

UREA BERTHELOT/COLORIMETRIC METHOD IVD



REF NO DESCRIPTION CS612 UREA

PAKAGE SIZE

CS 612-1	2 X 500 ML	CS 612-5	6 X 20 ML
CS 612-2	4 X 250 ML	CS 612-6	2 X 50 ML
CS 612-3	6 X 50 ML	CS 612-5R1	1 X 5 L
CS 612-4	2 X 100 ML	CS 612-5R2	1 X 5 L

INTENDED USE

For the quantitative determination of Urea in serum, plasma & urine.

INTENDED USER: Professional Use Only

CLINICAL SIGNIFICANCE

Urea is the end product of the protein metabolism. It is synthesized in the liver from the ammonia produced by the catabolism of amino acids. It is transported by the blood to the kidneys from where it is excreted. Increased levels are found in renal diseases, urinary obstructions, shock, congestive heart failure and burns. Decreased levels are found in liver failure and pregnancy

PRINCIPLE

Urease catalyses the conversion of urea to ammonia. In a modified Berthelot reaction, the ammonium ions react with a mixture of salicylate, hypochlorite and nitroprusside to yield a blue-green dye (Indophenol.) The intensity of this dye is proportional to the concentration of urea in the sample.

Urease Urea + H2O ----------→ 2 NH3 + CO2

Nitroprusside

REAGENT COMPOSITION

UREA REAGENT 1

120 mmol/L Phosphate buffer Sodium Salicylate 60 mmol/L Sodium nitroprusside 5 mmol/l **EDTA** 1 mmol/L Urease 5 KU/L

UREA REAGENT 2

Phosphate buffer 120 mmol/L Sodium Hydroxide 400 mmol/L Sodium Hypochlorite 10 mmol/L

UREA STANDARD

Urea standard concentration 80 mg/dL or 13.3mmol/L

REAGENT PREPARATION

Reagents and standard are ready for use.

REAGENT STORAGE AND STABILITY

The reagents and standard are stable up to the expiry date when stored at 2 - 8° C.

SPECIMEN

Serum Plasma (provided the anticoagulant used does not contain ammonium or fluoride) and urine dilute (urine 1 + 100) with distilled water) Urea in serum is stable at 2-8° C for 3 days. Do not use lipaemic samples.

To avoid contamination, use clean laboratory wares. Serum specimens should be considered infectious and handled appropriately.

ASSAY

Wavelength 578 nm Cuvette 1 cm light path Temperature 20-25°C, or 37°C Measurement Against reagent blank

PROCEDURE

Pipette into cuvettes	Blank	Standard	Sample			
Reagent-1	1000 μL	1000 μL	1000 μL			
Sample			10 μL			
Standard		10 μL				
Mix and incubate for 5 minutes at 20-25°C or 3 minutes at 37°C						
Reagent-2	1000 μL	1000 μL	1000 μL			

Mix and incubate for 10 minutes at 20-25°C or 5 minutes at 37°C Measure the absorbance of the sample (As) and the standard(Astd) against the reagent blank

CALCULATION

ΔA sample Urea Conc. (mg/dL) X 80 (Std.conc.)

ΔA standard

Urea (g/24 urine) = mg/dL X volume of 24 hour urine To convert mg/dL to mmol/L divide by 6.01

Serum values up to 400 mg / dL or 66.6 mmol/L. Urine values up to 40 g/1

For higher values dilute sample 1+1 with distilled water, repeat assay and multiply the results by 2.

NORMAL RANGE

Serum	10 - 50 mg/dL	1.66 - 8.30 mmol/L
Urine	10 – 35 g/L	1.66 - 5.83 mol/L

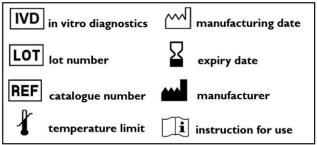
QUALITY CONTROL

All control sera with Urea values estimated by this method can be used.

NOTES

- The test is not influenced by haemoglobin values up to 200 mg/dL or by bilirubin values up to 10mg/dL.
- The standard contains sodium azide (0.1%) as preservative. Do not swallow and avoid contact with skin and mucous membranes.
- Sodium hydroxide and hypochlorite in reagent 2 are irritants. In case of contact with eyes or mucous membranes wash immediately with
- 1mg of urea corresponds to 0.467 mg of urea nitrogen.

SYMBOL ON LABELS



BIBILOGRAPHY

- Berthelot A et at Clin. Chem 25 (2), 336, 1979 1-
- Tobacco, A et at , Clin, Chem 25 (2), 336 , 1979 2-
- Chaney A. L and Marbach E.P., Clin. Chem. 8.130 . 1962

