UREA (2–8°C)

GLDH (KINETIC UV)

CATALOGUE NUMBER	KIT SIZE (ML)
MPRURE1	1x60ml / 1x12ml / 1x5ml
MPRURE2	4x60ml / 2x24ml / 1x5ml

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

Clinical Significance:
The determination of urea is the most widely used test for the evaluation of kidney function. It is frequently used in conjunction with creatinine determination for the differential diagnosis of pre-renal hyperuraemia, renal hyperuraemia (glomerulonephritis, chronic nephritis, polycystic kidney, nephrosclerosis, tubular nephrosis) and post renal hyperuraemia (obstructions of the urinary tract).

Test Principle:
Urea is hydrolysed in presence of urease to produce ammonia and CO_2. The ammonia produced combines with 2–oxoglutarate and NADH in presence of GLDH to yield glutamate and NAD.
The decrease in absorbance, which can be measured photometrically, is proportional to the Urea concentration.

Reagent Composition

REAGENT	COMPONENT	CONCENTRATION
Reagent 1	Tris Buffer pH 7.8	50 mmol/l
	GLDH	> 80 U/l
	Urease	> 12 U/ml
Reagent 2	Tris Buffer pH 9.6	100 mmol/l
	2-oxoglutarate	8.30 mmol/l
	NADH	> 0.23 mmol/l
Standard	Urea	50 mg/dl (8.33 mmol/l)

Reagent Preparation and Stability:
R1: Liquid, ready to use
R2: Liquid, ready to use
Standard: Liquid, ready to use
R1 and R2 are stable to the stated expiry date when stored unopened at 2 - 8°C. Onboard an analyser the reagents are stable for a period of 28 days.
Dispose of reagents carefully in line with local guidelines.

Sample / Sample Preparation / Sample Stability:
Collect serum and Li-heparin, Na- heparin or K2EDTA plasma by standard venepuncture technique. Do not use Ammonium heparin.
Serum and plasma is stable up to 7 days at 20 - 25°C and at 2 - 8°C, 1 year at -20°C.
Collect urine without preservatives. Stable up to 7 days at 2 - 8°C, 2 days at 20 - 25°C and 1 month at -20°C.
Use automatic dilution mode on analysers to dilute urine 1+19 prior to assay with saline or distilled water, the result is automatically converted. For manual analysis dilute urine 1+9 (multiply result by 10).

Assay Procedure:
Prepare a Working Reagent by mixing 5 volumes of R1 with 1 volume of R2 (5+1 ratio). The Working Reagent is stable for up to 14 days at 2 - 8°C and for up to 3 days at 20 - 25°C.

WAVELENGTH	340 nm
TEMPERATURE	37°C
CUVETTE	1cm Path Length
BLANK	Distilled water

	Blank	Standard	Sample
Sample	-	-	10µl
Standard	-	10µl	-
Working Reagent	1000 µl	1000 µl	1000 µl
Mix and read absorbance A1 after exactly 30 secs, then read absorbance A2 after exactly 60 secs against the Reagent Blank. Calculate the ΔAbs (A1-A2) for the samples and standard.			

Calculation:

$$\text{Concentration} = \frac{\Delta\text{Abs Sample}}{\Delta\text{Abs Standard}} \times \text{Concentration of Standard}$$

mg/dl x 0.166 = mmol/l (urea)
mg/dl urea x 0.467 = mg/dl urea-nitrogen

Performance Characteristics:
Measuring range:
Serum/Plasma: 5 - 400 mg/dl (0.83 - 66.4 mmol/l)
Urine: 50 - 4400 mg/dl (8.33 - 730 mmol/l) (minimum, linearity may be higher on various automatic analysers. Repeat samples with higher concentration using the rerun function,

Analytical Sensitivity: (Lowest detection limit):
5 mg/dl (0.83 mmol/l)

Imprecision
Intra-Assay Precision:

Sample	Mean (mg/dl)	SD (mg/dl)	CV %
Pool 1	41.8	1.34	3.21
Pool 2	98.4	1.63	1.66
Pool 3	142	3.03	2.13

Inter-Assay Precision:

Sample	Mean (mg/dl)	SD (mg/dl)	CV %
Pool 1	43.5	1.34	3.07
Pool 2	65.6	2.05	3.12
Pool 3	140.2	3.26	2.32

Method Comparison:
Prestige Diagnostics Urea Reagent (y) was compared with another commercially available reagent (x) and gave the following results:
y = 0.993 x + 0.389 r = 0.998

Interferences:
Criterion: Recovery within +/- 10% of initial value.
Icterus: No significant interference up to 100 mg/dl of Bilirubin.
Haemolysis: No significant interference up to 800 mg/dl Haemoglobin.
Lipaemia: No significant interference up to 2400 mg/dl of Triglycerides
There is poor correlation between turbidity and triglycerides concentration.
The Ammonia produced during a GLDH or lactate UV determination interferes with the Urea/BUN assay. The urea / BUN must not be therefore installed on the analyser together with reagents for the GLDH or lactate UV test. Endogenous ammonium ions in urine interfere with the Urea/BUN assay. Elevated concentrations can also occur under acidic conditions (acidosis). Great care must be taken to prevent ammonia contamination of the specimens and calibrators to be analysed for urea/urea nitrogen.

Reference Range:

Serum/Plasma	Urine (24 hour)
10 – 50 mg/dl 1.7 – 8.3 mmol/l	10 – 35 g/24 hr 170 – 580 mmol/l /24 hr

Each laboratory should establish its own mean reference range according to the population.

Limitations:
The result from this test should not be used as the sole criteria for the diagnosis of renal disorder, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

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. Berthelot MPE Report Chim Appl 1859; 282
2. Fawcett JK Scott JE J Clin Chem 1962:13:156
3. Chaney AL Marbach EP Clin Chem 1962:8:131
4. Gentzkow CJ J Biol Chem 1942; 143:531
5. Glick M. R. Ryder K W, Jackson SA. Graphical Comparisons of Interferences in Clinical Chemistry Instrumentation. ClinChem 1986; 32:470-474
6. Bablok W. et al. A General Regression Procedure ofr Method Transformation. Clin Chem Clin Biochem 1988; 26: 783-790

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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