UREA COLOUR (2-8°C)

(COLORIMETRIC)

CATALOGUE NUMBER	KIT SIZE (ML)
MPRURB1	2x50ml / 2x5ml / 2x10ml / 1x5ml

Intended Use:
The Urea Colour kit is intended for the quantitative determination of Urea in serum, plasma and urine.
For *In Vitro* diagnostic use by trained professionals only.

Clinical Significance:
The determination of urea is the most widely used test for the evaluation of kidney function. The test is frequently used in conjunction with the determination of Creatinine for the differential diagnosis of Prerenal hyperuremia, renal hyperuremia and post renal hyperuremia. Urea is the final degradation product of protein and amino acid metabolism. In the liver proteins are broken down to amino acids and deaminated and the ammonia formed in this process is enzymatically converted to urea in the liver.

Test Principle:
The Berthelot reaction has been long used for the measurement of urea and ammonia. The urea colorimetric procedure described below is a modification of the Berthelot reaction. Urea is converted to ammonia by the addition of urease. Ammonium ion then reacts with a mixture of salicylate, sodium nitroprusside and hypochlorite to yield a blue green chromophore. The intensity of the colour formed is directly proportional to the urea concentration in the sample tested.

Reagent Composition

REAGENT	COMPONENT	CONCENTRATION
R1 Urea Buffer	Phosphate Buffer	50 mmol/l
	Sodium Nitroprusside	>10 mmol/l
	Salicylate	>5 mmol/l
R2 Urease	Urease	10 KU/l
	EDTA	2.4 mmol/l
R3 Hypochlorite	Sodium Hypochlorite	10% v/v
	NaOH	0.9 mmol/l
	Sodium Azide	0.95 g/l
Urea Standard	Aqueous Urea Standard	40 mg/dl (6.66 mmol/l)

Reagent Preparation and Stability:
All reagents are supplied ready to use.
When stored between 2 - 8°C, the reagents are stable till the expiry date.

Sample Collection, Preparation and Stability:
Collect serum and plasma by standard venepuncture technique. Collect urine samples in clean containers. Dilute urine samples 1 + 49 parts with distilled/deionised water before assay. Multiply assay result x 50.
Samples are stable for 7 days at 2 - 8°C or 1 year at -20°C.

Assay Procedure:

WAVELENGTH	578 nm
TEMPERATURE	37°C / 25°C
CUVETTE	1cm Path Length
BLANK	Reagent Blank

	Blank	Standard	Sample
R1 – Urea Buffer	1000 µl	1000 µl	1000 µl
R2 – Urease	100 µl	100 µl	100 µl
Sample	-	-	10 µl
Standard	-	10 µl	-
Mix and incubate for 5 minutes at 37°C or 10 minutes at room temperature.			
R3 Hypochlorite	200 µl	200 µl	200 µl
Mix and incubate for 5 minutes at 37°C or 10 minutes at room temperature. Measure absorbance of Standard and Sample against the Reagent Blank.			

Calculation:

$$\text{Urea Concentration (mg/dl)} = \frac{\text{Abs Sample}}{\text{Abs Standard}} \times \text{Urea Standard Concentration}$$

Performance Characteristics:

Measuring range:
0 – 250 mg/dl (0 – 37.5 mmol/l)
Dilute samples with activity higher than 250 mg/dl using Normal saline and rerun the assay. Multiply the concentration result obtained by the dilution factor.

Interferences:
Lipaemia (triglycerides up to 1000 mg/dl) and Bilirubin up to 20 mg/dl do not interfere. Haemolysis (Hb 2 g/l) and elevated ammonia interfere with the assay. Other drugs and substances may interfere.

Reference Range:

Serum / Plasma	15 – 50 mg/dl (2.49 – 8.33 mmol/l)

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

Quality Control and Calibration Material:
It is recommended that laboratories use reference control sera to verify the reagent performance. Results obtained should fall within the specified ranges. If results fall outside these ranges actions should be taken in line with the laboratory's internal quality procedures.
AMS recommends the following calibrator and controls:
Calibration Serum: **QCCCAL1 / QCCCAL2**
Human Assayed Control Normal: **QCCHAN1 / QCCHAN2**
Human Assayed Control Elevated: **QCCHAE1 / QCCHAE2**

Notes and Limitations
1. The reagents contain sodium azide (0.1%). Avoid contact with skin and mucosa. Sodium azide may react with copper and lead in drainage piping to form explosive metal azide. Therefore, on reagent disposal flush with a large volume of water and / or dispose of according to local regulations.
2. Do not mix reagents from different kit lots. The components of the kit are precisely matched to give optimal performance of the test.
3. All samples from human origin should be regarded as potentially infectious. All laboratory staff should wear appropriate protective equipment to ensure personal safety.
4. The urea result from this test should not be used as the sole criteria for the diagnosis of renal disorders, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

References:
Tietz N W et al., Fundamentals of Clinical Chemistry, Philadelphia W.B Saunders & Co., p991 (1976). Talke H, Schubert GE, Klin Wchers (1965), 3, 17.

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

CE

Prestige Diagnostics UK Ltd 40 Ballymena Business Centre, Galgorm, Co. Antrim, BT42 1FL, United Kingdom. Tel: +44 (0) 28 2564 2100
www.prestigediagnostics.co.uk info@prestigediagnostics.co.uk

V3: rev Aug 2018