URIC ACID LR liquid reagent

REF E1005100 R1 5x80 ml / R2 1x100 ml
E1000550 R1 5x40 ml / R2 1x50 ml
E100340130 R1 3x40 ml / R2 1x30 ml

CE IVD For in vitro medical device

Use

Kit for measurement of uric acid in serum, plasma and urine
Colorimetric enzymatic method Uricase-POD-PAP.

Summary

Uric acid measurements are used in the diagnosis and treatment of gout and impaired renal fuction.

Principle

End point analysis. Uric acid is converted by uricase and H_2O_2 which, under the catalytic influence of peroxide (POD), oxidizes compound, reacts with 4-aminophenazone and 3,5-diclorophenol-sulphonate giving a red coloured compound. The increase in absorbance generated by the red dye is proportional to the uric acid concentration in the sample.

Reagents

R1	Goods buffer pH 8.0	100.0 mmol/l
	ascorbate oxidase	≥ 200 U/l
	3,5-diclorophenol-sulphonate	2.5 mmol/l
R2	Goods buffer pH 8.0	100.0 mmol/l
	4-aminophenazone	0.8 mmol/l
	Peroxidise	≥ 3000 U/l
	Uricase	≥ 600 U/l

Reagents Preparation

Reagents are liquid and ready to use. About using as monoreagent ("sample-starter" procedure) add for every 4 ml of R1 reagent, 1 ml of R2 reagent. Keep out the reagents from refrigerator only for the use and recap them immediately.

Storage And Stability

- Store the kit at 2-8°C.
- After opening, the vials R1 and R2 are stable 90 days if recapped immediately and protected from contamination, evaporation, direct light, and stored at the correct temperature.
- Working solution stability (R1+ R2): 30 days at 2-8°C.

Precaution in Use

The product is not classified as dangerous (DLg. N. 285 art. 28 l. n. 128/1998).
The final concentration of the components is below the limits imposed by Regulation (EC) No. 1272/2008 - CLP (and subsequent amendments) and Directive 88/379/CEE and subsequent amendments to the classification-packaging and labeling of dangerous substances.
However the reagent should be handled with care, according to good laboratory practice.
Caution: the reagents contain Sodium Azide (0.095%) as preservative. Avoid swallowing and contact with skin, eyes and mucous membranes.

Waste Management

Please refer to the local legal requirements.

Specimen Collection and Preparation

- Serum or heparinized plasma.
- Diluted urine 1:10
- Do not use samples with haemolysis.
- Do not use oxalate as anticoagulant. It's not advisable using EDTA and fluoride because they could cause positive interferences.
- The uric acid in the serum and in the plasma is stable for 3 days if kept at 2-8°C or 6 months at -20°C.

Note

- The kit, according to this method, must be used in manual procedures. About automatic use follow specific applications.
- Avoid direct light, contamination and evaporation.
- The volumes in the procedure can be changed proportionally.
- In case of complaint or quality control request, refer to the lot number on the package or the lot number on the singles vials.

Procedures

Wavelength	λ: 510 (500- 550) nm
Working temperature	37°C
Optical path	1 cm
Reaction	"end point" (increasing)

Bring the reagents at 15-25°C before use them.

Monoreagent Procedure "sample starter"

	BLANK	STD	SAMPLE
Working reagent	1000 µl	1000 µl	1000 µl
Distilled Water	25 µl	--	--
Sample	--	--	25 µl
Standard	--	25 µl	--

Mix, then incubate for 5' at 37 °C. Measure the absorbance of sample (EC) and standard (ESTD) against the reagent blank.

Bireagent Procedure "substrate starter"

	BLANK	STD	SAMPLE
Reagent R1	800 µl	800 µl	800 µl
Distilled Water	25 µl	--	--
Sample	--	--	25 µl
Standard	--	25 µl	--

Mix, incubate at 37°C for 1' and then add:

	BLANK	STD	SAMPLE
Reagent R2	200 µl	200 µl	200 µl

Mix, then incubate for 5' at 37°C.
Measure the absorbance of sample (EC) and standard (ESTD) against the reagent blank.

Calculation

Uric acid (mg/dl) or (µmol/l) =
EC/ESTD x Conc. STD

Diluted urines: multiply the result for diluting factor.

Conversion Factor

Uric acid [mg/dl] x 59.48 = Uric acid [µmol/l]

Reference Values to 37°C

Serum - plasma

Women	2.4- 6.0 mg/dl	(0.14 - 0.35 mmol/l)
Men	3.4-7.2 mg/dl	(0.20 – 0. 42 mmol/l)
Urine	250-750 mg/24h	(1.5 – 4.50 mmol/24h)

Reference values are considered indicative since each laboratory should establish reference ranges for its own patient population. The analytical results should be evaluated with other information coming from patient's clinical history.

ANALYTICAL PERFORMANCES

Linearity

The reaction is linear in concentration range between 0.5 and 25 mg/dl. Reaction is linear up to a concentration of 25 mg/dl. Samples with values exceeding this range must be diluted with saline solution. Then, multiply the result for diluting factor.

Analytical Sensitivity

The test sensitivity in terms of detection limit is 0.50 mg/dl.

"Intra-Assay" precision (within-Run)

Determined on 20 samples for each control (N-H) (Normal-High). Results:

MEAN (mg/dl)	N = 4.40	H = 12.64
S.D.	N = 0.14	H = 7.66
C.V.%	N = 3.09	H = 2.61

"Inter-Assay" precision (between-run)

Determined on 20 samples for each control (N-H). Results:

MEAN (mg/dl)	N = 4.48	H = 10.89
S.D.	N = 0.12	H = 0.24
C.V.%	N = 2.77	H = 2.23

Correlation

A study based comparing this method with a similar method on 20 samples has given a correlating factor **r = 0.99**

y = 1.00x + 0.2737

Interferences

No interferences was observed by the presence of :

Bilirubin	≤ 15 mg/dl
Triglycerides	≤ 800 mg/dl
Ascorbate acid	≤ 20 mg/dl
Hemoglobin	≤ 50 mg/dl

Lipemic specimens should not be used for analysis.For a comprehensive review of interfering substances, refer to the publication by Young.

Quality Controls

It's necessary, each time the kit is used, to perform the quality controls and to check that values obtained are within the acceptance range provided in the insert. Each laboratory should estabilish its own mean and standard deviation and adopt a quality control program to monitor laboratory testing.

Bibliography

Kaplan LA, Pesce AJ: "Clinical Chemistry", Mosby Ed. (1996). Barham D, Trinder P: Analyst, 97 142 (1972).
Fossati P, Prencipe L, Berti G: Clin. Chem., 26(2) 227 (1980).
Young D.S., Effects of Drugs on Clinical Laboratory Tests,AACC Press, Washington, DC 5th ed.2000.

Symbols

CE	CE Mark (98/79 CE regulation)
IVD	in vitro medical device
LOT	Batch Code
	Use by
	Storage temperature limits
	Read instruction for use
	Gesan Production srl