Creatinine Assay Kit (CRE)

Method: Enzymatic

Cat .No.	Size	Instrument
GB9300S	R1: 2×90 ml R2: 1×60 ml	For Hitachi 717 &ShimadzuCL7200/8000
GS9301S	R1: 3×60 ml R2: 1×60 ml	For Hitachi917 &OlympusAU640/400/600
GH9301S	R1: 2×48 ml R2: 2×16 ml	For Hitachi902
GX9301S	R1: 2×60 ml R2: 2×20 ml	For SYNCHRON CX4-5-7-9/ LX20/DXC600-800

INTENDED USE

For the *in vitro* quantitative determination of Creatinine in serum, plasma or urine. This product is suitable for Manual use. This product is suitable for use on Hitachi 704/717/737/902/ 904/911/912/917, Synchron CX4/5/7/9/LX20, Olympus400/640/2700 and all automatic analyzer.

CLINICAL SIGNIFICANCE

Creatinine is a break-down product of creatine phosphate in muscle, and is usually produced at a fairly constant rate by the body (depending on muscle mass).
High creatinine blood levels can mean serious kidney damage or disease is present. Other conditions that can cause high blood creatinine levels include blockage of the urinary tract (such as by kidney stone), heart failure, dehydration, excessive blood loss that causes shock, gout, or muscle conditions (such as rhabdomyolysis, gigantism, acromegaly, myasthenia gravis, muscular dystrophy, and polymyositis).
Urine creatinine is increased in hypothyrosis, wasting disease, dermatomyositis, tetanus or typhus, but decreased in amyotrophy or leukemia.

ASSAY PRINCIPLE

The enzymatic method involves a series of coupled enzymatic reactions.
First step: the endogenous creatine is eliminated by Creatinase, sarcosine oxidase.
Second step: creatinine in the specimen is converted to creatine by creatininase, and then the product creatine is hydrolyzed to sarcosine by creatinase, followed by the oxidation of sarcosine by sarcosine oxidase (SOD) producing hydrogen peroxide (H_2O_2) which is quantified by a Trinder reaction.

$$\text{Creatinine} + H_2O \xrightarrow{\text{Creatininase}} \text{Creatine}$$

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

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

$$2H_2O_2 + \text{TODB} + \text{4-AAP} \xrightarrow{\text{POD}} \text{pigment}$$

REAGENT COMPOSITION

Contents	Concentration of Solutions
Reagent 1 (R1)	
GOOD'S buffer	
Creatinase	>20U/ml
sarcosine oxidase	>4U/ml
TODB	>0.5mmol/L
Reagent 2 (R2)	
GOOD'S buffer	
Peroxidase	>4U/ml
Creatininase	>200U/ml
4-AAP	>0.5mmol/L

SPECIMEN COLLECTION AND PREPARATION

Serum, plasma or urine.
Urine: diluted 1 + 9 with redistilled water.
Serum / plasma creatinine is stable for 7 days at 20 - 25°C, 7 days at 4 - 8°C and 3 months at - 20°C.
Urine creatinine is stable for 2 days at 20 - 25°C, 6 days at 4 - 8°C and 6 months at - 20°C.

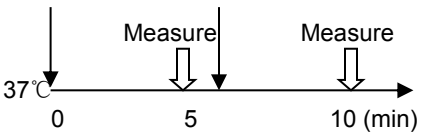
STABILITY AND PREPARATION OF REAGENTS

All reagents are ready to use.
Stable up to the expiry date when stored at 2-8℃.
Once opened contents are stable for 1 month at 2-8℃.

ASSAY PROCEDURE

Test Procedure for Analyzers (Hitachi 7170/917)
Assay Mode: 2 Point END, 16-34
Wave length (main/sub): 546 nm/700 nm

Sample:4 µl
R1: 210 µl R2:70µl



CALIBRATION

Recommend that this assay should be calibrated using Gcell calibration serum. Randox calibration also can be used.

CALCULATION OF RESULTS

$$\text{Concentration} = \frac{\Delta A_{sample} - \Delta A_{blank}}{\Delta A_{calibrator} - \Delta A_{blank}} \times \text{Calibrator value}$$

mg/dl ×88.4= µmol/L

QUALITY CONTROL

Beijing Strong Biotechnologies, Inc.
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Randox Control serum are recommended.
Values should fall within a specific range. If these values fall outside the range the following steps should be taken:

1. Check instrument settings and light source.
2. Check reaction temperature.
3. Check expiration date of kit and contents.

NORMAL RANGE

Serum/plasma (adults)
Men:59–104μmol/L(0.67–1.17mg/dl)
Women:45–84μmol/L(0.51–0.95mg/dl)

1st morning urine (adults)
Men: 3540–24600μmol/L(40–278mg/dl)
Women: 2550–20000μmol/L(29–226 mg/dl)

24-hour urine (adults)
Men: 8.6 – 19.4mmol/24h (980 – 2200 mg/24h)
Women: 6.3 – 13.4mmol/24h (720 – 1510mg/24h)

Creatinine clearance
66–143ml/min
It is recommended that each laboratory should assign its own normal range as this is dependent upon geographical location.

SPECIFIC PERFORMANCE CHARACTERISTICS

LINEARITY

The linearity of Gcell Creatinine kit is up to 8840 μmol/L,when the deviation is in the range of ±10%.The sample for linearity test is prepared by pure material.

PRECISION

Serum Precision		GQ-1	GQ-2	Sample
NO.of Data Points		80	80	80
Mean(μmol/L)		128.38	375.78	79.83
Within-Run	SD	0.84	2.13	0.55
(S_r)	CV	0.65%	0.57%	0.69%
Within-Laboratory	SD	1.38	3.53	1.11
(S_T)	CV	1.07%	0.94%	1.39%

INTERFERENCE

The following analytes were tested up to the levels indicated and found not to interfere:

Intralipid	up to 1000 mg/dl
Ascorbic Acid	up to 50 mg/dl
Direct bilirubin	up to 30 mg/dl
Creatine	up to 10 mg/dl

SAFETY PRECAUTIONS AND WARNINGS

1. For in vitro diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.
2. Reagent contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.
3. Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent azide from building up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.
4. Specimens should be treated as potentially infectious (HIV, Hepatitis B virus, Hepatitis C virus, etc.) and handled with appropriate caution.
5. Reagents with different lot numbers should not be interchanged or mixed.

REFERENCES

1. Chernecky CC, Berger BJ, eds. (2004). Laboratory Tests and Diagnostic Procedures, 4th ed. Philadelphia: Saunders.
2. Fossati P, Prencipe L, Berti G. Enzymatic creatinine assay: a new colorimetric method based on hydrogen peroxide measurement. Clin Chem 1983, 29:1494-1496.
3. Mazzachi BC, Peake M, Erhardt V. Reference range and method comparison studies for enzymatic and Jaffé Creatinine assays in plasma and serum and early morning urine. Clin Lab 2000, 46:53-55.
4. Junge W, Wilke B, Halabi A, Klein G. Determination of reference intervals for serum creatinine, creatinine excretion and creatinine clearance with an enzymatic and amodified Jaffé method. Clin Chim Acta 2004, 344:137-148.

INDEX OF SYMBOLS

	Manufacture
REF	Catalogue Number
LOT	Lot number
	Date of manufacture
	Use by(Expiration date)
IVD	For In-Vitro Diagnostic use only
2℃ 8℃	Stored at 2-8℃
	Attention:See instruction for use
EC REP	Authorized Representative in the European Company

Manufacture：Beijing Strong Biotechnology, Inc.
Address ： No. 15, Yanqi North Second Street, Yanqi Economic Development Area, Huairou District, Beijing 101400, P. R. China
Tel：+86 10 61667168

EC REP :Lotus NL B.V.
Address：Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
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