

This package insert must be read carefully prior to use.

Plasminogen assay kit
(Classification No.: 30578000)

Testzym S PLG

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. 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.
4. 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.
5. Carefully read the operating instructions for each type of automated analyzers prior to using this product. Parameters for each type of analyzers are available, and can be requested from SEKISUI MEDICAL CO., LTD. if required.
6. Perform a quality control test prior to assay to ensure accuracy.

Description (Kit Components) **

Component	Ingredients
Streptokinase Solution:	Streptokinase (derived from β -hemolytic streptococcus)
Substrate Solution:	H-D-valyl-L-leucyl-L-lysyl-p-nitroanilide dihydrochloride (S-2251)

Intended Use

Measurement of plasminogen plasma

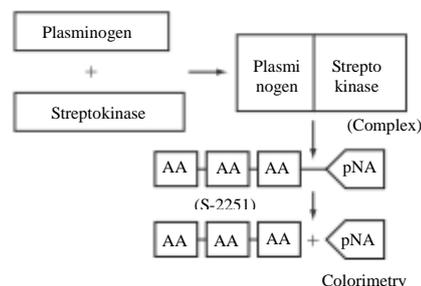
Plasminogen is a precursor of plasmin in the blood. It is activated to form plasmin by various in vivo activators and plays an important role in fibrinolysis. The blood level of plasminogen is altered in patients with various diseases and symptoms, e.g., it shows a marked decrease in patients who have plasminogen abnormalities, disseminated intravascular coagulation (DIC), and liver disorders. Therefore, measurement of plasminogen activity is useful when screening for these diseases, as well as for analysis of disease pathology, estimation of the prognosis, and evaluation of the effect of fibrinolytic therapy.

Assay Principle

1. Assay Principle

When an excess of streptokinase is added to a sample for measurement of plasminogen, plasminogen forms a complex with streptokinase. This complex has plasmin-like activity and decomposes the synthetic chromogenic substrate (S-2251) to release p-nitroaniline. The activity of

plasminogen in the sample is determined through measurement of released p-nitroaniline by colorimetry.



2. Features

- 1) Dilution of the sample is not necessary.
- 2) Liquid reagents, ready-to-use.
- 3) The synthetic chromogenic substrate used in this product shows extremely high specificity for plasmin.
- 4) Because the streptokinase activation method is used, the influence of inhibitors in plasma is avoided.
- 5) This product shows good quantification and excellent reproducibility.
- 6) Applicable to various automated analyzers.

Procedural Precautions **

1. Properties of Samples and Sampling Methods

- 1) Samples
 - (1) Plasma (Citrate plasma) may be used.
 - (2) Heparin plasma or EDTA plasma should not be used.
- 2) Storage of samples
 - (1) If the isolated serum sample cannot be tested on the same day, specimens should be stored as follows:
 - 2–10°C: for tests within 1 week
 - ≤ -20°C: for tests within 1 month
 Bring samples to room temperature (15–30°C) before use.
 - (2) Avoid repeated freezing and thawing, or errors in the assay results may occur.
 - (3) Use plastic containers and test tubes for dilution and/or storage of plasma.

2. Interfering substances

Assay results are not affected by free bilirubin (up to 50 mg/dL), conjugated bilirubin (up to 50 mg/dL), or hemoglobin (up to 1000 mg/dL).

3. Others

- 1) Always use Normal plasma “Daiichi” for calibration.
- 2) Precautions for assay range
If the activity of sample exceeds assay range, dilute the sample with saline and repeat the measurement.

Dosage/Administration (Assay Procedure) **

1. Preparation of reagents

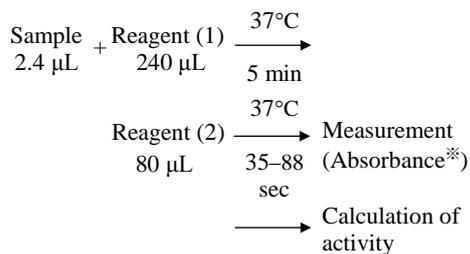
Reagent (1): Streptokinase Solution is ready to

use.

Reagent (2): Substrate Solution is ready to use.

2. Assay Procedure

This product is compatible with various types of automated analyzer. An example of the assay procedure is indicated below.



* Absorbance : The difference in absorbance between 405 nm and 505 nm.

Calibration material: Normal plasma “Daiichi” (Manufacture's assigned value)

Reagent blank: Purified water or saline

Assessment of Assay Results

1. Reference standard range

106.5 \pm 15.3 %²⁾

80–130 %³⁾

(Relative to healthy volunteers [100 %])

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

Performance

1. Sensitivity

1) Reagent blank: Reagent blank: absorbance variation being -0.02 to 0.02

2) Sensitivity: The difference of absorbance between 100 % normal plasma and physiological saline is from 0.15 to 0.35.

2. **Accuracy:** 90–110 % of the expected assay value

3. Within-run Reproducibility:

Coefficient of variation \leq 5 %

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

4. **Measurement Range**⁶⁾: (On Hitachi 7170 automated analyzer)

4–180 %

5. Correlation⁶⁾

Plasma N=99 $r=0.984$ $y=1.01x-0.82$

Control method: Approved in vitro diagnostic (synthetic chromogenic substrate method)

6. Standard Material

Pooled plasma obtained from healthy volunteers (in-house reference standard)

Precautions for Use or Handling * *

1. Precautions for Handling (to Ensure Safety)

- 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.
- Streptokinase Solution and Normal plasma “Daiichi” contains human-derived components

determined as HBsAg-negative, HIV antibody (AIDS virus antibody) negative, and HCV antibody negative. When using, however, it should be handled very carefully as with samples, considering the risk of infectious.

- Sodium azide is added as an antiseptic agent in the Streptokinase Solution and Substrate 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

- This product should be stored as directed, without freezing. Freezing can deteriorate the reagents, which can produce inaccurate results. Therefore, avoid using the reagents which have been previously frozen.
- Do not use expired reagents. Use of such reagents cannot guarantee the reliability of measurement values.
- Do not replenish the reagents.
- Do not perform the assay under direct sunlight

3. Precautions for Disposal

- 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.
- 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%.
- The reagents and treated samples should be discarded as medical waste or industrial waste according to the waste disposal regulations.
- The reagents should be disposed of in accordance with the Water Pollution Control act or related regulations.
- Sodium azide has been added as an antiseptic agent in the Streptokinase Solution and Substrate 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: 13 months from the date of manufacture

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

Packaging

Name		Package
Testzym S PLG	Streptokinase Solution	2 \times 6.0 mL
	Substrate Solution	1 \times 4.0 mL

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

References *

- 1) Friberger P., Knos M.: Chromogenic Peptide Substrates Ed. Kakkar V.V., p.128, Churchill Livingstone, London, 1979.
- 2) Endo T. et al.: J Clin Lab Inst Reag, 6, 339, 1983.
- 3) Fujimaki M: Thrombi and Hemorrhage, DIC Made Simple, Murakami K. (supervisor), Masuda T. (editor), 114, Yodosha, 1981.
- 4) Kondo H. et al.: J Clin Lab Inst Reag, 19, 289, 1996.
- 5) Kotani T. et al.: J Jpn Soc Clin Labo Autom, 21, 285, 1996.
- 6) In house data, SEKISUI MEDICAL CO., LTD.

Contact *

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Manufacturer **

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