (15–30°C) before use.
 - (2) Immediately thaw frozen samples at 37°C to avoid degeneration of fibrinogen. Avoid repeated freezing and thawing, or errors in the assay results may occur.

2. Interfering substances

Assay results are not affected by free bilirubin (up to 25 mg/dL), conjugated bilirubin (up to 25 mg/dL), hemoglobin (up to 500 mg/dL), formazin turbidity (up to 3000 FTU), or heparin sodium (up to 8 U/mL).

3. Others

- 1) Always use Calibrator N for Coagpia for calibration.
- 2) If the concentration of the plasma sample exceeds the measurement range, dilute the sample 1:20 with the Sample Dilution Solution and perform re-measurement.
- 3) A commercially available diluent may also be used as the Sample Dilution Solution. Please contact SEKISUI MEDICAL CO., LTD. for further information about use of this product.

Dosage/Administration (Assay Procedure) **

1. Preparation of reagents

Sample Dilution Solution: Ready to use.
Thrombin Reagent: 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.

(Sample preparation)

Plasma Sample Dilution
sample + Solution $\xrightarrow{37^{\circ}\text{C}}$ Sample
10 μL 90 μL 100 μL

(Measurement of clotting time)

Sample Thrombin
100 μL + Reagent $\xrightarrow{37^{\circ}\text{C}}$ Measurement of
50 μL clotting time

Calibration material: Calibrator N for Coagpia
(Manufacture's assigned value)

3. Calculation of plasma fibrinogen level (mg/dL)

- 1) Dilute Calibrator N for Coagpia to 1:5, 1:10, and 1:20 with the Sample Dilution Solution.
- 2) Add the Thrombin Reagent to each of the above diluted samples, and measure the coagulation time.
- 3) Plot the fibrinogen level (mg/dL) on the x-axis and coagulation time on the y-axis to create a calibration curve. At this time, the fibrinogen levels in the calibrator diluted 1:5, 1:10, and 1:20 are specified as 2, 1, and 1/2 times the indicated values of the calibrator, respectively.
- 4) Dilute the plasma sample to 1:10 with the Sample Dilution Solution, add the Thrombin Reagent, and measure the coagulation time. Use this time to calculate the fibrinogen level (mg/dL) from the calibration curve that was previously plotted.

Operations 1)–4) are performed automatically by the analyzer (blood coagulation analyzer), and the fibrinogen level (mg/dL) is calculated.

4. Precautions for testing

After completion of measurement, tightly close the container of this product, and store it in a refrigerator.

Assessment of Assay Results

1. Reference standard range³⁾

200–400 mg/dL

Performance **

1. Sensitivity

When the test is performed using normal plasma diluted to 1:10 and 1:20, the coagulation time per 300 and 150 mg/dL of fibrinogen is 7–13 and 15–24 seconds, respectively.

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

3. Within-run Reproducibility:

Coefficient of variation $\leq 10\%$

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

4. Measurement Range⁴⁾: (Coagulex 800)

40–800 mg/dL

5. Correlation⁴⁾

1) $N=87$ $r=0.990$ $y=1.03x+0.68$

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

6. Standard Material

NIBSC Reference Standard 98/612 (NIBSC)

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) Proclin 300, which possesses skin-irritative potential, is added as an antiseptic agent in the Sample Dilution Solution and Thrombin Reagent. Therefore, if the reagent comes in contact with skin or clothes, rinse immediately with ample water, and consult the doctor if skin irritation develops.

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 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 121°C 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.

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 Fbg	Sample Dilution Solution	10 × 10 mL
	Thrombin Reagent	10 × 3 mL

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

References **

- 1) Edited by the Japanese Society for Laboratory Hematology: Standard Laboratory Hematology, 136–139, Ishiyaku Shuppan, 2003.
- 2) Edited by the Japanese Society for Laboratory Hematology: J Jpn Soc Lab Hematol, 17(2), 149–157, 2016.

- 3) Kanai M. (supervising editor): Kanai's manual of clinical laboratory medicine. 34th ed. 402, Kanehara Shuppan, 2015.
- 4) In house data, SEKISUI MEDICAL CO., LTD.

Contact

SEKISUI MEDICAL CO., LTD.
international@sekisui.com

Manufacturer **

SEKISUI MEDICAL CO., LTD.
1-3, Nihonbashi 2-chome, Chuo-ku, Tokyo, Japan