



Reagent blank: Purified water or saline

### Assessment of Assay Results

#### 1. Reference standard range<sup>2)</sup>

Male: 0.8–1.2 mg/dL

Female: 0.6–0.9 mg/dL

- 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

- 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.

- 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<sup>4)</sup>: (On Hitachi 7170S automated analyzer)

0.1–60.0 mg/dL

#### 5. Correlation<sup>4)</sup>

- Serum N=60  $r=0.999$   $y=0.96x+0.26$   
Control method: Approved in vitro diagnostic (enzymatic method)
- 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

- 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.
- Do not replenish the reagents.
- 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.
- 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%.
- The reagents and treated samples should be discarded as medical waste or industrial waste

according to the waste disposal regulations.

- 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 \*

- Storage temperature: room temperature
- 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 \*\*

- Sasaki M. et al.: Sampling of constituents of the human body, 106, Kodansha, 1972.
- 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.
- In house data, SEKISUI MEDICAL CO., LTD.

### Contact

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### Manufacturer \*

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