

# BioMed-Urea

## Enzymatic, Colorimetric



REF: URE120120 ( 1x120 ml )  
URE120240 ( 2x120 ml )

### INTENDED FOR USE

For the quantitative determination of urea in serum, plasma and urine.

### PRINCIPLE :

Urea is hydrolyzed by urease forming ammonia and carbamic acid. Carbamic acid spontaneously decomposes into ammonia and carbon dioxide.

The released ammonium, in the presence of salicylate and nitroferrocyanide reacts in alkaline solution of sodium hypochlorite, to form a green dye compound.

The intensity of the green color produced is directly proportional to the amount of urea concentration.

### SPECIMEN COLLECTION :

Serum, plasma and urine.

Use heparin (Na/K/Li), EDTA as anticoagulant to obtain plasma.

Do not use KF or other agents containing ammonium ions.

Urine: urine must be diluted 1:100 with physiological solution.

Do not use hemolyzed samples.

Urea in serum or plasma is reported stable up to 24 hours at room temperature (+15-25°C.), at least 7 days in refrigerator(+2-8°C) and up to 2-3 months at - 20°C.

Shake and bring samples at room temperature(+15-25°C) before using.

### REAGENTS COLLECTION :

<b>R1</b>	Urea Standard	50mg/dl
<b>R2 Urease</b>	Urease	>5000 U/l
<b>R3</b>	Phosphate Buffer pH 8.0	50 mmol/l
	Sodium Salicylate	52 mmol/l
	Sodium nitroprusside	1.0 mmol/l
<b>R4 CORROSIVE</b>	Sodium Hydroxide	20 mmol/l
	Sodium Hypo-chlorite	10 mmol/l

### PACKAGE : Collection & storage .

Store in refrigerator (+2-8°C.). Stable until expiration date reported upon the package. After the unsealing and the taking of the reagent, it is advised to close up the bottle immediately in order to avoid evaporation, direct light exposure and bacterial contamination

### PRECAUTIONS & WARNING :

#### Avoid pipetting with mouth.

According to current regulation, Reagents (R3) and (R4) are classified as not dangerous. Reagent (R4) contains: **sodium hydroxide** and is classified as: **C-Corrosive R31**-Contact with acid liberates toxic gas.

**R35**-Causes severe burns.

**S26**-In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

**S28**-After contact with skin, wash immediately with plenty of water.

**S45**-In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible)

**S50**-Do not mix with acid.

**S36/37/39**-Wear suitable protective clothing, gloves and eye/face protection.

A safety and precautions form is available on request. The total concentration of non active components (preservatives, detergents, stabilizers) is below the minimum required for citation.

Anyway handle with care, avoid ingestion, avoid contact with eyes, skin and mucous membranes. The samples must be handle as potentially infected from HIV or Hepatitis

### REAGENT PREPARATION & STABILITY :

All reagents are ready for use and stable up to expiry date given on label when stored at 2-8°C.

### REQUIRED MATERIALS NOT PROVIDED :

General Laboratory Equipment and instruments .

### PROCEDURE :

Wave length : 578 nm ( 578-630 )  
Optical Path : 1 cm light path  
Temperature : 37°C  
Reading : Against reagent blank  
Assay type End point

#### Pipetting in tubes :

	BLANK	STANDARD	SAMPLE	
Reagent (R3)	1000	1000	1000	µL
R2	Drop 50u/l	Drop 50 u/l	Drop 50 u/l	
Standard		10		µL
Sample			10	µL

Mix and incubate for 3 min at 37°C or 5 min at 20-25° C.

#### Add in same tubes:

Reagent (R4)	200	200	200	µL
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Min, incubate for 5 min at 37°C or 10 min at 25°C and read sample and standard extinction against blank.

Volumes can be proportionally modified.

This methodology describes the manual procedure to use the kit.

For automated procedure , ask for specific application.

### CALCULATION :

$$\text{UREA mg/dl} = \frac{\text{(A) Sample}}{\text{(A) Standard}} \times 50$$

Unit conversion

$$\text{mg/dl} \times 0.166 = \text{mmol/l}$$

$$\text{BUN} = \text{Urea} / 2.14$$

For urine specimen the results must be multiplied by the dilution factor and 24 hours collections by volumes in litres.

## EXPECTED VALUE :

<b>Serum-Plasma:</b>	15-45 mg/dl	2.5-7.5 mmol/l
<b>Urine:</b>	20-35 g/24h	330-580 mmol/24h

The above mentioned values are to be considered as a reference. It is strongly recommended that each laboratory establish its own normal range according to its geographic area.

## WASTE DISPOSAL :

**Do not dispose in the environment owing to Reagent (R4)**

The disposal of the product must be in accordance with local regulation concerning waste

## QUALITY CONTROL

It is recommended to execute the quality control at every kit utilization to verify that values are within the reference range indicated by the methodology.

## REFERENCES:

Chaney, et al. Clin. Chem. and al., 8, 130, (1962).

Vassault, A. et al. Ann. Biol. Clin., 44, 686, (1986).

## PERFORMANCE:

MEASURE INTERVAL / LINEARITY	3 -200 mg/dl
DETECTION LIMIT:	3 mg/dl
SENSITIVITY:	1mg/dl =0.002646A a 578 nm

### INTRA-ASSAY PRECISION: n=10

LOW LEVEL	M=14.5mg/dL	C.V.=2.83%
MEDIUM LEVEL	M=50.1mg/dL	C.V.=3.25%
HIGH LEVEL		

### INTRA-ASSAY PRECISION: n=10

LOW LEVEL	M=14.7mg/dL	C.V.=1.36%
MEDIUM LEVEL	M=51.6mg/dL	C.V.=2.94%
HIGH LEVEL		
INTER. ANALYZED		
CORRELATION	r =0.985	n=30
LIN. REGRESSION	y= 0.986+0.64	n=30






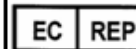



## INTERFERENCE:

Interferences are negligible up to :		
Bilirubin	30 mg/dl	Hemoglobin 100 mg/dl

## METHOD LIMITATIONS :

For concentration higher than 200 mg/dl, repeat the measure on a sample diluted 1:2 with saline solution and multiply the results x 2. Samples with high ammonia concentration could cause high urea results.

For a thorough evaluation of the interfering substances, consult : Young, D.S., et al., Clin. Chem. 21:1D (1975).

	Consult Instructions for Use
	Caution, consult accompanying Documents
	In Vitro Diagnostic Medical Device
	Temperature limitation
	Manufacturer
	Authorized Representative in the European Community
	Catalogue number
	Batch code
	Use by

 <b>Egy-Chem</b> for lab technology	 
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