

This package insert must be read carefully prior to use.

Creatinine assay kit  
(Classification No.: 30161002)

## Pureauto S CRE-L

### 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. For the effects of an administered drug on the measured value, carefully read the Precautions for Use in the package insert of the drug, especially the section about the effects on laboratory test results. Please also read carefully the “2. Interfering Substances,” in the “Procedural Precautions” section, as well as “2. Precautions for Assessment” in the “Assessment of Assay Results” section, of this package insert.
4. 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.
5. 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.
6. 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.
7. Perform a quality control test prior to assay to ensure accuracy.

### Description (Kit Components) \*\*

Component: Ingredients

CRE-L Enzyme Solution 1:	Creatine amidinohydrolase
	Sarcosine oxidase
	N-ethyl-N-(3-sulfopropyl)-3-methylaniline
CRE-L Enzyme Solution 2:	Creatinine amidehydrolase
	4-Aminoantipyrene

### Intended Use

#### Measurement of creatinine concentration in serum, plasma, 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.

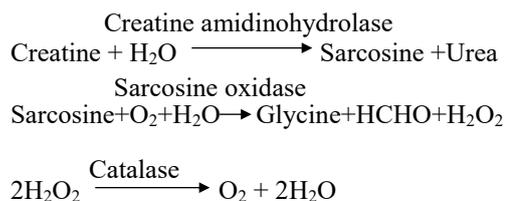
### Assay Principle \*\*

#### 1. Assay Principle

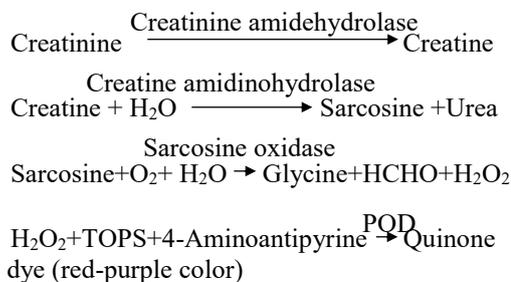
In the first reaction, creatine in samples is degraded into water and oxygen by the action of creatine amidinohydrolase, sarcosine oxidase, and catalase.

In the second reaction, creatinine in samples is converted to creatine by the action of creatine amidinohydrolase and then sarcosine is produced by the action of creatine amidinohydrolase. In the presence of hydrogen peroxide produced from sarcosine by sarcosine oxidase and peroxidase (POD), oxidative condensation of N-ethyl-N-(3-sulfopropyl)-3-methylaniline (TOPS) and 4-aminoantipyrene is allowed to occur. The concentration of creatinine is determined by measuring the absorbance of the resulting quinone dye (red-purple).

First reaction:



Second reaction:



#### 2. Features

- 1) Liquid reagents, ready-to-use.
- 2) The enzymatic method is employed.
- 3) Applicable to various automated analyzers.

### Procedural Precautions \*\*

#### 1. Properties of Samples and Sampling Methods

- 1) Samples  
Serum, plasma, or urine (1:21 dilution) may be used.
- 2) Storage of samples<sup>3)</sup>  
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  
≤ -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.



explosive metallic azide. When disposing of this product, flush it away with copious amounts of water.

#### 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
Pureauto S CRE-L	(1) CRE-L Enzyme Solution 1	2 × 200 mL
	(2) CRE-L Enzyme Solution 2	2 × 100 mL

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

#### References \*\*

- 1) Yoshimura M. et al.: Jpn J Clin Med (extra edition), 53, 464, 1995. Japanese.
- 2) Osawa S.: Med Tech, 26, 389, 1998. Japanese.
- 3) Sasaki M. et al.: Sampling of constituents of the human body. Tokyo: Kodansha; 1972. Japanese.
- 4) Kanai M, editor. Kanai's manual of clinical laboratory medicine. 35th ed. Tokyo: Kanehara Shuppan; 2020. Japanese.
- 5) Sasaki T: Mod Med Lab, 15, 259, 1987. Japanese.
- 6) Suzuki M., Yoshida M.: Clin. Chim. Acta. 143, 147, 1984.
- 7) Yasuhara M et al.: Mod Med Lab, 18, 31, 1990. Japanese.
- 8) Japan Society of Clinical Chemistry: Jpn J Clin Chem, 23, 326, 1994. Japanese.
- 9) SEKISUI MEDICAL CO., LTD. In house data. Japanese.

#### Contact

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#### Manufacturer

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