BioMed-Urea

Enzymatic, Colorimetric

REF: URE118100 (2x 50 ml)
URE118120 (2x 60 ml)
URE118240 (2x120 ml)
URE118200 (2x100 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 nitroferricyanide 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.

SPECEMEN 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 COMPOSITION:

R1	Urea Standard	50mg/dl
R2 Urease	Urease	>5000 U/l
R3	Phosphate Buffer pH 8.0 Sodium Salicylate Sodium nitroprusside	50 mmol/l 52 mmol/l 1.0 mmol/l
R4 CORROSIVE	Sodium Hydroxide Sodium Hypo-chlorite	20 mmol/l 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 :	20-25/37°C
Reading :	Against reagent blank
Assay type	End point

Pipetting in tubes:

	BLANK	STANDARD	SAMPLE
Reagent (R3)	1000 µL	1000 µL	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 µL	200 µL	200 µL

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 :

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

Unit conversion
mg/dl x 0.166 = mmol/l
BUN=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 :

Serum-Plasma:	15-45 mg/dl	2.5-7.5 mmol/l
Urine:	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.

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. ANALIZED		
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).

REFERENCES:

Chaney, et al.Clin.Chem.and al.,8,130,(1962).
Vassault,A. et al. Ann.Biol.Clin.,44,686,(1986).

	Consult Instructions for Use
	Caution, Consult accompanying
IVD	In Vitro Diagnostic Medical
2°C 8°C	Temperature Limitation
	Manufacturer
EC REP	Authorized Representative in the European Community
REF	Catalogue Number
LOT	Batch Code
	Use by

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