

REF NO DESCRIPTION
CS612 UREA

PACKAGE 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.



REAGENT COMPOSITION

UREA REAGENT 1

Phosphate buffer	120 mmol/L
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.

PRECAUTION

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

$$\text{Urea Conc. (mg/dL)} = \frac{\Delta A \text{ sample}}{\Delta A \text{ standard}} \times 80 (\text{Std. conc.})$$

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

LINEARITY

Serum values up to 400 mg / dL or 66.6 mmol/L. Urine values up to 40 g/l or 6.66 mol/l
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 water.
- 1mg of urea corresponds to 0.467 mg of urea nitrogen.

SYMBOL ON LABELS

 IVD in vitro diagnostics	 manufacturing date
 LOT lot number	 expiry date
 REF catalogue number	 manufacturer
 temperature limit	 instruction for use

BIBLIOGRAPHY

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



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CS612-UREA
R2/01-12-2020

EC REP

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