



**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	LP80501	R1	4 x 30 mL	R2	1 x 30 mL	R3	1 x 10 mL
REF	LP80601	R1	4 x 100 mL	R2	1 x 100 mL	R3	2 x 10 mL



IN VITRO DIAGNOSTIC USE

## TECHNICAL SUPPORT AND ORDERS

Tel : (33) 03 23 25 15 50  
Fax: (33) 03 23 256 256  
support@biolabo.fr

## CLINICAL SIGNIFICANCE (1) (2)

Uric acid (UA) 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 chemotherapeutic 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 yield quinoneimine, a red coloured complex. The absorbance measured at 505 nm is proportional to the amount of uric acid in the specimen.

## REAGENTS

<b>R1</b>	<b>BUFFER</b>	<b>BUF</b>	<b>UA</b>
Tris pH 8.0 at 25°C		50	mmol/L
Dichlorohydroxybenzen sulfonate		3	mmol/L
Potassium hexacyanoferrate (II)		53	µmol/L
3-DDAPS		0.7	mmol/L
EDTA		2	mmol/L
Preservative			

<b>R2</b>	<b>ENZYMES</b>	<b>ENZ</b>	<b>UA</b>
Peroxidase		≥ 2000	U/L
Amino-antipyrine		750	µmol/L
Uricase		≥ 500	U/L
Preservative			

<b>R3</b>	<b>STANDARD</b>	<b>STD</b>
Uric Acid		10 mg/dL

According to 1272/2008 regulation, these reagents are not classified as dangerous

## SAFETY CAUTIONS

BIOLABO reagents are designated for professional, in vitro diagnostic use (do not pipette with mouth).

- Refer to current Material Safety Data Sheet available on request or on www.biolabo.fr
- Verify the integrity of the contents before use.
- Waste disposal: Respect legislation in force in the country.

All specimens or reagents from biological origin should be handled as potentially infectious using appropriate precautions. Respect legislation in force in the country.

## MATERIAL REQUIRED BUT NOT PROVIDED

- Basic medical analysis laboratory equipment.
- Spectrophotometer or Biochemistry Clinical Analyzer



## REAGENTS PREPARATION

Separated reagents R1 and R2: Ready for use

## STABILITY AND STORAGE

Stored away from light, well capped in the original vial at 2-8°C, and used as described, reagents are stable:

Unopened:

- Until expiry date stated on the label of the kit.

Once opened:

- Transfer requested quantity, well recap vials and store at 2-8°C,
- 2 separated reagents are stable for at least 3 months without contamination,
- Discard any cloudy reagent or if reagent blank is > 0.100 at 505 nm.

## SPECIMEN COLLECTION AND HANDLING (4)

Serum or Plasma (Heparin or EDTA).

Urines:

- Add NaOH to keep urine alkaline and to prevent uric acid precipitation.
- 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 when freeze at -20°C

## LIMITS (3) (5)

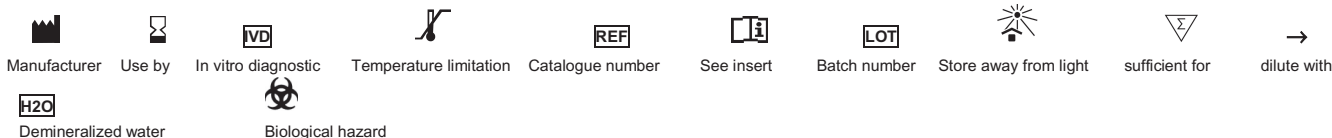
Patient under vitamin C therapy: In order to reduce acid ascorbic interference, let stand specimen 2 hours at room temperature before performing the assay.

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

## CALIBRATION (6)

- REF 95015 BIOLABO Multicalibrator traceable to SRM 913b or
- Standard (vial R3)

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



Made in France

Latest revision: www.biolabo.fr

Revision: 12/02/2019

## QUALITY CONTROL

- **REF** 95010 BIOLABO EXATROL-N Level I
- **REF** 95011 BIOLABO EXATROL-P Level II
- **REF** 95012 Urinary controls
- 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	[ $\mu$ mol/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 at 37°C on KENZA 240TX

**Linearity Range:** between 0.36 mg/dL (LQ) and 25 mg/dL

**Detection limit:** approx. 0.36 mg/dL

**Precision:**

	Within-run N = 20	Low level	Normal level	High level	Between Run N = 20	Low level	Normal level	High level
Mean (mg/dL)	3.03	5.93	7.61		Mean (mg/dL)	3.15	5.90	7.41
S.D. mg/dL	0.07	0.11	0.09		S.D. mg/dL	0.07	0.06	0.08
C.V. %	2.3	1.9	1.1		C.V. %	2.2	1.0	1.05

**Comparison studies with commercially available reagent:**

Realised on human specimens (n=102) between 1.74 and 15.14 mg/dL

$$y = 0.9554 x + 0.1973 \quad r = 0.9988$$

**Analytical sensitivity (505 nm):** approx. 0.0451 abs for 1 mg/dL

**Interferences:**

Turbidity	Positive interference from 0.048 abs
Total bilirubin	Negative interference from 157 $\mu$ mol/L
Direct bilirubin	Negative interference from 133 $\mu$ mol/L
Ascorbic acid	Negative interference from 95 mg/dL
Glucose	No interference up to 964 mg/dL
Haemoglobin	Positive interference from 185 $\mu$ mol/L

Other substances may interfere (see § Limits)

**On the board stability:** 2 months

**Calibration Stability:** 2 months

Make a new calibration when changing reagent batch, if quality control results are found out of the established range and after maintenance operations.

## PROCEDURE

Detailed KENZA 240TX procedure is available on request.

Wavelength: 505 nm

Temperature: 37°C

Let stand reagent and specimens at room temperature

	Automated analyzer	Manual procedure
<b>Reagent 1</b>	240 $\mu$ L	800 $\mu$ L
<b>Standard / Control or Specimen (1)</b>	8 $\mu$ L	25 $\mu$ L
<b>Reagent 2</b>	60 $\mu$ L	200 $\mu$ L

Mix. Let stands for 300 sec at 37°C.  
Record absorbance at 505 nm against reagent blank.  
Reaction is stable for 30 minutes.

**Notes:**

1. For urines prediluted (1+9) use standard (vial R3) to calibrate (do not dilute) and controls **REF** 95012 (to be treated as patient's urines)
2. Performances and stability data's have been validated with serum on KENZA 240TX and KENZA 450TX
3. With Manual Procedure on Spectrophotometer and on other automated analyzers, performances and stability should be validated by user
4. Applications proposal are available on request

## CALCULATION

Calculate the result as follows:

Serum or plasma:

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

Urines:

Multiply the above result by dilution factor 10.

## REFERENCES

- (1) TIETZ N.W. Text book of clinical chemistry, 3<sup>rd</sup> 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. 2<sup>ed</sup> 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, 4<sup>th</sup> Ed., N.W. TIETZ (2006) p. 1098-1099.
- (5) YOUNG D.S., Effect of Drugs on Clinical laboratory Tests, 4<sup>th</sup> Ed. (1995) p 3-609 to 3-622
- (6) SRM: Standard Reference Material ®