Urea-LQ

Urease-GLDH. Kinetic. Liquid

Quantitative determination of urea

IVD

Store at 2-8ºC

PRINCIPLE OF THE METHOD

Urea in the sample is hydrolized enzymatically into ammonia (NH_4^+) and carbon dioxide (CO_2).

Ammonia ions formed reacts with α-ketoglutarate in a reaction catalysed by glutamate dehydrogenase (GLDH) with simultaneous oxidation of NADH to NAD^+:

$$\text{Urea} + H_2O + 2\,H^+ \xrightarrow{\text{Urease}} (NH_4^+)_2 + CO_2$$

$$NH_4^+ + \alpha\text{- Ketoglutarate} + \text{NADH} \xrightarrow{\text{GLDH}} H_2O + NAD^+ + \text{L-Glutamate}$$

The decrease in concentration of NADH, is proportional to urea concentration in the sample[1].

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.

REAGENTS

R 1 Buffer	TRIS pH 7,8	80 mmol/L
	α-Ketoglutarate	6 mmol/L
	Urease	75000 U/L
R 2 Enzymes	GLDH	60000 U/L
	NADH	0,32 mmol/L

PREPARATION

All the reagents are ready to use.

STORAGE AND STABILITY

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8ºC, 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.

ADDITIONAL EQUIPMENT

- MINDRAY BS-120 / BS-200E Autoanalyzer.
- General laboratory equipment(Note 1).

SAMPLES

- Serum or heparinized plasma[1]: Do not use ammonium salts or fluoride as anticoagulants.
- Urine[1]: 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 2-8ºC for 5 days.

REFERENCE VALUES[4,5]

Serum or plasma:

15-45 mg/dL ≅ 2,5-7,5 mmol/L

Urine:

26 – 43 g/24 h ≅ 428-714 mmol/24 h

These values are for orientation purpose; each laboratory should establish its own reference range.

QUALITY CONTROL

Control sera and calibrators are recommended to monitor the performance of assay procedures: SPINTROL H Calibrator, SPINTROL H Normal and Pathologic (Ref. 1002011, 1002120 and 1002210).

If control values are found outside the defined range, check the instrument, reagents and technique for problems.

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

MINDRAY BS-120 / BS-200E APPLICATION

PARAMETERS				
Test	UREA / UREA	R1		240 / 240
Nº	**	R2		60 / 60
Full Name	UREA / UREA	Sample volume		3 / 3
Standard Nº		R1 Blank		
Reac. Type	Fixed T / Fixed T	Mixed Rgt Blank		
Pri. Wavelength	340 / 340	Linearity Range	5 mg/dL	250 mg/dL
Sec. Wavelength		Linearity Limit		*
Direction	Decrea / Decrea	Substrate Limit		*
Reac. Time	2_5 / 1_10	Factor		*
Incuba. Time		Prozone check		*
Units	mg/dL / mg/dL	q1		q2
Precision	0.1 / 0.1	q3		q4
		PC		Abs

CALIBRATION (Cal + Rgt Blk)	
Rule	One-point Linear / Two-point Linear
Sensitivity	1 / 1
Replicates	2 / 2
Interval (days)	0 / 0
Difference Limit	
SD	
Blank Response	
Error Limit	
Correlation Coefficient	

*Blank parameter must be performed in order to get good results in CALIB screen from main menu. The blank calibration is stable until **35 days.** After this period the blank parameter must be performed again in order to validate the calibration.*

PERFORMANCE CHARACTERISTICS

Measuring range*:* From *detection limit* 0,743 mg/dL to *linearity limit* 400 mg/dL.

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

Precision:

	Intra-assay (n=20)		Inter-assay (n=20)	
Mean (mg/dL)	37,5	120	40,0	126
SD	1,05	0,92	1,06	2,07
CV (%)	2,79	0,77	2,65	1,65

Sensitivity: 1 mg/dL = 0,00180 A.

Accuracy: Results obtained using SPINREACT reagents (y) did not show systematic differences when compared with other commercial reagent (x).

The results obtained using 50 samples was the following:

Correlation coefficient $(r)^2$: 0,98209.

Regression equation y= 1,0343x – 1,2105.

The results of the performance characteristics depend on the analyzer used.

NOTES

1. Glassware and distilled water must be free of ammonia and ammonium salts[1].
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.

BIBLIOGRAPHY

1. Kaplan A. Urea. Kaplan A et al. Clin Chem The C.V. Mosby Co. St Louis. Toronto. Princeton 1984; 1257-1260 and 437 and 418.
2. Young DS. Effects of drugs on Clinical Lab. Tests, 4th ed AACC Press, 1995.
3. Young DS. Effects of disease on Clinical Lab. Tests, 4th ed AACC 2001.
4. Burtis A et al. Tietz Textbook of Clinical Chemistry, 3rd ed AACC 1999.
5. Tietz N W et al. Clinical Guide to Laboratory Tests, 3rd ed AACC 1995.

PACKAGING

Ref. MI41041	Cont.	R1: 5 x 25 mL R2 : 1 x 32 mL

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