BIOLABO
www.biolabo.fr
MANUFACTURER:
BIOLABO SAS,
Les Hautes Rives
02160, Maizy, France

URIC ACID Uricase method

Reagent for quantitative determination of uric acid in human serum and plasma, or urines.

REF 80351	**R1**	6 x 30 mL	**R2**	6 x 30 mL	**R3**	1 x 5 mL
REF 80001	**R1**	2 x 100 mL	**R2**	2 x 100 mL	**R3**	1 x 5 mL
REF 87601	**R1**	6 x 200 mL	**R2**	6 x 200 mL	**R3**	1 x 10 mL

TECHNICAL SUPPORT AND ORDERS
Tel : (33) 03 23 25 15 50
Fax: (33) 03 23 256 256

CE

IVD IN VITRO DIAGNOSTIC USE

CLINICAL SIGNIFICANCE (1) (2)

In humans, uric acid is the major product of the catabolism of the purine nucleosides, adenosine and guanosine.
Major causes of hyperuricemia are primary gout (due to metabolic overproduction of purines or underexcretion of uric acid), or secondary gout which may be due to renal diseases, administration of drugs (diuretics or chemiotherapeutic agents...) Hyperuricemia is also attributable to primary defects of enzymes in the pathway of purines metabolism or to hematologic disease.
Hypouricemia is much less common than hyperuricemia.

PRINCIPLE (1) (3)

Uricase acts on uric acid to produce allantoin, carbon dioxide and hydrogen peroxide. Hydrogen peroxide in the presence of peroxidase reacts with a chromogen (amino-antipyrine and dichloro-hydroxybenzen sulfonate) to yeld quinoneimine, a red coloured complex. The absorbance measured at 520 nm (490-530) is proportional to the amount of uric acid in the specimen.

REAGENTS

Vial R1 **ENZYMES**

Potassium hexacyanoferrate (II)	42	µmol/L
Peroxidase	≥ 450	U/L
Amino-antipyrine	0,150	mmol/L
Uricase	≥ 120	U/L

Vial R2 **BUFFER**

Dichlorohydroxybenzen sulfonate	2	mmol/L
Tris pH 8.0 at 25°C	50	mmol/L
Preservative		

Vial R3 **STANDARD**

Uric acid 10 mg/dL (595 µmol/L)

SAFETY CAUTIONS

BIOLABO reagents are designated for professional, in vitro diagnostic use.
- Verify the integrity of the contents before use.
- Use adequate protections (overall, gloves, glasses).
- Do not pipette by mouth.
- In case of contact with skin or eyes, thoroughly wash affected areas with plenty of water and seek medical advice.
- Reagents contain sodium azide (concentration < 0.1%) which may react with copper and lead plumbing. Flush with plenty of water when disposing.
- Material Safety Data Sheet is available upon request.
- Waste disposal: Respect legislation in force in the country.

All specimens should be handled as potentially infectious, in accordance with good laboratory practices using appropriate precautions. Respect legislation in force in the country.

REAGENTS PREPARATION

Vial R1: Use a non-sharp instrument to remove aluminium cap.
Add promptly the contents of vial R1 (Enzymes) into vial R2 (Buffer).
Mix gently until complete dissolution before using reagent (approximately 2 minutes).

STABILITY AND STORAGE

Store at 2-8°C, well recap in the original vial and away from light.
- Standard (vial R3): transfer requested quantity, well recap the vial and store at 2-8°C
- Reagent R1 (unopened) and reagents R2 and R3 are stable until expiry date stated on the label of the kit when stored and used as described.
- Once reconstituted, working reagent is stable for 1 month when free from contamination.
- Discard any reagent if cloudy or if absorbance at 520 nm > 0.100.
- Don't use working reagent after expiry date stated on the label.

SPECIMEN COLLECTION AND HANDLING (4)

Unhemolysed serum or plasma (Heparin or EDTA).
Urines: to be diluted (1+9) in demineralised water before assay.

Uric acid is stable in the specimen for:
- 3 days at room temperature.
- 1 week at 2-8°C.
- 6 months freezed at – 20°C.

Add NaOH to keep urine alkaline and to prevent uric acid precipitation.

INTERFERENCES (3) (5)

High bilirubin or ascorbic acid levels may result in negative interference. Grossly lipemic or hemolysed specimen can cause falsely increased uric acid values.
Patient under vitamin C therapy: In order to reduce acid ascorbic interference, let stand specimen 2 hours at room temperature before performing the assay.

For a more comprehensive review of factors affecting this assay refer to the publication of Young D.S.

MATERIAL REQUIRED BUT NOT PROVIDED

1. Basic medical analysis laboratory equipment.
2. Normal and pathological control sera.

CALIBRATION

- Standard (vial R3) enclosed in the kit or BIOLABO Multicalibrator REF 95015 traceable to SRM 913a.
- Or any calibrator traceable to a reference method or material.

The calibration frequency depends on proper instrument functions and on the preservation of reagent.

It is recommended to calibrate in the following cases:

1. When using a new batch of reagent.
2. After maintenance operations on the instrument.
3. When control values are out of range, even after using a new vial of fresh serum.

QUALITY CONTROL

- BIOLABO EXATROL-N Level I REF 95010.
- BIOLABO EXATROL-P Level II REF 95011.
- Assayed control sera referring to the same method.
- External quality control program.

It is recommended to control in the following cases:

- At least once a run.
- At least once within 24 hours.
- When changing vial of reagent.
- After maintenance operations on the instrument.

If control is out of range, apply following actions:

1. Repeat the test with the same control.
2. If control is still out of range, prepare a fresh control serum and repeat the test.
3. If control is still out of range, use a new vial of calibrator or a fresh calibrator and repeat the test.
4. If control is still out of range, calibrate with a new vial of reagent.
5. If control is still out of range, please contact BIOLABO technical support or your local Agent.

EXPECTED VALUES (4)

Serum or plasma	URIC ACID	
	mg/dL	[µmol/L]
Child(*)	2.0-5.5	[119-327]
Men	3.5-7.2	[208-428]
Women(**)	2.6-6.0	[155-357]

Urines	250-750 mg/24h	[1.48-4.43 mmol/24 h]

(*) Higher value in newborn.
(**) Lower during pregnancy.

Each laboratory should establish its own normal ranges for the population that it serves.

PERFORMANCES CHARACTERISTICS

Within run N = 20	*Normal level*	*High level*
Mean mg/dL	5.32	8.97
S.D. mg/dL	0.049	0.049
C.V. %	0.9	0.55

Between run N = 20	*Normal level*	*High level*
Mean mg/dL	5.26	9.02
S.D. mg/dL	0.12	0.12
C.V. %	2.2	1.3

Detection limit: approximately 0.3 mg/dL

Sensitivity for 10 mg/dL: approximately 0.370 Abs. at 520 nm.

Comparison study with commercially available reagent:

y = 0,9953 x – 0,025 r = 0,9923

LINEARITY

The reaction is linear up to at least 20 mg/dL (1190 µmol/L).

Above, dilute specimen with saline solution and reassay taking into account dilution factor to calculate the result. Linearity limit depends on specimen/reagent ratio.

MANUAL PROCEDURE

Let stand reagent and specimens at room temperature.

Pipette into well identified test tubes:	Blank	Standard	Assay
Working Reagent	1 mL	1 mL	1 mL
Specimen (Note 1)			25 µL
Standard		25 µL	
Demineralised water	25 µL		

Mix. Let stands for 5 minutes at 25°C.
Record absorbance at 520 nm (490-530) against reagent blank.
Colour is stable for 30 minutes.

Notes:

1. Serum, plasma, or urines diluted (1+9) with demineralised water.
2. Specific procedures are available upon request for automated instruments. Please contact BIOLABO technical support.
3. Specimen: a 20 µL volume may be used (increased linearity but slightly decreased sensitivity)

CALCULATION

Calculate the result as follows:

Serum or plasma:

$$\text{Result} = \frac{\text{Abs (Assay)}}{\text{Abs (Standard)}} \times \text{Standard concentration}$$

Diluted urines (1+ 9): Multiply the above result by dilution factor 10.

REFERENCES

(1) *TIETZ N.W. Text book of clinical chemistry, 3rd Ed. C.A. Burtis, E.R. Ashwood, W.B. Saunders (1999) p. 1245-1250.*

(2) *BERNARD S. Biochimie clinique - Instruments et techniques de laboratoire - Diagnostiques médicaux chirurgicaux.2cd éd.1989 p153-156 Ed. MALOINE PARIS.*

(3) *FOSSATI, P., PRENCIPE L., and BERTI G., Use of 3.5-dichloro-2-Hydroxybenzene sulfonic acid / 4 Amino phenazone chromogenic system in direct enzymatic assays of uric acid in serum and urine. Clin. Chem.: 26(227-231) 1980*

(4) *Clinical Guide to Laboratory Test, 4th Ed., N.W. TIETZ (2006) p. 1098-1099.*

(5) *YOUNG D.S., Effect of Drugs on Clinical laboratory Tests, 4th Ed. (1995) p 3-609 to 3-622*

(6) *SRM: Standard Reference Material ®*

Manufacturer | Use by | IVD In vitro diagnostic | Temperature limitation | REF Catalogue number | See insert | LOT Batch number | Store away from light | sufficient for | → dilute with