BIOLABO
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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

TECHNICAL SUPPORT AND ORDERS
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Latest revision : www.biolabo.fr

CE

IVD

Made In France

I: corresponds to significant modifications

I INTENDED USE

This reagent is designated for professional use in laboratory (manual or automated method).
It allows the quantification of uric acid in human serum and plasma, or urines to assess uric acid homeostasis.

I GENERALITIES (1) (2)

In humans, uric acid is the major product of the catabolism of the purine nucleosides, adenosine and guanosine. With progressive renal insufficiency, there is retention of urea, creatinine and uric acid in blood. Elevate uric acid level may be indicative of renal insufficiency and is commonly associated with gout.

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-hydroxybenzene sulfonate) to yield quinoneimine, a red coloured complex.
The absorbance measured at 505 nm (495-505) is proportional to the amount of uric acid in the specimen.

REAGENTS

R1 URIC ACID Enzymes

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

According to 1272/2008 regulation, this reagent is not classified as dangerous

R2 URIC ACID Buffer

Dichlorohydroxybenzene Sulfonate	2	mmol/L
Tris pH 8.0 at 25°C	50	mmol/L

Preservative
According to 1272/2008 regulation, this reagent is not classified as dangerous

R3 URIC ACID Standard
Uric acid 10 mg/dL (595 µmol/L)

ATTENTION: Flam. Liq.1: H226 Flammable liquid and vapor

P210: Keep away from heat/sparks/open flames/hot surfaces – No smoking, P233: Keep container tightly closed, P280 : Wear protective gloves/protective clothing/eye protection/face protection. P403+235: Store in a well-ventilated place. Keep cool. P501: Dispose of contents/container in accordance with dangerous waste disposal regulations in force in the country. Classification is due to ethanol 10 - < 25%. For more details, see Safety Data Sheet (SDS)

SAFETY CAUTIONS

- 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 of biological origin should be handled as potentially infectious. Respect legislation in force in the country.

Any serious incident that has occurred in connection with the device is notified to the manufacturer and the competent authority of the Member State in which the user and/or patient is based.

REAGENTS PREPARATION

Use a non-sharp instrument to remove aluminium cap.
Add promptly the contents of vial R1 into vial R2.
Mix gently until complete dissolution.
Vial R3: Ready for use

STABILITY AND STORAGE

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

Unopened,
- Until the expiry date stated on the label of the Kit.

Once opened:
- Reconstitute immediately substrate (vial R1)
- Vial R3: Transfer requested quantity and store the vial at 2-8°C.

Once reconstituted
- Transfer requested quantity and store in the original vial at 2-8°C.
- Working reagent is stable at least 1 month.
- Discard any reagent if cloudy or if absorbance at 505 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: 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.

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

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.

MATERIAL REQUIRED BUT NOT PROVIDED

1. Basic medical analysis laboratory equipment.
2. Spectrophotometer or Biochemistry Clinical Analyzer

QUALITY CONTROL

- REF 95010 EXATROL-N Level I
- REF 95011 EXATROL-P Level II
- REF 95012 Urinary Controls (Level1, Level 2)
- 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. Prepare a fresh control serum and repeat the test.
2. If control is still out of range, use a new vial of calibrator or a fresh calibrator and repeat the test.
3. If control is still out of range, repeat the tests with a new vial of reagent.

If control is still out of range, please contact BIOLABO technical support or your local Agent.

REFERENCE INTERVAL (4)

Serum or plasma	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

On Kenza 240TX, 37°C, 505nm

Detection limit: aprox. 0.03 mg/dL

Precision:

Within run N = 20	*Normal level*	*High level*
Mean mg/dL	3.24	9.05
S.D. mg/dL	0.003	0.007
C.V. %	1%	0.8%

Between run N = 20	*Normal level*	*High level*
Mean mg/dL	6.84	9.4
S.D. mg/dL	0.076	0.172
C.V. %	1.1%	1.8%

On Cobas Mira, 37°C, 505 nm

Measurement interval: between 0.3 mg/dL and 20.0 mg/dL

Comparison study with commercially available reagent:

With n=98 specimens between 2,0 and 200 mg/dL

y = 0,9953 x – 0,025 r = 0,9923

Interferences:

Turbidity	Positive from 0.060 abs
Total bilirubin	Positive interference from 500 µmol/L
Ascorbic acid	Negative interference from 0.5 mg/dL
Hemoglobin	No interference up to 115 µmol/L
Glucose	No interference up to 1010 mg/dL

Other substances may interfere (see § Limits)

CALIBRATION

- REF 95015 Multicalibrator traceable *to SRM 913*
- Standard (vial R3): With manual procedure and urines.

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

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

PROCEDURE

Manual method

Let stand reagent and specimens at room temperature.

Reagent	1000 µL
Calibrator, Control or Specimen	25 µL

Mix. Let stands for 5 minutes at 25°C.
Record absorbance at 505 (495-505) nm against reagent blank.
Colour is stable for 30 minutes.

Notes:

1. Serum, plasma, or urines diluted (1+9) with demineralised water.
2. Performances with manual procedure should be validated by user.
3. Kenza applications and other applications proposal are available on request.

CALCULATION

Serum or plasma:

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

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

REFERENCES

(1) *TIETZ N.W. Textbook 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	Expiry date	In vitro diagnostic	Storage temperature	Dematerialized water	Biological risk
Product Reference	See Insert	Batch number	Store away from light	Sufficient for	Dilute with