Creatinine (CRE) Diagnostic Reagent Kit (Sarcosine Oxidase Method) Product Instruction

Product name
Creatinine (CRE) Diagnostic Reagent Kit (Sarcosine Oxidase Method)
Abbreviation: CRE

Package Specifications

R1	R2
45ml×1	15ml×1
60ml×1	20ml×1
60ml×2	20ml×2

Calibrator (liquid):
Specification 1 (1.0mL×1; 1 level);
Quality Control (liquid):
Specification 1 (1.0mL×1; 1 level);

Intended use
Creatinine (CRE) diagnostic reagent is used for quantitative in vitro determination of creatinine in human serum and urine on photometric systems.

Clinical significance
Creatinine is produced endogenously from creatine and creatine phosphate as a result of muscle metabolic processes. It is excreted by glomerular filtration during normal renal function. Creatinine assays are conducted for diagnostic purposes, for therapeutic monitoring of acute and chronic renal diseases, and for monitoring kidney dialysis. The urinary creatinine concentration can also be used as a reference parameter for analyte excretion (albumin, α-amylase).

Principle
The assay consists of four reaction steps:

1. Creatininase
Creatinine + H_2O ⟶ Creatine

2. Creatinase
Creatine + H_2O ⟶ Urea + Sarcosine

3. Sarcosine oxidase
Sarcosine+H_2O+O_2 ⟶ Glycine+ HCHO+ H_2O_2

4. Peroxidase
H_2O_2+F-DAOS+4-Aminoantipyrine ⟶ Blue dye

The increase of OD of this dye measured at 546 nm is proportional to the concentration of creatinine in the sample.

Main ingredient

Name	Ingredient
R1	MOPS Buffer 50 mmol/L, TOPS 1.5 mmol/L, CR 60 KU/L, SOX 20 KU/L, POD 2 KU/L.
R2	MOPS Buffer 50 mmol/L, CRN 300 KU/L, 4-AAP 4 mmol/L, Proclin300 0.1%.

Storage and stability
This kit stays stable for 18 months when stored in a dark condition at 2-8° C (do not freeze). After being opened for the first time, the kit can be stored at 2-8° C in an anti-pollution environment and stays stable for 14 days.

Specimen preparation
Fresh serum.
-20℃, stable for 7 days.

Assay procedure
1. Reagent preparation
This reagent is liquid and can be used directly.

Main wavelength	546 nm	Sample	3 μl
Subwavelength	700 nm	Reagent 1	150 μl
Reation temperature	37℃	Reagent 2	50 μl
Cuvette light path	1cm	Reaction type	Two Point End

2. Operation steps

Add to the cuvette:	
Sample (S)	3 μl
R1	150 μl
Mix well, incubate at 37° C for 5 minutes, then add	
R2	50 μl
Mix well, incubate at 37℃for 1 minute, absorbance A1; incubate at 37℃for 5 minutes, absorbance A2 △A= A2-A1	

Calculations

$$\text{Conc. of CRE} = \frac{A(\text{sample}) - A(\text{blank})}{A(\text{Cal.}) - A(\text{blank})} \times \text{conc. of Cal.}$$

Reference interval
31.8umol/L - 93.7umol/L
It is recommended that each laboratory should establish its own reference interval.

Quality control
The control intervals and limits should be adapted to each laboratory’ s individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the limits.

Performance characteristics
1. Measuring range
30umol/L - 8000umol/L
Samples above this concentration should be diluted

1+1 with 0.9% NaCl solution and the result multiplied by 2.

Interference

The effect of the following substances can be neglected if the concentrations of the following substances are at or below the given values.

Substances	Concentrations
Bilirubin	440μmol/L
Haemoglobin	2 g/L

Automation

Special adaptations for automatic analyzers can be made on request.

General precautions

For in vitro diagnostic use only.
Diagnosis should only be made after taking clinical symptoms and the results of other tests into consideration.
Exercise the normal precautions required for handling all laboratory reagents.
Disposal of all waste material should be in accordance with local guidelines.

Precautions for measurement

Specimens should be treated as potentially infectious (HIV, Hepatitis B virus, Hepatitis C virus, etc.) and handled with appropriate caution.
Reagents with different lot numbers should not be interchanged or mixed.
For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.
Material safety data sheet available for professional user on request.

Parameter settings

HITACHI	
Model	7180
Assay Code	2 Point End
Reaction Time	10
Assay Point	16-34
Wave Length Sec	700
Wave Length Prim	546
ABS. Limit	32000
Sample Volume（uL）	3
R1 Volume（uL）	150
R2 Volume（uL）	0
R3 Volume（uL）	50
Calibration Type	LINER
Calibration Point	2
Span Point	2
SD Limit	999
Duplicate Limit	1000 or (0%-1000Abs)
Sensitivity Limit	0
Prozone Limit	32000

OLYMPUS 400	
Sample Volume（uL）	3
Sample DIL. VOL.	/
R1 Volume（uL）	150
R2 Volume（uL）	50
Reagent DIL. VOL.	/
Measure Wave 1	540
Measure Wave 2	700
METHOD	End
SLOPE	-
Method Point	9-27
Linear Limit	-
NO LAG TIME	Yes
OD L	-
OD H	-
Reagent OD Limit	
FIRST	-2.0-+2.5
LAST	-2.0-+2.5
Dynamic Range L	-9999999
Dynamic Range H	9999999
Correlation Factor A	1.0
Correlation Factor B	0.0
Calibration Type	AB
Formula	liner
STD(1) Conc.#	*
Unit	umol/L

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