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

In Vitro Diagnostics
Certification No. 220ADAMX00136000

** Revised: January 2017 (6th edition)
* Revised: June 2016 (5th edition)

This package insert must be read carefully prior to use.

Cystatin C assay kit
（Classification No.: 83002000 ）

NORUDIA CYSTATIN C

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
Cystatin C Buffer Solution 1
Cystatin C Latex Reagent 2:
Anti-human cystatin C mouse monoclonal antibody- coated latex

Intended Use

Measurement of cystatin C in serum or plasma

Cystatin C is a basic low-molecular protein. Cystatin C has been reported to increase with a decrease of glomerular filtration rate (GFR) and is correlated with aggravation of GFR.[1)]

Assay Principle

1. Assay Principle
In samples, an antigen-antibody reaction occurs between cystatin C and anti-human cystatin C mouse monoclonal antibody-coated latex, resulting in agglutination and an increase of turbidity. The concentration of cystatin C in samples is determined by measuring the agglutination as absorbance.

2. Features
1) Liquid reagents, ready-to-use.
2) Applicable to various automated analyzers.

Procedural Precautions * *

1. Properties of Samples and Sampling Methods
1) Samples
Serum and plasma (heparin plasma and EDTA plasma) may be used.
2) Storage of samples[1)]
If the isolated serum or plasma sample cannot be tested on the same day, specimens should be stored as follows:
2–10°C: for tests within 1 week
≤ -80°C: for tests after more than 1 week
Bring samples to room temperature (15–30°C) before use.

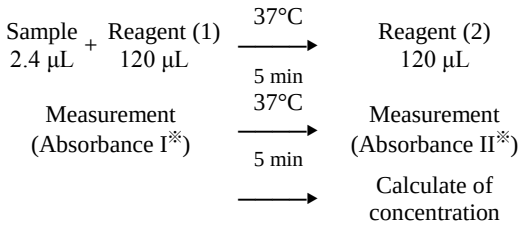
2. Interfering substances
Assay results are not affected by free bilirubin (up to 20 mg/dL), conjugated bilirubin (up to 20 mg/dL), hemoglobin (up to 500 mg/dL), formazin turbidity (up to 2000 FTU), or rheumatoid factors (up to 500 IU/mL).

3. Others
1) Always use Cystatin C 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): Cystatin C Buffer Solution 1 is ready to use.
Reagent (2): Cystatin C Latex Reagent 2 is ready to use.
Before using this product, gently invert the Cystatin C 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 analyzers. 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: Cystatin C Calibrator N (Manufacture's assigned value)
Reagent blank: Saline

Assessment of Assay Results *

1. Reference standard range[2)]
Male: 0.58–0.98 mg/L (mean age: 51.2)
Female: 0.52–0.88 mg/L (mean age: 51.9)
Analytical results were obtained in 501 healthy donors (338 men and 163 women, mean age: 51.4).

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 0.01
2) Sensitivity: The difference in absorbance between cystatin C (0.5 mg/L) and reagent blank is 0.015–0.045.

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[2]: (On Hitachi 7180 automated analyzer)
0.1–10 mg/L

5. Correlation[2]

1) Serum N=55 r=0.999 y=0.97x +0.08
Control method: Approved in vitro diagnostic (latex immune agglutination method)
2) Plasma N=58 r=0.998 y=0.93x+0.09
Control method: Approved in vitro diagnostic (latex immune agglutination method)

6. Standard Material
ERM-DA471/IFCC (IRMM)

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 preservative in the Cystatin C Buffer Solution 1 and Cystatin C 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. Calibration should be performed when changing to new lot of reagents.
4) 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
NORUDIA CYSTATIN C	Cystatin C Buffer Solution 1	2 × 12 mL
	Cystatin C Latex Reagent 2	2 × 12 mL

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

References

1) Grubb A.: Clin Nephrol, 38 Suppl 1, S20-7, 1992.
2) In house data, SEKISUI MEDICAL CO., LTD.

Contact

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Manufacturer **

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