This product marketed by SEKISUI MEDICAL CO., LTD., Tokyo, Japan is manufactured subject to our supervision as stipulated in the Pharmaceutical Affairs Law of Japan and is certified by Registered Third Party to be marketed in Japan. For details, please contact us or your local distributors.

Cystatin C Kit

NORUDIA™ CYSTATIN C

General Precautions

1. This product is for in vitro diagnostic use only, 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. Reliability of values cannot be guaranteed if this product is used for purposes or tested by methods other than those stated.
4. If the reagents come in contact with eyes or mouth, rinse thoroughly with water as first aid, and seek medical treatment if necessary.
5. Read the user’s manual of your automated analyzer prior to using this kit. Parameters for different automated analyzers are available upon request.
6. Perform a quality control test prior to assay to ensure accuracy.

Description (Kit Components)

<table>
<thead>
<tr>
<th>Component</th>
<th>Ingredients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cystatin C Buffer Solution 1</td>
<td>anti-human cystatin C mouse monoclonal antibody coated latex</td>
</tr>
<tr>
<td>Cystatin C Latex Reagent 2</td>
<td>anti-human cystatin C mouse monoclonal antibody coated latex</td>
</tr>
</tbody>
</table>

Intended Use

For the measurement of Cystatin C in serum or plasma

Cystatin C is a basic protein with a low-molecular-weight. Its concentration in serum and plasma are closely correlated to the glomerular filtration rate (GFR)\(^1\).

Assay Principle

1. Assay Principle

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

2. Features

   1) Ready-to-use liquid reagents
   2) Compatible with various types of automated analyzers.

Procedural Precautions

1. Sample Collection and Storage

   1) Samples
   - Serum or plasma (heparinized plasma or EDTA-treated plasma) can be used.
   2) Sample Storage
   - Isolated serum or plasma should be tested on the day of blood collection. If the sample cannot be tested on the same day, store as follows:
     - For assays within a week store at 2 - 10ºC
     - For long-term storage, store at ~80ºC
   Bring samples to room temperature (15-30ºC) before use.

2. Interfering substances

   Assay results will not be 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 units), and rheumatoid factor (up to 500 IU/mL).

3. Other Precautions

   1) Calibration Material
   - Use Cystatin C Calibrator for NORUDIA™ Cystatin C (manufactured by SEKISUI MEDICAL CO., LTD.) as the calibration material.
   2) Measurement Range
   - When the concentration of Cystatin C in a sample exceeds the measurement range, dilute the sample with physiological saline solution, and repeat the measurement.

Assay Procedure

1. Preparation

   Reagent 1: Cystatin C Buffer Solution 1 - Ready-to-use
   Reagent 2: Cystatin C Latex Reagent 2 - Ready-to-use

2. Assay Procedure

   This product is compatible with various types of automated analyzers. Below is a general example of the assay procedure.

<table>
<thead>
<tr>
<th>Sample</th>
<th>Reagent 1</th>
<th>Reagent 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.4 μL</td>
<td>120 μL</td>
<td>5 min</td>
</tr>
</tbody>
</table>

   Measurement (absorbance I*)
   
   Measurement (absorbance II*)

   Calculate concentration

*Absorbance I, II:
Difference between absorbance at 570 nm and 800 nm

Calibration material:
Cystatin C Calibrator for NORUDIA™ CYSTATIN C (value assigned by SEKISUI MEDICAL CO., LTD.)
Reagent blank: saline

**Assessment of Results**

1. **Reference Interval**
   The normal range determined by measurements obtained from 501 healthy subjects (338 male and 163 female) was from 0.57 to 1.01 mg/L.

2. **Precautions for Assessment**
   There may be reactions with non-target substances or interfering reactions. If measurement results appear unreliable, repeat the measurement (if necessary, after dilution) or try another analytical method.

**Performance**

1. **Sensitivity**
   1) Absorbance of reagent blank: absorbance ≤ 0.01
   2) Sensitivity:
      The difference in absorbance between Cystatin C (0.5 mg/L) and the reagent blank: 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**
   (On Hitachi 7170 automated analyzer)
   0.1- 10 mg/L

5. **Correlation**
   1) Serum
      N = 53  r = 0.998  y = 1.07x + 0.052
      Reference method: Latex turbidimetric immunoassay (MHLW approved IVD)
   2) Plasma
      N = 58  r = 0.998  y = 0.93x + 0.09
      Reference method: Latex turbidimetric immunoassay (MHLW approved IVD)

**Standard Calibration Material**
Human cystatin C (in-house standard material)

**Precautions and Warnings**

1. **Handling Precautions**
   1) All samples used in the test should be handled as if potentially infectious for HIV, HBV and HCV. To prevent infection, use disposable gloves and avoid mouth pipetting during the test.
   2) This product contains Proclin300 as a preservative, which may irritate the skin. If the reagents comes in contact with the skin or clothes, rinse the affected area immediately with a large amount of water. Seek medical treatment if the skin inflammation develops.

2. **Precautions for Use**
   1) This product should be stored as directed. Avoid freezing. Freezing can cause deterioration of the reagents, which can produce inaccurate results.
   2) Do not use expired reagents. Reliable assay values cannot be obtained if expired reagents are used.
   3) Do not replenish the reagents. Calibrate when changing lots.
   4) Do not perform the assay under direct sunlight.

3. **Precautions for Disposal**
   1) Before disposal, used samples and their containers must be soaked in sodium hypochlorite solution at a concentration of greater than 0.1% for more than an hour or autoclaved at 121ºC for 20 minutes.
   2) To prevent infections from spilled samples or solutions containing samples, wipe the spill area thoroughly with disinfectants such as sodium hypochlorite solution at a concentration greater than 0.1%.
   3) The reagents and samples should be disposed in accordance with medical waste disposal regulations or related regulations.
   4) The reagents should be disposed in accordance with water pollution control regulations or related regulations.

4. **Other Precautions**
   Do not use the containers for other purposes.

**Storage and Shelf life**
1. Storage temperature: 2-10ºC
2. Shelf life: 2 year from the date of manufacture
   (The expiration date is printed on the Outside of the package.)

**Package Contents**

<table>
<thead>
<tr>
<th>Description</th>
<th>Configuration</th>
</tr>
</thead>
<tbody>
<tr>
<td>NORUDIA™ CYSTATIN C</td>
<td>Cystatin C Buffer Solution 1 12 mL x 2</td>
</tr>
<tr>
<td></td>
<td>Cystatin C Latex Reagent 2 12 mL x 2</td>
</tr>
</tbody>
</table>

Reagents are available in other configurations. Contact SEKISUI MEDICAL CO.,LTD. for details.

**References**
2. SEKISUI MEDICAL CO.,LTD. In-house data.

**Marketing Authorization Holder**
SEKISUI MEDICAL CO.,LTD.

Revised: (Aug) 2010 (4th edition)
This product marketed by SEKISUI MEDICAL CO., LTD., Tokyo, Japan is manufactured subject to our supervision as stipulated in the Pharmaceutical Affairs Law of Japan and is certified by Registered Third Party to be marketed in Japan. For details, please contact us or your local distributors.

13-5, Nihonbashi 3-chome, Chuo-ku, Tokyo, Japan
international@sekisui.com

"NORUDIA" is a trademark owned by SEKISUI MEDICAL CO.,LTD. JAPAN, and is registered in Japan and/or other countries.