In Vitro Diagnostics Marketing Approval No. 20300AMZ00140000 ** Revised: July 2019 (9th edition) * Revised: January 2017 (8th edition)

This package insert must be read carefully prior to use.

Class II General and Biochemical Test Series (Classification No.: 80022002) Creatinine assay kit (Classification No.: 30161002)

Clinimate CRE

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

CRE Coloring Solution 1: Sodium hydroxide Surfactant CRE Coloring Solution 2: 2,4,6-Trinitrophenol

Intended Use

Measurement of creatinine in serum or urine

Creatinine is a degradation product of high-energy creatine phosphate that is released into the blood from the muscles and nerves. Creatinine is filtered by the renal glomeruli and is excreted in the urine, mostly without reabsorption.

Because the blood level of creatinine is increased in patients with renal failure, uremia, and heart failure, it plays an important role as an index of kidney function in the diagnosis and evaluation of these diseases.

Assay Principle

1. Assay Principle

Creatinine reacts with 2,4,6-trinitrophenol (picric acid) in alkaline solutions to form red creatinine picrate. The creatinine content is determined by measuring the absorbance of this red sample.

Alkaline

Creatinine + Picric acid → Creatinine picrate (red color)

2. Features

- 1) This product shows high sensitivity and excellent reproducibility.
- 2) Analytical results are hardly affected by interfering substances, because the rate method is used.

Procedural Precautions * *

- 1. Properties of Samples and Sampling Methods 1) Samples
 - Serum and urine may be used.

2) Storage of samples¹⁾If the isolated serum sample cannot be tested on the same day, specimens should be stored as follows:

- 2–10°C: for tests within 1 week
- \leq -20°C: for tests after more than 1 week

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

Urine samples should be tested on the same day.

2. Interfering substances

Assay results are not affected by bilirubin (up to 20 mg/dL), hemoglobin (up to 500 mg/dL), or ascorbic acid (50 mg/dL).

3. Others

- 1) Always use Anaserum CRE standard solution for calibration.
- 2) Precautions for assay range

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

3) Due to individual differences in acetone bodies, pyruvic acid and other substances in healthy human serum, compared to enzymatic methods this assay yields results that are 0.2 - 0.3 mg/dL higher.³⁾

Dosage/Administration (Assay Procedure) *

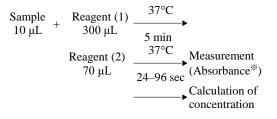
1. Preparation of reagents

Reagent (1): CRE Coloring Solution 1 is ready to use.

Reagent (2): CRE Coloring Solution 2 is ready to use.

2. Assay Procedure

This product is compatible with various types of automated analyzers. An example of the assay procedure is indicated below.



**Absorbance: The difference in absorbance between 600 nm and 505 nm

Calibration material: Anaserum CRE standard solution (Manufacture's assigned value)

Reagent blank: Purified water or saline

Assessment of Assay Results

- 1. Reference standard range²⁾ Male: 0.8–1.2 mg/dL Female: 0.6–0.9 mg/dL
- 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 0.01/min
- Sensitivity: The change of absorbance is 0.07– 0.10/min per 10 mg/dL of creatinine.
- 2. Accuracy: 90–110% of the expected assay value
- 3. Within-run Reproducibility:
 - Coefficient of variation $\leq 3\%$
- (Test methods used for 1. -3. are in-house methods.)
- **4. Measurement Range**⁴): (On Hitachi 7170S automated analyzer)
- 0.1–60.0 mg/dL 5. Correlation⁴⁾
 - Serum N=60 r=0.999 y=0.96x+0.26 Control method: Approved in vitro diagnostic (enzymatic method)
 - 2) Urine N=10 r=0.999 y=1.08x+0.01 Control method: Approved in vitro diagnostic (Jaffe method)
- 6. Standard Material SRM914a (NIST)

Precautions for Use or Handling *

1. Precautions for Handling (to Ensure Safety) 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. 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.
- 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 perform the assay under direct sunlight

3. Precautions for Disposal

- 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°C 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: room temperature
- 2. Shelf life: 2 years from the date of manufacture
- (The expiration date is printed on the outer package.)

Packaging

Name			Package
Clinimate CRE	(1)	CRE Coloring Solution 1	4 × 100mL
	(2)	CRE Coloring Solution 2	4 × 100mL

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

References **

- 1) Sasaki M. et al.: Sampling of constituents of the human body, 106, Kodansha, 1972.
- 2) Kitamura M. (author and editor): Practical Clinical Chemistry, 253, Ishiyaku Shuppan, 1974.
- Kanai I and Kanai M. (author and editor): Kanai's manual of clinical laboratory medicine. 34nd ed. 475, Kanehara Shuppan, 2015.
- 4) In house data, SEKISUI MEDICAL CO., LTD.

Contact

SEKISUI MEDICAL CO., LTD. international@sekisui.com

Manufacturer *

SEKISUI MEDICAL CO., LTD.

1-3, Nihonbashi 2-chome, Chuo-ku, Tokyo, Japan