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

In Vitro Diagnostics
Certification No. 220ADAMX00059000

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This package insert must be read carefully prior to use.

Soluble fibrin monomer complex assay kit
(Classification No.: 43421000)

Nanopia SF

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 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.
7. Perform a quality control test prior to assay to ensure accuracy.

Description (Kit Components)

Component	Ingredients
SF Buffer Solution 1	
SF Latex Reagent 2:	Anti-human SF mouse monoclonal antibody-coated latex※

※It is an abbreviation for anti-human soluble fibrin monomer complex mouse monoclonal antibody-coated latex.

Intended Use

Detection of soluble fibrin monomer complex in plasma

An increase of soluble fibrin monomer complex (SF) in plasma reflects the formation of fibrin from fibrinogen by thrombin in vivo. Therefore, it is used as a molecular marker of coagulation to assess thrombosis and prothrombotic states including DIC.[1)]

Assay Principle

1. Assay Principle

In samples, an antigen-antibody reaction occurs between SF and anti-human SF mouse monoclonal antibody-coated latex, resulting in agglutination of the latex.

The SF level in the sample is determined by measuring the change of absorbance due to agglutination of the latex.

2. Features

1) Fibrin monomers and SF created from fibrinogen by thrombin are detected, but SF that has undergone degradation by plasmin is not detected. Fibrinogen/fibrin degradation products and fibrinogen are not detected.
2) Applicable to various automated analyzers.

Procedural Precautions **

1. Properties of Samples and Sampling Methods

1) Samples

Plasma (citrated plasma) may be used. Do not use plasma treated with an anti-coagulant other than sodium citrate.

2) Storage of samples

After separation of plasma, store the sample in a refrigerator (2–10°C) and perform measurement on the same day.

If measurement cannot be performed on the day of separation, the plasma sample may be stored for up to 1 month at -30°C or below. However, it may only be frozen and thawed once.

Thaw frozen samples rapidly in a warm water bath at 37°C.

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

2. Interfering substances

1) Assay results are not affected by free bilirubin (up to 20 mg/dL), conjugated bilirubin (up to 20 mg/dL), formazin turbidity (up to 2000 FTU), rheumatoid factors (up to 200 IU/mL), or heparin sodium (up to 5 U/mL).
2) Assay results are not affected by hemoglobin (up to 50 mg/dL). However, do not measure samples that are severely hemolyzed, because artifactual elevation of the SF level may occur.

3. Others

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

If the SF concentration in a sample exceeds the measurement range, dilute the sample with normal human plasma (SF < 3 μg/mL) and perform re-measurement.

3) Exercise caution, because contamination of the reaction mixture with thrombin may result in artifactual elevation of the SF level.

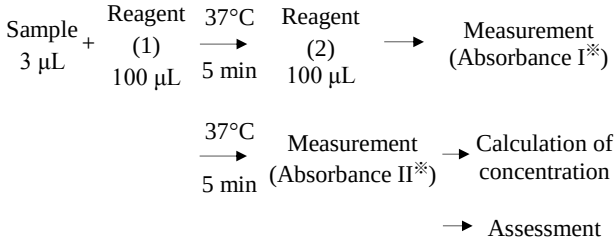
Dosage/Administration (Assay Procedure) **

1. Preparation of reagents

Reagent (1): SF Buffer Solution 1 is ready to use.
Reagent (2): SF Latex Reagent 2 is ready to use.
Before using this product, gently invert the SF Latex Reagent 2 bottle to mix it thoroughly, and check that there are no bubbles.

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 570 nm and 800 nm.
Calibration material: SF Calibrator (Manufacture's assigned value)
Reagent blank: Saline

3. Precautions for testing

After completion of measurement, tightly close the vials containing SF Buffer Solution 1 and SF Latex Reagent 2, and store in a refrigerator.

Assessment of Assay Results

1. Assessment criteria[2)]

Negative: < 7 μg/mL, Positive: ≥ 7 μg/mL

2. There may be reactions or interfering reactions with non-target substances. If plasma with difficult sampling was used, falsely high values may be obtained.[3)] 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 being equal to or lower than 0.01
2) Sensitivity: The absorbance is 0.02–0.10 per 10 μg/mL of SF.

2. Accuracy:

The result is negative when negative control plasma is tested, while it is positive when positive control plasma is tested.

3. Within-run Reproducibility:

The result is always negative when 10 samples of negative control plasma are tested simultaneously, while it is always positive when 10 samples of positive control plasma are tested simultaneously. (Test methods used for 1.–3. are in-house methods.)

4. Measurement Range[4)]: (On Hitachi 7170 automated analyzer)

3–100 μg /mL

5. Correlation[4)]

1) Approved in vitro diagnostic (latex immuno-turbidimetric assay)
N = 132, sensitivity (PPV) 96% (55/57), specificity (NPV) 91% (68/75), total concordance rate 93% (123/132)
2) Approved in vitro diagnostic (hemagglutination assay)
N = 132, sensitivity (PPV) 100% (54/54), specificity (NPV) 90% (70/78), total concordance rate 94% (124/132)

6. Standard Material

Purified fibrin monomer (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 SF Buffer Solution 1 and SF 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, without freezing. Freezing can deteriorate the reagents, which can produce inaccurate results. Therefore, avoid using the reagents which have 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 mix SF Latex Reagent 2 from different kit lot numbers.
6) 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 months from the date of manufacture
(The expiration date is printed on the outer package.)

Packaging

Name		Package
Nanopia SF	SF Buffer Solution 1	1×10.5mL
	SF Latex Reagent 2	1×10mL

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. 429, Kanehara Shuppan, 2015.
2) Edited by the Japanese Society for Laboratory Hematology: Standard Laboratory Hematology, 60–63, Ishiyaku Shuppan, 2003.
3) Wada H. et al.: Modern Med Lab, 34, 800, 2006.
4) In house data, SEKISUI MEDICAL CO., LTD.

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Manufacturer * *

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