

**PRODUCT CODE**  
CS027

**INTENDED USE**

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

**CLINICAL SIGNIFICANCE**

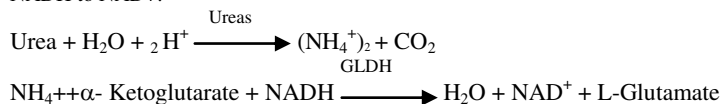
Urea is the final result of the metabolism of proteins; It is formed in the liver from their destruction.

It can appear the urea elevated in blood (uremia) in: diets with excess of proteins, renal diseases, heart failure, gastrointestinal hemorrhage, dehydration or renal obstruction 1,4,5.

Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data

**PRINCIPLE**

Urea in the sample is hydrolyzed enzymatically into ammonia (NH<sub>4</sub><sup>+</sup>) and carbon dioxide (CO<sub>2</sub>). Ammonia ions formed reacts with α-ketoglutarate in a reaction catalysed by glutamate dehydrogenase (GLDH) with simultaneous oxidation of NADH to NAD<sup>+</sup>:



The decrease in concentration of NADH, is proportional to urea concentration in the sample.

**REAGENT COMPOSITION**

**UREA REAGENT 1**

TRIS pH 7.8	80 mmol/L
α-Ketoglutarate	6 mmol/L
Urease	75000 U/L

**UREA REAGENT 2**

GLDH	60000 U/L
NADH	0,32 mmol/L

**UREA**

UREA CAL	50 mg/dL
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**REAGENT PREPARATION**

Working reagent (WR): Mix 4 vol. R1 Buffer + 1 vol. R2 enzymes.

The (WR) is stable for 1 month at 2-8°C.

UREA CAL: Ready to use.

**REAGENT STORAGE AND STABILITY**

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8°C, protected from light and contaminations prevented during their use. Do not use reagents over the expiration date

**Signs of reagent deterioration**

Presence of particles and turbidity, Blank absorbance (A) at 340 nm < 1,00.

**SPECIMEN**

- Serum or heparinized plasma: Do not use ammonium salts or fluoride as anticoagulants.

- Urine: Dilute sample 1/50 in distilled water. Mix. Multiply the results by 50 (Dilution factor). Preserve urine samples at pH <4.

Urea is stable at 2-8°C for 5 days.

**PRECAUTION**

Working reagent (WR): Mix 4 Vol . R1 Buffer +1 Vol. R2 enzymes

The (WR) is stable for 1 month at 2-8°C .

Urea Calibrator : Ready to use

**PROCEDURE**

**1.ASSAY conditions:**

Wavelength	340 nm
Cuvette	1 cm light path
Temperature	15-25°C, or 37°C

**2.Adjust the instrument to zero with distilled water.**

**3. Pipette into cuvettes**

	Blank	Standard	Sample
Working reagent	1000 µL	1000 µL	1000 µL
Standard	--	10 µL	--
Sample	--	--	10 µL

**4.Mix and read the absorbance after 30 s (A1) and 90 s(A2).**

**5.Calculate: ΔA= A1 – A2.**

**CALCULATION**

$$\text{Urea Conc. (mg/dL)} = \frac{\Delta A \text{ sample} - \Delta A \text{ Blank}}{\Delta A \text{ standard} - \Delta A \text{ Blank}} \times 50 \text{ (Std. conc.)}$$

mg/dL urea x 0,466 = mg/dL urea BUN (Blood Urea Nitrogen)

Conversion factor: mg/dL x 0,1665 = mmol/L.

**LINEARITY**

From detection limit 1.241 mg/dL to linearity limit 530 mg/dL.

If the concentration is greater than linearity limit dilute 1:2 the sample with NaCL 9 g/L and multiply the result by 2.

**NORMAL RANGE**

Serum	15 - 45 mg/dL
Urine 24hrs	20 – 25 g/24 h

**QUALITY CONTROL**

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















Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances .

**NOTES**

1. Glassware and distilled water must be free of ammonia and ammonium salts.
2. Calibration with the aqueous standard may cause a systematic error in automatic procedures. In these cases, it is recommended to use a serum Calibrator.
3. Use clean disposable pipette tips for its dispensation.



## SYMBOL ON LABELS

Symbols	Signify	Symbols	Signify
	Catalogue Number		Pack Size
	Expiry Date		Volume
	Storage Condition		Lot Number
	Instruction for Use		In Vitro Diagnostics
	Manufacturing Date		Manufacturer
	Number of Tests		For Single Use Only
	EC Representative		European conformity

## BIBLIOGRAPHY

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