

This package insert must be read carefully prior to use.

Fibrin degradation product assay kit
(Classification No.: 30576000)

Nanopia D-dimer

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

D-dimer Buffer Solution 1

D-dimer Latex Reagent 2:

Anti-human D-dimer mouse
monoclonal antibody-coated latex

Intended Use

Measurement of D-D dimer concentration in plasma or serum

D-dimer (D-D dimer) is a kind of fibrin/fibrinogen degradation product (FDP) that is produced when stabilized fibrin, which has been cross-linked by active factor XII, is degraded by plasmin. There are various molecular species of D dimer in the blood, such as YY/DXD, YD/DY, DD/E, and DD complexes.

An increase of the blood level of D-dimer indicates that thrombi are being formed in vivo and that the fibrinolysis system has been activated. D-dimer is known to increase in various diseases, such as malignancies, obstetric diseases, vascular diseases,

and disseminated intravascular coagulation (DIC).

Assay Principle

1. Assay Principle

D-dimer in the sample reacts with the mouse anti-human D-dimer monoclonal antibody-coated latex, resulting in agglutination of the latex particles and an elevation of turbidity. The resulting turbidity changes are then measured

using a spectrophotometer, allowing quantitative measurement of the D-dimer concentration in the sample.

2. Features

- 1) Assay range is wide as up to 60 µg/mL which can be measured without dilution.
- 2) Either plasma or serum can be used as samples.
- 3) Applicable to various automated analyzers.

Procedural Precautions **

1. Properties of Samples and Sampling Methods

1) Samples

Plasma (citrate plasma) and serum may be used. When using serum, it should be sampled with specific tubes for FDP containing thrombin and aprotinin.

2) Storage of samples⁵⁾

If the isolated serum or plasma sample cannot be tested on the same day, specimens should be stored as follows: Specimens may be stored up to 1 day at 2–10°C and 1 month at -80°C. The freeze-thaw cycle for a sample is limited to one time only.

Bring samples to room temperature (15–30°C) before use.

2. Interfering substances

Assay results are not hardly affected by free bilirubin (up to 17 mg/dL), conjugated bilirubin (up to 21 mg/dL), hemoglobin (up to 500 mg/dL), chyle formazin turbidity (up to 1960 FTU), or rheumatoid factors (up to 500 IU/mL).

3. Others

- 1) Always use D-dimer Calibrator for calibration.
- 2) Precautions for assay range
If the concentration of sample exceeds assay range, dilute the sample with saline and repeat the measurement.

Dosage/Administration (Assay Procedure) **

1. Preparation of reagents

Reagent (1): D-dimer Buffer 1 is ready to use.
Reagent (2): D-dimer Latex Reagent 2 is ready to use.

Invert the P-FDP Latex Reagent 2 gently to mix before use, and check that there is no formation of foam.

2. Assay Procedure

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

Sample 12 L	+	Reagent (1) 100 L	$\xrightarrow[5 \text{ min}]{37\text{C}}$	Reagent (2) 100 L	$\xrightarrow[35 \text{ sec}]{37\text{C}}$	Measurement (Absorbance I [※])
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$\xrightarrow[1.4 \text{ min}]{37\text{C}}$ Measurement
(Absorbance II[※])
 \longrightarrow Calculation of
concentration

※Absorbance I and II: The difference in absorbance between 570 nm and 800 nm
Calibration material: D-dimer Calibrator (Manufacture's assigned value)
Reagent blank: Purified water or saline

Assessment of Assay Results

1. Reference standard range¹⁾

≤ 1.0 µg/mL

- There may be reactions or interfering reactions with non-target substances. If plasma with difficult sampling was used, falsely high values may be obtained. If assay results appear to be unreliable, repeat the measurement (if necessary, after dilution) or try another analytical methods.

Performance

1. Sensitivity

- Reagent blank: change in absorbance being equal to or lower than 0.01/min
- Sensitivity: The change in absorbance is 0.01–0.05/min per 10 µg/mL of D-dimer.

2. Accuracy: 85–115% 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 Range⁴⁾: (On Hitachi 7170 automated analyzer)

0.5–60 µg/mL

5. Correlation⁴⁾

- Plasma N=120 $r=0.99$ $y=0.97x+0.81$

Control method: Approved in vitro diagnostic product (latex immuno-turbidimetric assay)

- Serum N=67 $r=0.99$ $y=0.97x-0.79$

Control method: Comparison with the values obtained simultaneously with the plasma samples.

6 Standard Material.

Fibrin degradation product (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.
- Proclin 300, which possesses skin-irritative potential, is added as an antiseptic agent in the D-dimer Buffer Solution 1 and D-dimer Latex Reagent 2. 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

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

- Do not replenish the reagents.

- Do not mix latex reagents from different kit lot numbers.

- 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.

4. Other precautions

Do not use the containers for other purposes.

Storage and Shelf Life **

- Storage temperature: 2–10°C

- Shelf life: 2 years from the date of manufacture (The expiration date is printed on the outer package.)

Packaging

Name			Package
Nanopia D-dimer	(1)	D-dimer Buffer Solution 1	1 × 10.5 mL
	(2)	D-dimer Latex Reagent 2	1 × 10 mL

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

References **

- Kurokawa K. et al.: Laboratory test data book 2013–2014, 385, 2013.
- Takada A. et al.: J Jpn Soc Clin Labo Autom, 30, 721, 2005.
- Kikuchi M. et al.: J Jpn Soc Lab Hematol, 6, 349, 2005.
- In house data, SEKISUI MEDICAL CO., LTD.

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Manufacturer **

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