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

In Vitro Diagnostics
Certification No.21400AMZ00010000

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This package insert must be read carefully prior to use.

Fibrin/fibrinogen degradation products assay kit
(Classification No.: 30575000)

Nanopia P-FDP

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

P-FDP Buffer Solution 1:
2-Amino-2-hydroxymethyl-1,3-propanediol buffer

P-FDP Latex Reagent 2:
Anti-FDP mouse monoclonal antibody-coated latex

Intended Use

Measurement of fibrin and fibrinogen degradation products (FDP) in plasma or serum

Products generated from fibrin/fibrinogen decomposition, which result from fibrinolysis due to the action of plasmin, are collectively referred to as FDP.

An increase in the level of FDP in the blood demonstrates in vivo hyperfi brinolysis, and is found in several diseases such as malignant tumor, obstetric diseases, vascular diseases or disseminated intravascular coagulation syndrome (DIC). In particular, DIC, which is known to develop due to significant hyperfibrinolysis or hypercoagulation, is diagnosed and followed up by measuring the FDP level as one of the essential indices.

Assay Principle

1. Assay Principle

FDP in samples agglutinates with mouse anti-human FDP monoclonal antibody-coated latex through an antigen-antibody reaction. The change in absorbance caused by this agglutination is measured to determine the FDP level in the sample.

2. Features

1) Either plasma or serum can be used as samples.
2) Assay range is wide as up to 120 μg/mL which can be measured without dilution.

Procedural Precautions * *

1. Properties of Samples and Sampling Methods

1) Samples

Citrated plasma and serum can be used.
When using serum, it should be sampled with specific tubes for FDP containing thrombin and aprotinin.

2) Storage of samples[5)]

Samples should be centrifuged immediately after sampling and should be tested on the same day. If samples cannot be tested on the same day, they may be stored up to 1 day at 4−8°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 affected by free bilirubin (up to 22 mg/dL), conjugated bilirubin (up to 19 mg/dL), hemoglobin (up to 470 mg/dL), formazin turbidity (up to 2900 FTU), or rheumatoid factors (up to 470 IU/mL).

3. Others

1) Always use FDP Calibrator N for calibration.
2) Precautions for assay range

If the concentration of sample exceeds assay range, dilute the sample with saline and repeat the measurement.

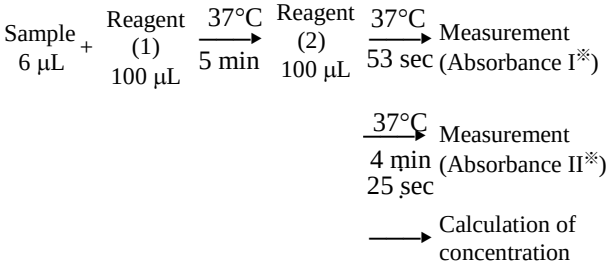
Dosage/Administration (Assay Procedure) * *

1. Preparation of reagents

Reagent (1): P-FDP Buffer Solution 1 is ready to use.
Reagent (2): P-FDP 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.



※Absorbance I and II: The difference in absorbance between 800 nm and 570 nm

Calibration material: FDP Calibrator N (in-house indicated values)

Reagent blank: Purified water or saline

Assessment of Assay Result

1. Reference standard range[1)]

< 5 μg/mL

2. 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: absorbance being equal to or lower than 0.02
2) Sensitivity: The absorbance is 0.01–0.1 per 10 μg/mL of FDP.

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 Range[5)]: (On Hitachi 7170 automated analyzer)

2.5−120 μg/mL

5. Correlation[5)]

1) Serum N=143 r=0.98 y=1.03x −0.21
Control method: Approved in vitro diagnostic (latex immunoturbidimetric)
2) Plasma N=127 r=0.992 y=0.96x+0.43
Control method: Comparison with serum collected simultaneously and measured by this method (dedicated blood tube).

6. Standard Material

Purified fibrinogen (in-house reference standard)

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 P-FDP Buffer Solution 1 and P-FDP 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

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 mix latex reagents from different kit lot numbers.
4) Do not replenish the reagents.
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.

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
Nanopia P-FDP	P-FDP Buffer Solution 1	1 × 10 mL
	P-FDP Latex Reagent 2	1 × 10 mL

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

References **

1) Kurokawa K. et al.: Laboratory test data book 2013–2014, 383, 2013.
2) Amemiya N. et al.: J Jpn Soc Lab Hematol, 3, 143, 2002.
3) Moriai R. et al.: J Med Pharm Sci, 47, 977, 2002.
4) Mitsuhashi H. et al.: Jpn J Clin Med, 57 (1999 extra edition), 566, 1999.
5) In house data, SEKISUI MEDICAL CO., LTD.

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