GENESIS

Instructions For Use

Urea (Colorimetric Method)

Cat no.	size
1109 101	2*100

INTENDED USE

The Urea Reagent Is intended for in vitro Quantitative diagnostic determination of urea in human serum and plasma.

DIAGNOSTIC CHARACTERISTICS

Urea is the major end product of protein nitrogen metabolism. It is synthesized by the urea cycle in the liver and excreted through the kidneys. The circulating levels of urea depend upon protein intake, protein and kidney functions. Elevated urea levels can occur due to renal impairment or in some diseases such as diabetes, infection, congestive heart failure and during different liver diseases. Determination of urea is the most widely used screening test for renal function together with serum Creatinine.

PRINCIPLE OF THE METHOD

The Berthelot reaction has long been used for the measurement of urea . The present method is a modified Berthelot.

$UREA + H_2O \xrightarrow{UREASE} 2NH_3 + CO_2$

$NH3 + Salicylate + Hypochlorite \longrightarrow 2,2\ dicarboxyindophenol$

The urea colorimetric procedure is a modification of the Berthelot reaction. Urea is converted to ammonia by the use of urease. Ammonium ion then reacts with a mixture of salicylate, sodium nitroprusside, and hypochlorite to yield ablue-green chromophore. The intensity of the color formed is proportional to the urea concentration in the sample.

COMPOSITION

BUFFER (R_1)	Phosphate buffer	100 mmol/L
	Sodium nitroprusside	20 mmol/L
	Sodium salycialate	25 mmol/L
UREASE(R_2)	Urease enzyme	20,000 U/L
ALKALINE REAGENT (R_3)	Sodium hydroxide	45 mmol/L
	Sodium hypochlorite	20 mmol/L
STANDARD (S)		50.0 mg/dL

STORAGE

Store at 2-8ºC.

Reagent and Standard are stable until the expiry date shown on the Vial label when stored tightly closed and if contaminations are prevented during their use.

REAGENT PREPARATION

Reagents provided are ready to use.

ADDITIONAL EQUIPMEN

− Thermostatic water bath at 37ºC

− Analyzer, spectrophotometer able to read at 578nm

SPECIMEN

1.Test specimens should be human serum and free from hemolysis.

2.Plasma may be substituted provided the anticoagulant used is free of ammonium salt.

3.All material coming in contact with the sample must be free of ammonia and heavy metals.

4.Urea in serum is reported stable for seventy-two (72) hours Refrigerated at 2 – 8 °C and for 8 hours at 15 – 25 °C.

5.Un-refrigerated serums should be used within eight (8) hours.

6.Urea in Urine is Stable For 3 Days at Room Temperature if microbial growth is prevented .

Precautions and Warnings

Do not ingest or inhalate. In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.

Symbols in Product Labeling

EC REP	Authorized Representative		Expiration date
IVD	For in-vitro diagnostic use	⚠	CAUTION, consult instructions for use
REF	Catalogue number		Manufactured by
LOT	Lot number		

PROCEDURE:

1. Bring the Reagent to room temperature.
2. Pipette into labeled test tubes:

	Blank	Standard	Sample
Buffer (R_1)	1 ml	1 ml	1 ml
urease (R_2)	1 drop	1 drop	1 drop
Standard (S)	-	10 µL	-
Sample	-	-	10 µL
1-Mix thoroughly and incubate the tubes for **5 minutes** at room temperature (15-25ºC) or for **3 minutes** at 37ºC.			
Alkaline Reagent (R_3)	200 µL	200 µL	200 µL
2-Mix thoroughly and incubate the tubes for **10 minutes** at room temperature (16-25ºC) or for **5 minutes** at 37ºC. 3- Measure the absorbance (A) of the Standard and Sample at 578 nm against the Blank. The color is stable for at least 1hour.			

CALCULATIONS

The urea concentration in the sample is calculated using the following general formula:

$$\frac{A\ Sample}{A\ Standard} \times 50 = mg/dL\ urea$$

$$\times 8.33 = mmol/L\ urea$$

BUN= UREA/2.14

REFERENCE VALUES

urea		**BUN**	
Adults<65years	15 - 50 mg/dL	7 - 23.5	mg/dL
Adults>65years	< 70 mg/dL	7 - 32.9	mg/dL
Children		5 - 18	mg/dL
Urine (24) hours			
Urea : 20 - 35 g/24hrs			
BUN : 9.3 -16.4 g/24hrs			

QUALITY CONTROL

It is recommended to use the Control Serum level I and II to verify the performance of the measurement procedure.

METROLOGICAL CHARACTERISTICS

- Detection limit: urea 1.3 mg/dL = BUN 0.60 mg/dL
- Linearity limit: urea 300 mg/dL = BUN 140 mg/dL

For higher values dilute sample **1/2** with physiological saline and repeat measurement.

− Repeatability (within Run)

Mean Concentration	cv	n
26 mg/dL	1.6 %	20
86 mg/dL	0.8%	20

− Reproducibility (run to run):

Mean Concentration	cv	n
0.59 mg/dL	2.4 %	20
6.74 mg/dL	1.3 %	20

INTERFERENCES

Lipemia (triglycerides 10 g/L) and bilirubin (20 mg/dL) do not interfere. Hemolysis (hemoglobin 2 g/L) and elevated ammonia interfere. Other drugs and substances may interfere.

BIBLIOGRAPHY

1.Chaney AL, Marbach EP. Modified reagents for determination of urea and ammonia. ClinChem 1962; 8:130-132

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