CREATININE ENZYMATIC (2-8°C)

CATALOGUE NUMBER	KIT SIZE (ML)
CRE1201	1x30ml / 1x10ml
CRE2401	1x30ml / 1x10ml
CRE4201	1x60ml / 1x20ml

Intended Use:
For *In Vitro* diagnostic use by trained professionals only.
This reagent is intended for the quantitative determination of creatinine in human serum, plasma and urine.

Clinical Significance:
Increased creatinine levels usually indicate renal function impairment but would not be considered a sensitive indicator of early renal disease. Plasma concentrations can be more sensitive to changes in glomerular function where a chronic renal disease state exists. Urinary creatinine is only useful when performed as part of a creatinine clearance test. This involves a 24 hour urine collection for determination of urinary creatinine which is used in ratio with plasma creatinine concentration.

Test Principle:
The first step in the reaction is the elimination of endogenous creatine by Creatinase, sarcosine oxidase and catalase. Once the elimination reaction is complete, the Creatinine in the patient sample is converted into creatine by creatininase and then hydrolysed to sarcosine by creatinase which is followed by the oxidation of sarcosine by sarcosine oxidase producing hydrogen peroxide which is quantified by the Trinders reaction.

Reagent Composition

REAGENT	COMPONENT	CONCENTRATION
R1 - Buffer	MOPS Buffer (pH 7.5)	25 mmol/l
	Creatinase	10 U/ml
	Sarcosine Oxidase	5 U/ml
	Catalase	3 U/ml
R2 – Enzyme Reagent	MOPS Buffer (pH 7.5)	90 mmol/l
	Peroxidase	10 U/ml
	Creatininase	30 U/ml
	TOPS/4-Aminoantipyrine	0.5 mmol/l

Reagent Preparation and Stability:
R1: Liquid, ready to use
R2: Liquid, ready to use
R1 and R2 are stable to the stated expiry date when stored unopened at 2 - 8°C. Once opened R1 an R2 are stable up to 8 weeks at 2 - 8°C.
Dispose of reagents carefully in line with local guidelines.

Sample Collection, Preparation and Stability:
Collect serum and plasma by separation after standard venepuncture technique. Creatinine is stable in serum or plasma for 24 hours at 2 - 8°C.
Random or 24 hour urine collection. Dilute urine 1/50 with normal saline or distilled water prior to assay. Urine creatinine is stable for 24 hours at 2 - 8°C and 3 months at -20°C.

Assay Procedure:

WAVELENGTH	546nm (525 – 565 nm)
TEMPERATURE	37°C
CUVETTE	1cm Path Length
BLANK	Sample Blank

	Blank	Standard	Sample
Sample	10µl	-	10µl
Standard	or 10µl	10µl	-
R1	450µl	450µl	450µl
Mix and incubate for 5 minutes at assay temperature. Read the absorbance (Abs 1) of the Standard and Samples against respective Blanks.			
R2	150µl Saline	150µl	150µl
Mix and incubate for 5 minutes at assay temperature. Read the absorbance (Abs 2) of the Standard and Samples against respective Blanks.			

Calculation:
Calculate change in absorbance: ΔAbs = Abs 2 – Abs 1

$$\text{Creatinine (µmol/l)} = \frac{\Delta\text{Abs Sample} - \Delta\text{Abs Sam Blank}}{\Delta\text{Abs Calibrator} - \Delta\text{Abs Cal Blank}} \times \text{Concentration of Calibrator}$$

Performance Characteristics:
Measuring range:
15900 µmol/l (180 mg/dl)
Dilute samples with higher concentrations using Normal saline 1+1 and rerun the assay. Multiply the result by the dilution factor (for 1+1 dilution, the dilution factor is 2)

Analytical Sensitivity: (Lower detection limit):
20 µmol/l (0.23 mg/dl)

Imprecision
Intra-Assay Precision:

Sample	Mean (µmol/l)	SD (µmol/l)	CV %
Pool 1	76.91	0.01	1.63
Pool 2	337.69	0.06	1.44

Inter-Assay Precision:

Sample	Mean (µmol/l)	SD (µmol/l)	CV %
Pool 1	76.91	0.02	2.31
Pool 2	331.50	0.06	1.72

Method Comparison:
Prestige Creatinine reagent (y) was compared with another commercially available enzymatic reagent (x) and gave the following results:
y = 1.066 x - 0.020, r = 0.973

Interferences:
The following analytes were found not to interfere in the assay up to the levels indicated:
Haemoglobin up to 5 g/dl
Direct Bilirubin up to 40 mg/dl

Reference Range:

	Serum/Plasma	Urine (24 hours)
Male	79.6 – 115 µmol/l (0.9 – 1.3 mg/dl)	8.6 – 19.4 mmol/24h (980 – 2200 mg/24h)
Female	53.0 – 97.2 µmol/l (0.6 – 1.1 mg/dl)	6.3 – 13.4 mmol/24h (720 – 1510 mg/24h)

1st Morning urine: Men: 3540 – 24600 µmol/l (40 – 278 mg/dl)
1st Morning urine: Women: 2550 – 20000 µmol/l (29 – 226 mg/dl)
Creatinine Clearance: 66 – 143 ml/min
Each laboratory should establish its own mean reference range according to the population.

Automated systems:
Contact Prestige Diagnostics Technical Department for applications on a wide range of automated analysers.
For automation we recommend the use of a serum based calibrator.

Quality Control and Calibration Material:
Calibration Serum: **QCCCAL1 / QCCCAL2**
Human Assayed Control Normal: **QCCHAN1 / QCCHAN2**
Human Assayed Control Elevated: **QCCHAE1 / QCCHAE2**

References:

1.Junge W, Wilke B, Halabi A, Klein G. Determination of reference intervals for serum creatinine, creatinine excretion and creatinine clearance with an enzymatic and a modified Jaffe method. Clin Chim Acta 2004, 344: 137-148
2. Fossati P, Prencipe L, Berti G. Enzymatic Creatinine assay: a new colorimetric method based on hydrogen peroxide measurement. Clin Chem 1983, 29: 1494-96
3. Tietz NW, *Clinical Guide to Laboratory Tests*, 3rd Edition
4. Henry RJ et al *Clinical Chemistry – Principles and Techniques*. Harper & Row 11th Edition

REF	Catalogue number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by Date
	Manufacturer		

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