BioMed-Uric acid L.S

Enzymatic, Colorimetric

REF:

UA119090 (3x30 ml)	UA119240 (2 x120 ml)
UA119120 (2x60 ml)	UA1191001 (5 x 20 ml)
UA119100 (2x50 ml)	UA119200 (10 x 20 ml)

INTENDED FOR USE

For the quantitative determination of Uric acid in serum and plasma.

PRINCIPLE :

Uric Acid is oxidized by Uricase to allantoin and hydrogen peroxide.
The released hydrogen peroxide together with DCHBS* and 4-aminoantipyrine, in the presence of peroxidase , forms a red dye compound .
The intensity of the red colour produced is directly proportional to the uric acid quantity in serum.

SPECIMEN COLLECTION:

Unhemolyzed serum or heparinized plasma or EDTA and urine.

Note:

Uric Acid in serum is stable for 3 days at room temperature and up to 6 months if stored in refrigerator at - 20°C .
Dilute urine 1:10 with physiological solution.
If urine sample is turbid, heat for 10 min at 60°C. then centrifuge and dilute.
Shake and bring the samples at room temperature (+15-25°C) before using.

REAGENT COMPOSITION:

R1	Uric acid standard	6 mg/dL
R2	Goods buffer Ph 7.8	100 mmol/L
	Uricase	150 U/L
	Peroxidase	2000 U/L
	4-AAP	1 mmol/L
	DHBS	2 mmol/L

PACKAGE : Collection & storage .

Store at + **2-8°C**.
Stable until the expiration date indicated on the bottle.
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 pipette with mouth.
The preparation, according to current regulation, is classified as not dangerous.
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

Liquid Reagent must be at room temperature (+15-25°C) before using.
The Reagent is limpid and rose-colored
A light reagent coloration (less than 0.050 O.D.) due to air or direct light exposure, will not impair its functioning.
Stable until the expiration date indicated on the label

REQUIRED MATERIALS NOT PROVIDED

General Laboratory Equipment and instruments.

PROCEDURE :

Wave length :	500 - 550 nm
Optical Path:	1 cm
Temperature :	37° C or 20-25
Reading :	Against reagent blank

Pipetting in cuvette :

	BLANK	STANDARD	SAMPLE
Reagent (R2)	1000 µL	1000 µL	1000 µL
Distilled water	20 µL		
Standard		20 µL	
Sample			20 µL

Mix, incubate for 5 min at 37°C or 10 min at room temperature (+15-25°C.) and read sample and standard extinction against reagent blank.
Color is stable for 30 min at room temperature.
Volumes can be proportionally modified.
This methodology describes the manual procedure to use the kit
For automated procedure, ask for specific application.

CALCULATION::

$$\textbf{Uric Acid}\ \text{mg/dl} = \frac{\text{(A) Sample}}{\text{(A) Standard}} \times 6$$

Standard Value 6mg/ dL = 357 mmol/L.
Urine: Uric Acid mg/24h =
Uric Acid mg/dl x 10 (dilution factor) x Urine Volume 24/h(dl)

EXPECTED VALUE :

Serum, Plasma :		
Men	3.5 – 7.0mg/dL	208 – 416µmol/L
Women	2.4 – 5.7mg/dL	142 – 339µmol/L
Urine:	250 - 750mg/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, according to IFCC protocol.

WASTE DISPOSAL :

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

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:	0.28-25 mg/dL
DETECTION LIMIT(2 DS):	0.28mg/dL
SENSITIVITY:	1mg/dL= 0.0249A a 510nm

PRECSION AMONG SERIES : n=20

LOW LEVEL	M=2.60mg/dL	C.V.=2.47%
MEDIUM LEVEL	M=6.30mg/dL	C.V.=2.94%
HIGH LEVEL	M=10.87mg/dL	C.V.=2.54%

PRECISION AMONG SERIES : n=20

MEDIUM LEVEL	M=2.52mg/dL	C.V. = 4.0%
HIGH LEVEL	M=6.08mg/dL	C.V. = 5.1%
INTER.ANALIZED	M=10.31mg/dL	
CORRELATION	r = 0.999	n = 60
LIN. REGRESSION	y = 0.998x - 0.017	n = 60

INTERFERENCE : (IN ACCORDDANCE WITH RACCOMANDATION SFBC)

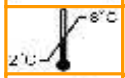
Interferences are negligible up to :			
Bilirubin	25mg/dl	Hemoglobin	0.5g/dL
Triglycerids	1000mg/dl	Ascorbic Acid	1mg/dL

METHOD LIMITATIONS :

For concentration higher than 25 mg/dL, repeat the measure on a sample diluted 1:2 with saline solution e multiply the results by 2.
Grossly lipemic sample or sample with a content of bilirubin > 10 mg\dl will cause false values; consequently a serum blank should be run. Add physiological solution instead of Reagent (R2). Ascorbic Acid may cause a false decrease in Uric Acid value.
For a thorough evaluation of the interfering substances, consult: Young, D.S.,et al.,Clin.Chem. 21:1D (1975).

REFERENCES:

Trinder P., Ann.Clin.Biochem. 6,24, (1969).
Vassault,A. et al. Ann.Biol.Clin.,44,686,(1986).
Fossati P., Prencipe L., Berti G., Clin.Chem.26.277(1980).

	Consult Instructions for Use
	Caution, Consult accompanying
	In Vitro Diagnostic Medical
	Temperature Limitation
	Manufacturer
	Authorized Representative in the European Community
	Catalogue Number
	Batch Code
	Use by

EGY- CHEM for lab technology
Badr City, Industrial Area Piece 170
250 Fadan In East of Elrubaki, EGYPT
Office Tel: +202 26236727 / +202 26236598
Factory Tel: +202 23108170 / +202 23108171
Fax: +202 26240986
www.egy-chem.com

CE
EC REP
MDSS GmbH
Schiffgraben 41
30175 Hannover,
Germany