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

In Vitro Diagnostics
Marketing Approval No. 21600AMZ00527000

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*Revised: April 2008 (4th edition)

This package insert must be read carefully prior to use.

Prostate specific antigen assay kit
(Classification No.: 37286000)

Nanopia PSA

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
PSA Buffer Solution 1: N-(2-Hydroxyethyl)piperazine-N'-2-ethane sulfonic acid) (HEPES) buffer solution
PSA Latex Reagent 2: Anti-human PSA mouse monoclonal antibody-coated latex

Intended Use

Measurement of prostate specific antigen (PSA) in serum

PSA is a glycoprotein with a molecular weight of approximately 34000 that is specifically produced by glandular epithelial cells in the prostate. PSA is released into the blood when glandular epithelial cells are damaged by prostate cancer or other prostate abnormalities. Measurement of the blood level of PSA is widely used in the urology field for diagnosis of prostate cancer and for monitoring the response to treatment. PSA has great significance as a prostate cancer marker.[1] Usefulness of the blood level of PSA in screening for early detection of prostate cancer has also attracted attention.

Assay Principle

1. Assay Principle

In samples, an antigen-antibody reaction occurs between PSA and anti-human PSA mouse monoclonal antibody-coated latex beads, resulting in agglutination of the beads. The PSA content is determined by measuring the agglutination as the change of absorbance.

2. Features

1) This product is a reagent for measuring the serum PSA concentration based on latex immunonephelometry. It can conveniently and accurately measure serum PSA levels.
2) PSA can be measured using general-purpose biochemical automated analyzers.
3) This product has a wide measurement range from very low to high concentrations.

Procedural Precautions * *

1. Properties of Samples and Sampling Methods

1) Samples
Serum may be used.
2) Storage of samples[1)]
Centrifuge the sample immediately after collection, and perform measurement on the same day. If measurement cannot be performed on the day of separation, it may be stored for up to 1 week under refrigeration (2–10°C) or for 1 month in a freezer (-20°C or lower). It may only be frozen and thawed once.
Bring samples to room temperature (15–30 °C) before use.

2. Interfering substances

1) Assay results are not affected by free bilirubin (up to 50 mg/dL), conjugated bilirubin (up to 50 mg/dL), hemoglobin (up to 500 mg/dL), formazin turbidity (up to 2000 FTU), rheumatoid factors (up to 500 IU/mL), or ascorbic acid (up to 100 mg/dL).
2) Erroneous results may be obtained if the sample contains a substance other than PSA, such as immunoglobulin, that can react with the mouse monoclonal antibody.

3. Others

1) Before use, invert the Reagent (2) bottle to mix it thoroughly.
2) Always use PSA Calibrator for calibration.
3) Precautions for assay range
If the PSA concentration in the sample exceeds the measurement range, dilute the sample with a separately sold PSA Sample Dilution Solution (manufactured by SEKISUI MEDICAL CO., LTD.), and perform re-measurement.

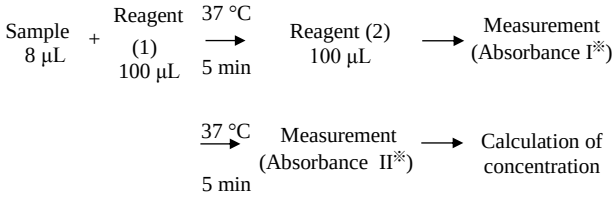
Dosage/Administration (Assay Procedure) * *

1. Preparation of reagents

Reagent (1): PSA Buffer Solution 1 is ready to use.
Reagent (2): PSA Latex Reagent 2 is ready to use.
Before using this product, gently invert the PSA Latex Solution 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: PSA calibrator (Manufacture's assigned value)
Reagent blank: Calibrator with the PSA concentration of 0 ng/mL

Assessment of Assay Results **

1. Reference standard range[2)]
Normal: ≤ 1.1 ng/mL
Cut-off value: ≤ 4.0 ng/mL
Gray zone: 4.1–10.0 ng/mL
Abnormal: ≥ 10.1 ng/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: change in absorbance being equal to or lower than 0.15
2) Sensitivity: The change of absorbance is 0.01–0.15/min per 10 ng/mL of PSA (PSA 1–20 ng/mL).

2. Accuracy: 80–120 % 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)
0.5–100 ng/mL

5. Correlation[5)]
Serum N=84 r=0.980 y=0.97x–0.59
Control method: Approved in vitro diagnostic (Two-site IRMA method※)
※two−site immunoradiometric assay method

6. Standard Material
National Institute for Biological Standards and Control (96/970) (WHO International Standard Material [90:10])
※National institute for biological standards and control

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 PSA Buffer Solution 1 and PSA Latex Reagent 2. 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 reagents from different lots because it may lead to inaccurate results.
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 121 ºC 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: 1 year from the date of manufacture
(The expiration date is printed on the outer package.)

Packaging

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

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

References * *

1) Kuriyama M. et al.: Comprehensive blood and urine chemical tests and immunological tests (4). Jpn J Clin Med, 57, 520 (1999 extra edition).
2) Kanai M. (supervising editor): Kanai's manual of clinical laboratory medicine. 34th ed. 601, Kanehara Shuppan, 2015.
3) Watanabe H. et al.: J Med Pharm Sci, 53, 831, 2005.
4) Ohira S. et al.: J Med Pharm Sci, 55, 139, 2006.
5) In house data, SEKISUI MEDICAL CO., LTD.

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