CE IVD

CRE-E Reagent Kit (Enzymatic Method)

Instructions for Use REF CC1026

PRODUCT NAME

CRE-E Reagent Kit (Enzymatic Method)

PACKAGE SPECIFICATION

R1: 1×15 mL	R2: 1×5 mL	R1: 1×30 mL	R2: 1×10 mL
R1: 1×45 mL	R2: 1×15 mL	R1: 1×60 mL	R2: 1×20 mL
R1: 2×30 mL	R2: 2×10 mL	R1: 2×45 mL	R2: 2×20 mL
R1: 2×55 mL	R2: 2×20 mL	R1: 2×60 mL	R2: 1×40 mL
R1: 2×60 mL	R2: 1×45 mL	R1: 2×60 mL	R2: 2×20 mL
R1: 2×90 mL	R2: 1×60 mL	R1: 3×40 mL	R2: 3×15 mL
R1: 3×60 mL	R2: 1×60 mL	R1: 4×30 mL	R2: 2×20 mL
R1: 4×45 mL	R2: 4×15 mL	R1: 4×45 mL	R2: 2×30 mL
R1: 4×55 mL	R2: 4×20 mL	R1: 4×60 mL	R2: 2×40 mL
R1: 4×60 mL	R2: 2×45 mL	R1: 4×90 mL	R2: 2×60 mL
600 T (R1: 1×51 mL R2: 1×26 mL)			
6×52 T (R1: 6×16.8 mL R2: 6×5.8 mL)			
Calibrator (Optional): 1×1 mL			

INTENDED USE

This test kit is intended for the *in vitro* quantitative determination of CRE-E concentration in human serum, plasma or urine, and is mainly used clinically for the auxiliary diagnosis of renal function. For professional and laboratory use only.

TEST PRINCIPLE

$$Creatinine+H_2O \xrightarrow{Creatinase} Creatine$$

$$Creatine+H_2O \xrightarrow{Creatinase} Sarcosine + Urea$$

$$Sarcosine+O_2+H_2O \xrightarrow{Sarcosine\ oxidase} Glycine+HCHO+H_2O_2$$

$$H_2O_2+4\text{-}AAP+TOOS \xrightarrow{POD} Quinoneimine\ dye+H_2O$$

The absorbance (△A) is directly proportional to the concentration of Cr at a certain wavelength.

MAIN COMPONENTS

Kit Components	Reagent Components	Content
Reagent 1	Creatinase	30 KU/L
	Sarcosine oxidase	40 KU/L
	Peroxidase	50 KU/L
	N-ethyl-n -(2-hydroxy-3-propyl sulfonyl) -3-methylaniline	0.8 g/L
	Creatinase	220 KU/L
Reagent 2	4-aminotipyrine	0.5 g/L
	Creatinase	30 KU/L
Calibrator (Optional)	Creatinine, water matrix	100-300 μmol/L

The components in different batches of a multi-component kit are not interchangeable.
Calibrator traceability: Traceable to standard reference material 909c.

STORAGE AND SHELF LIFE

Unopened reagents should be stored at 2°C-8°C away from light, with a shelf life of 18 months. Opened reagents are stable for 42 days when stored at 2°C-8°C.
Please refer to the label on the reagent kit for the production date and expiration date.

APPLICABLE INSTRUMENTS

The kit is applicable to the following instruments: fully automatic biochemistry analyzers from Hitachi High-Tech (Shanghai) International Trading Co., Ltd., models: 7100, 7170, 7180, 7600, LABOSPECT 008 AS, 3100, 3500; fully automatic biochemistry analyzers from Beckman Coulter Commercial Enterprise (China) Co., Ltd., models: DXC800, AU480, AU680, AU5800; fully automatic biochemistry analyzers from Canon Medical Systems (China) Co., Ltd., models: TBA-120FR, TBA-2000FR, TBA-FX8; fully automatic biochemistry analyzers from Shenzhen Mindray Bio-Medical Electronics Co., Ltd., models: BS-420, BS-490, BS-600, BS-800, BS-820, BS-2000; fully automatic biochemistry analyzers from Dirui Industrial Co., Ltd., models: CS-400, CS-600B, CS-1200; fully automatic biochemistry analyzers from Siemens Healthineers Diagnostics (Shanghai) Co. Ltd., models: 1800, 2400, ADVIA Chemistry XPT; fully automatic biochemistry analyzers from Roche Diagnostics (shanghai) Co., Ltd., models: cobas 6000 c 501, cobas 8000 c 502, 701, 702; clinical chemistry analyzers from Getein Biotech, Inc, models: CM-400, CM-430, CM-480, CM-600, CM-630, CM-680, CM-800, CM-830, CM-880, CM-2000, CM-1600, CM-1200, CM-1000; automatic biochemical analyzers from Changchun Blaser Medical Technology Co., LTD, models: BBA-400, BBA-300, BBA-480. If you need the application parameters of the fully automatic biochemistry analyzers, please contact our company.

SAMPLE REQUIREMENTS

Serum, heparin anticoagulant plasma can be used for the test. Serum samples can be stable for 7 days at 15-25°C, for 7 days at 2-8°C and for 3 months at -20°C.
Urine is diluted 100 times with distilled water and the result is multiplied by 100.Urine specimens may be stored for 2 days at 15-25°C, for 6 days at 2-8°C and for 6 months at -20°C.

TEST PROCEDURE

1. Reagents preparation: Use directly.
2. Test conditions: (Different load parameters can be requested based on different testing instruments)

Primary/secondary wavelength	546 nm/700 nm	**Calibration type**	Linearity
Sample/R1/R2	6/225/75 μL	**Serum+R1 time**	5 min
Method	Two-point endpoint method	**Reaction time after adding R2**	5 min
Calibration method	Two-point calibration	**Direction of reaction**	Upward

Operating procedures: Double reagent procedure

Temperature	37°C
Sample	6 μL
R1	225 μL
Mix well, incubate at 37°C for 5 min and measure the absorbance (A_0)	
R2	75 μL
Mix well, incubate at 37°C for 5 min, measure the absorbance (A_1) and calculate the change in absorbance ($\triangle A=A_1-A_0$)	

3. Calibration procedures: A calibrator from Getein is recommended, and a calibration serum from Randox can also be used.
4. Quality control procedure: Select the quality control serum of Randox, and the quality control measurement value should be within the range of its label claim. If the result deviates from the range, find out the reason according to the steps below:
   4.1 Check whether the parameter settings and light source are correct.
   4.2 Check whether the cuvettes and sampling probes are clean.
   4.3 Check whether water is contaminated, and bacterial growth will cause incorrect results.
   4.4 Check reaction temperature.
   4.5 Check the expiration date of the kit.
5. Result calculation:

$$\text{CRE-E Concentration (μmol/L)} = \text{Concentration of CRE-E Standard Reference Material (SRM)} \times \frac{\triangle A_{test\ sample}}{\triangle A_{SRM}}$$

REFERENCE RANGE

Serum: Male adult 44-97 μmol/L (5-11 mg/L)
Female adult 35-80 μmol/L (4-9 mg/L)
Urine（24 hours） 4.42-16.8 mmol/24 h (0.50-1.9 g/24 h)
The reference range is for reference only. It is recommended that each laboratory establish its own reference range for the difference between areas, nationalities, sexes and ages.

RESULT INTERPRETATION

Since hemolysis interferes with determination, it should be avoided as much as possible during operation. The placement time of sample also has an effect on the determination.

LIMITATIONS

There is no interference with measurement when hemoglobin ≤ 200 mg/dL, ascorbic acid ≤ 50 mg/dL, bilirubin ≤ 16 mg/dL and triglyceride ≤ 2000 mg/dL.

PERFORMANCE CHARACTERISTICS

1. Appearance
   Reagent 1 is a slightly yellow clear liquid, which may contain a small number of insoluble particles that do not affect determination. R2 is a colorless or slightly yellow clear liquid which may have a small number of insoluble particles that do not affect the determination.
2. Reagent blank absorbance
   Reagent blank absorbance $A_{546nm} \leq 0.20$.
3. Accuracy
   The relative deviation should be within ±10%.
4. Linear range
   Linear correlation coefficient (r) should be ≥ 0.990 in the range of [10, 1760] μmol/L.
   Within the range of [10, 50] μmol/L, the linear deviation should not be greater than ±7 μmol/L;
   Within the range of (50, 1760] μmol/L, the linear deviation should not be greater than ±10%.
5. Analytical sensitivity
   When a sample has a concentration of 100 μmol/L, its absorbance difference should be no more than 0.05.
6. Precision
   6.1. Repeatability
   CV should not be greater than 5.0%.
   6.2. Between-run precision
   Between-run precision should not be greater than 10.0%.

PRECAUTIONS

1. General precautions
   1.1 This product is for *in vitro* diagnosis only.
   1.2 For clinical diagnosis, please make a comprehensive judgment based on the measurements, clinical symptoms and other findings.
   1.3 Please use this product according to the IFU.
   1.4 The test results of the kit are only used as clinical auxiliary diagnostic basis for various diseases, and the clinical diagnosis and treatment of patients should be comprehensively considered in combination with their symptoms/signs, medical history, other laboratory tests and treatment response.
   1.5 There may be differences in the use of reagents from different manufacturers for testing the same sample, which should be comprehensively considered in the context of clinical practice.
2. Precautions for operation
   2.1 Please treat the specimens as dangerous substances that may be infected with HIV, HBV, HCV, etc. Please use disposable gloves to avoid or reduce the associated risk for infection.
   2.2 If the reagents get into the eyes or mouth, or come into contact with the skin, rinse them quickly and thoroughly with water, and receive medical treatment from a doctor when necessary.
3. Precautions for use
   3.1 Please store the reagents according to the storage method, and avoid freezing. Please do not use frozen reagents whose quality may change.
   3.2 Please do not use expired reagents whose test results may be inaccurate.
   3.3 Please avoid adding reagents halfway during a test.
   3.4 Please avoid direct sunlight during operation.
   3.5 The reagents cannot be used if they are cloudy.
4. Precautions for waste disposal
   Samples, waste liquids, etc. are potentially biologically contaminated. Operators should comply with the SOP for laboratory safety and dispose of waste liquids in accordance with local regulations for medical waste, infectious waste, industrial waste, etc.
5. Other precautions
   5.1 On a fully automatic biochemistry analyzer, the linearity range is related to the ratio of the amount of a sample to the amount of a reagent and the time of measurement.
   5.2 The amounts of the reagent and sample can be changed proportionally according to the requirements of different instruments.
   5.3 Please do not use the reagent bottles for other purposes.
   5.4 A result calculated with the k value is not as reliable as that obtained using the SRM (calibrator).
   5.5 Please do not mix reagents in different batches.

REFERENCE

1. Xu Guobin, Zhu Lihua, Xia Tie'an. Determination by creatinase method of glutamate dehydrogenase coupled with creatinine iminohydrolytic enzyme. Journal of Clinical Laboratory, 2001,19 (3): 149
2. Yang Changguo, Lu Bangtai, Xu Ye, et al. Two point method for the enzymatic determination of creatinine. Journal of Clinical Laboratory, 1999,17 (2): 71

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on CRE-E Reagent Kit (Enzymatic Method) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2021.

Key to symbols used					
	Manufacturer		Use-by date	REF	Catalogue number
	Date of manufacture	LOT	Batch code		Temperature limit
IVD	*In vitro* diagnostic medical device		Keep away from sunlight		Biological risks
	Consult *instructions for use* or consult electronic *instructions for use*		Do not use if package is damaged and consult *instructions for use*	EU REP	Authorized representative
CE	CE mark		This way up		Do not re-use

Getein Biotech, Inc.
Add: No.9 Bofu Road, Luhe District, Nanjing, 211505, China
Tel: +86-25-68568508
Fax: +86-25-68568500
E-mail: tech@getein.com.cn
overseas@getein.com.cn
Website: www.getein.com

EU REP CMC Medical Devices & Drugs S.L.
Add: C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain
Tel: +34951214054

CÔNG TY TNHH XUẤT NHẬP KHẨU VÀ THƯƠNG MẠI ROKO VIỆT NAM

Digitally signed by CÔNG TY TNHH XUẤT NHẬP KHẨU VÀ THƯƠNG MẠI ROKO VIỆT NAM
DN: C=VN, CN=CÔNG TY TNHH XUẤT NHẬP KHẨU VÀ THƯƠNG MẠI ROKO VIỆT NAM, L=Huyện Đông Anh, O=CÔNG TY TNHH XUẤT NHẬP KHẨU VÀ THƯƠNG MẠI ROKO VIỆT NAM, ST=Hà Nội, UID=MST:0106416199