

This package insert must be read carefully prior to use.

Creatinine assay kit
(Classification No.: 30161002)

QUALIGENT 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. 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 Enzyme Solution 1: Creatinase
Sarcosine oxidase
N-Ethyl-N-sulfobutyl-*m*-toluidine disodium salt
- CRE Enzyme Solution 2: Creatininase
4-Aminoantipyrine

Intended Use

Measurement of creatinine 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.

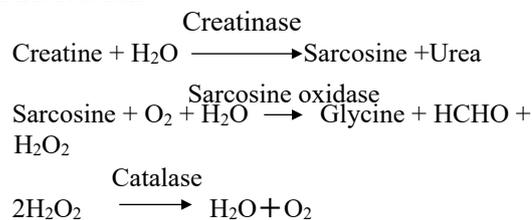
Because the blood level of creatinine is increased in patients with renal failure, uremia, and heart failure, it plays an important role as an index of kidney function in the diagnosis and evaluation of these diseases.

Assay Principle **

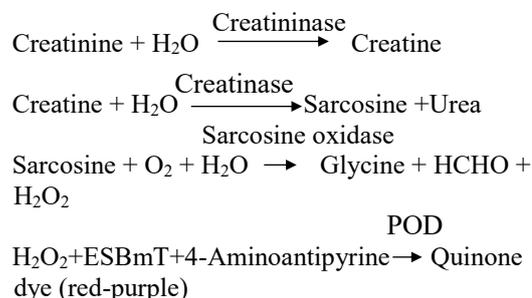
1. Assay Principle

In the first reaction, creatine in samples is degraded into water and oxygen by the action of creatinase, sarcosine oxidase, and catalase. In the second reaction, creatinine in samples is converted to creatine by the action of creatininase and then sarcosine is produced by the action of creatinase. In the presence of hydrogen peroxide produced by sarcosine oxidase and peroxidase (POD), oxidative condensation of N-ethyl-N-sulfobutyl-*m*-toluidine (ESBmT) and 4-aminoantipyrine 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.

Procedural Precautions **

1. Properties of Samples and Sampling Methods

- 1) Samples
Serum, plasma, or urine (primitive or diluted 1:21) may be used.
- 2) Storage of samples¹⁾
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.

2. Interfering substances

- 1) Assay results are not affected by free bilirubin (up to 20 mg/dL), conjugated bilirubin (up to

- 1) Do not use the containers for other purposes.
- 2) Do not take apart the reagent cartridge before use.

Storage and Shelf Life

1. Storage temperature: 2–10°C
2. Shelf life: 13 months from the date of manufacture
(The expiration date is printed on the outer package.)

Packaging *

Name	Package		
QUALIG ENT CRE	Set (Cassette for Hitachi 9000 series)	CRE Enzyme Solution 1 1 × 15.0 mL ----- CRE Enzyme Solution 2 1 × 7.5 mL	× 2
	L set (Set for Hitachi LABOSPEC T series)	CRE Enzyme Solution 1 1 × 40 mL ----- CRE Enzyme Solution 2 1 × 20 mL	× 2

References **

- 1) Sasaki M. et al.: Sampling of constituents of the human body, Tokyo: Kodansha; 1972. Japanese.
- 2) Kanai M. (supervising editor): Kanai's manual of clinical laboratory medicine. 35th ed. Tokyo: Kanehara Shuppan; 2015. Japanese.
- 3) Yoshimura M. et al.: Jpn J Clin Med (extra edition), 53, 464, 1995. Japanese.
- 4) Osawa S.: Med Tech, 26, 389, 1998. Japanese.
- 5) Nakahara M. et al.: Jpn J Med Tech, 45, 1106, 1996. Japanese.
- 6) Sasaki T: Mod Med Lab, 15, 259, 1987.
- 7) Suzuki M., Yoshida M.: Clin. Chim. Acta, 143, 147, 1984.
- 8) Yasuhara M et al.: Mod Med Lab, 18, 31, 1990. Japanese.
- 9) Japan Society of Clinical Chemistry: Jpn J Clin Chem, 23, 326, 1994. Japanese..
- 10) SEKISUI MEDICAL CO., LTD. In house data. Japanese.

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