Creatinine Assay Kit (CRE)

Method: Picric Acid

Cat .No	Size	Instrument
GS301S	R1: 6×60 ml R2: 2×45 ml	For Hitachi 717 &ShimadzuCL7200/8000
GB300S	R1:4×100 ml R2: 2×50 ml	For Hitachi917 &OlympusAU640/400/600
GH301S	R1: 4×50 ml R2: 2×25 ml	For Hitachi902
GX300S	R1: 2×80 ml R2: 2×20 ml	For SYNCHRON CX4-5-7-9/ LX20/DXC600-800
GT301S	R1: 5×48 ml R2: 2×30 ml	For TOSHIBA 40

INTENDED USE
For the *in vitro* quantitative determination of Creatinine in serum, plasma or urine.

CLINICAL SIGNIFICANCE
As a measure of kidney function, clinically the estimation of serum creatinine is considered superior to that of blood urea nitrogen, and the determination of the endogenous creatinine clearance is the commonly employed clinical measure of glomerular filtration rate.

ASSAY PRINCIPLE
Creatinine in the samples reacts with the picric acid in alkaline buffer solution to form a water soluble red compound, the colour intensity of which is proportional to the concentration of creatinine in the sample.

SAMPLE COLLECTION AND PREPARATION
Serum or heparinized plasma.
Stable for 7 days at room temperature, for several months when frozen.
Urine: diluted 1+49 with 0.9% NaCl.

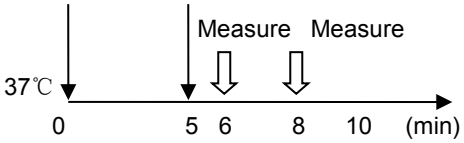
REAGENT COMPOSITION

Contents	Concentration of Solutions
Reagent 1 (R1)	
NaOH	0.16 mol/l
Reagent 2 (R2)	
Picric acid	4.0 mmol/l

STABILITY AND PREPARATION OF REAGENTS
All reagents are ready to use.
Stable up to the expiry date when stored at 2-8℃.
The reagents are stable for 1 month after opening and kept at 2-8 ℃.

ASSAY PROCEDURE
Test Procedure for Analyzers (HITACHI 7170/917)
Assay Mode: 2 point rate, 19 - 25
Wave Length (main/sub): 505 nm / 660 nm

Sample:10 µl
R1: 200 µl R2: 50 µl



1. Mix 10 µl sample with 200 µl R1 and incubate at 37℃ for 5 minutes.
2. Add 50 µl R2 into cuvette, mix and incubate for 1 minute at 37℃.
3. Read initial absorbance and start timer simultaneously, read again after 1 and 2 minutes.
4. Calculate absorbance change per minute (ΔA/min).

CALCULATION

$$\text{Concentration} = \frac{\Delta A_{sample}/\text{min}}{\Delta A_{calibrator}/\text{min}} \times \text{Calibrator value}$$

CALIBRATION
Recommend that this assay should be calibrated using Gcell WGC-CRE Calibrator.

QUALITY CONTROL
Randox Assayed Multi sera, are recommended for daily quality control. Values obtained should fall within a specified 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 expiry date of kit and contents.

REFERENCE VALUE

	Men	Women
Serum and plasma	43-133 µmol/l	70-106 µmol/l
Urine	8.84 - 13.3 mmol / 24 hrs 1 - 1.5 g / 24 hrs	

It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geographical location of the population.

SPECIFIC PERFORMANCE CHARACTERISTICS

LINEARITY
The method is linear to 1362 µmol/L. Sample above the top concentration should be diluted with 0.9% NaCl and reassay. Multiply the result by dilution factor.

PRECISION
The CV of the test should be ≤5%.

Intra assay precision		
N=20	Level1	Level 2
Mean (µmol/l)	128.6	335.3
SD	1.71	2.42
CV	1.33%	0.72%
Inter assay precision		
N=5	Level1	Level 2
Mean (µmol/l)	124.3	337.7
SD	1.71	2.83
CV	1.38%	0.84%

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SENSITIVITY
The minimum detectable level has been determined as 5.6 µmol/l.

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

Hemoglobin:	500 mg/dl
Intralipid	800 mg/dl
Bilirubin:	4 mg/dl
Ascorbic Acid:	30 mg/dl

CORRELATION
This method (Y) was compared with another commercially available method (X) and the following linear regression equation obtained:
y = 1.0257x-3.8238, and a correlation coefficient of 0.9993; 100 patient samples were analyzed .

SAFETY PRECAUTIONS AND WARNINGS
1. For in vitro diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handing laboratory reagents.
2. Reagents contain 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 build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.
4. All specimens used in this test should be considered potentially infectious. Universal Precautions, as they apply at your facility, should be used for handling and disposing of materials during and after testing.

REFERENCES
1. Osberg IM, Hammond KB. A solution to the problem of bilirubin interference with the kinetic Jaffe method for serum creatinine. Clin Chem 1978;24:1196-7.
2. Bowers LD, Wong ET. Kinetic serum creatinine assays. II. A critical evaluation and review. Clin Chem 1980;26:555-61.
3. Bowers LD. Kinetic serum creatinine assays. The role of various factors in determining specificity. Clin Chem 198026:551-.
4. Glick JH, Brown DM, Crocker CL, Haisten SM,Peine CA. Preparation of reagents for use with the Beckman Astra-8. Clin Chem 1980;26:358-9.

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

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