BIOLABO
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URIC ACID Uricase method

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

I REF	K1501	**R1** 2 x 16 mL	**R2**	1 x 8 mL
I REF	K2501	**R1** 2 x 32 mL	**R2**	2 x 8 mL
I REF	K4501	**R1** 2 x 40 mL	**R2**	1 x 20 mL

TECHNICAL SUPPORT AND ORDERS
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CE

IVD

Made In France

I: corresponds to significant modifications

I INTENDED USE

This reagent is designated for professional use in laboratory (automated method).
It allows the quantitative determination of uric acid in human serum and plasma, or urines.

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

REAGENTS

R1	**UA2**	Buffer
Tris pH 8.0 at 25°C	50	mmol/L
Dichloro-hydroxybenzene sulfonate	3	mmol/L
Potassium hexacyanoferrate (II)	53	µmol/L
3-DDAPS	0.7	mmol/L
EDTA	2	mmol/L
Preservative		
R2	**UA2**	Enzymes
Peroxidase	≥ 2000	U/L
Amino-antipyrine	750	µmol/L
Uricase	≥ 500	U/L
Preservative		

According to 1272/2008/EC Regulation, these reagents are not classified as dangerous.

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.

I 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

Ready for use.

STABILITY AND STORAGE

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

Unopened:

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

Once opened:

- 2 separated reagents are stable for at least 3 months
- Discard any reagent if cloudy or if reagent blank > 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 demineralized 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.

MATERIAL REQUIRED BUT NOT PROVIDED

1. Basic medical analysis laboratory equipment.
2. Biochemistry Clinical Analyzer Kenza One, Kenza 240TX/ISE or Kenza 450TX/ISE

EXPECTED VALUES (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, at 37°C, 505 nm

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*
Mean (mg/dL)	3.03	5.93	7.61
S.D. mg/dL	0.07	0.11	0.09
C.V. %	2.3	1.9	1.1

Between Run N = 20	*Low level*	*Normal level*	*High level*
Mean (mg/dL)	3.15	5.90	7.41
S.D. mg/dL	0.07	0.06	0.08
C.V. %	2.2	1.0	1.05

Comparison studies with commercially available reagent:
Realized on human specimens (n=116) between 1.6 and 14.1 mg/dL

y = 0.9123 x + 0.2582 r = 0.9947

Analytical sensitivity (505 nm): approx. 0.044 abs for 1 mg/dL

Interferences:

Turbidity	Positive interference from 0.048 abs
Total bilirubin	Negative interference from 157 µmol/L
Direct bilirubin	Negative interference from 133 µmol/L
Ascorbic acid	Negative interference from 95 mg/dL
Glucose	No interference up to 964 mg/dL
Hemoglobin	Positive interference from 185 µmol/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.

Performances and stability data on Kenza 450TX/ISE and Kenza One are available on request.

CALIBRATION (6)

- REF 95015 Multicalibrator traceable *to SRM 913*

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

QUALITY CONTROL

- REF 95010 EXATROL-N Level I
- REF 95011 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. Prepare a fresh control serum and repeat the test
2. If control is still out of range, use a new vial of fresh calibrator
3. If control is still out of range, use a new vial of reagent and reassay

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

PROCEDURE

Refer to validated application of the Kenza Analyzer used

CALCULATION

The analyzer provides directly final result.
Refer to the instruction of use of Kenza analyzer.

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	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