URIC ACID
Multi-Purpose (MPR)
Liquid Reagent

Glenbio
Diagnostics & Research Laboratory Solutions

KIT SPECIFICATIONS:

Cat. No.	*Quantity*	*Reagent*	*Storage*
GL803UA	10 x 15 ml	URIC ACID - 1	2-8°C
	2 x 15 ml	URIC ACID - 2	
	1 x 10 ml	URIC ACID - Standard	
GL813UA	5 x 50 ml	URIC ACID - 1	2-8°C
	1 x 50 ml	URIC ACID - 2	
	1 x 10 ml	URIC ACID - Standard	
GL823UA	4 x 200 ml	URIC ACID - 1	2-8°C
	1 x 160 ml	URIC ACID - 2	
	1 x 10 ml	URIC ACID - Standard	

INTENDED USE:

In Vitro Diagnostic reagent pack for the determination of Uric Acid in serum and plasma on automated and semi-automated analysers.

SUMMARY AND EXPLANATION: [1]

Uric acid is the major product of catabolism of the purine nucleosides, adenosine and guanosine. The daily synthesis rate of uric acid is approximately 400 mg and dietary sources contributed another 300 mg. Approximately 75% of uric acid is excreted by the kidney and the remainder is secreted into the intestine where it is degraded to allantoin by bacterial enzymes. Uric acid measurements are used in a diagnosis and treatment of numerous renal and metabolic disorders including renal failure, gout, leukaemia, psoriasis, starvation, other wasting conditions and patients in receipt of cytotoxic drugs.

PRINCIPLE OF THE TEST: [2]

This procedure involves the enzymes uricase and peroxidase (POD) in a coupled reaction. Ascorbate oxidase is included in reagent 1 to minimise the interference of ascorbic acid. The intensity of the red colour formed is proportional to the uric acid concentration. Enzymatic determination according to the following reactions:

$$\text{Uric Acid} + 2H_2O + O \xrightarrow{\text{Uricase}} \text{Allantoin} + CO_2 + H_2O_2$$

$$2H_2O_2 + \text{3,5-Dichloro-2-hydroxybenzenesulfonate} + \text{4-Aminoantipyrine} \xrightarrow{\text{POD}} \text{Quinoneimine dye} + 4H_2O$$

WARNINGS AND PRECAUTIONS:

For In Vitro Diagnostics Use Only - For Professional Use Only
Carefully read instructions for use. Deviations from this procedure may alter performance of the assay.

Components Colour and Appearance:
Reagent 1: Clear colourless liquid.
Reagent 2: Clear, pale yellow coloured liquid.
Any significant changes from the above could indicate that the assay might be compromised. Refer to Laboratory's QC program for actions to be taken. In case of serious damage to the bottle and/or cap, resulting in product leakage and/or contamination, do not use the reagent pack and contact your distributor.

Safety Precautions:
Product is not hazardous under EU specification. Contains Sodium Azide. Material Safety Data Sheet is available upon request.

Handling precautions:
- Take the necessary precautions required for handling all laboratory reagents.
- Do not use components past the expiry date stated on the Bottles.
- Do not Freeze Reagents.
- Do not use components for any purpose other than described in the "Intended Use" section.
- Do not interchange caps among components as contamination may occur and compromise test results.
- Refer to local legal requirements for safe waste disposal.

INSTRUMENTS:

Instrument application procedures are available upon request.

COMPONENT COMPOSITION:

Component	*Ingredients*	*Concentration in Tests*
Reagent 1	Phosphate Buffer pH 7.5	150 mmol/l
	Dichlorophenol Sulphonate	1.97 mmol/l
	Ascorbate Oxidase	2000 U/l
	Potassium Ferrocyanide	0.024 mmol/l
	PRESERVATIVES, STABILISERS & DETERGENTS	---
Reagent 2	Phosphate Buffer pH 7.5	150 mmol/l
	4 – Aminophenazone	1.50 mmol/l
	Peroxidase	5000 U/l
	Uricase	1000 U/l
	PRESERVATIVES, STABILISERS & DETERGENTS	---
Standard	Uric Acid	6 mg/dl

REAGENT PREPARATION AND STABILITY:

Before use, mix reagent by gently inverting each bottle.
If stored and handled properly, unopened components are stable until the expiry date stated on the label
Monoreagent procedure: Add 1 volume of Reagent 2 to 5 Volumes of Reagent 1.
Working reagent is stable 4 weeks at 2-8°C.
Bireagent procedure: Liquid reagent 1 and 2 are ready for use.

TYPE OF SPECIMEN: [1]

Use non-lipemic and free of haemolysis serum, heparin or EDTA plasma as specimen.
It is recommended to follow NCCLS procedures (or similar standardised conditions) regarding specimen handling. Specimen should be collected in an appropriate sample container, with proper specimen identification. Serum/plasma should be separated from cells within 2 hours after collection.
Stability [3]: up to 5 days at 4°C.

TEST PROCEDURE:

Materials required but not supplied:

Description	*Catalog. No.*	*Description*	*Catalog. No.*
General Chemistry Calibrator	GL983	Photometer	N/A
General Chemistry Control Level 1	GL922	General Laboratory Equipment	N/A
General Chemistry Control Level 2	GL932	Saline solution 0.9 g/l NaCl	N/A

Assay procedure:
Wavelength: λ: 510 nm (492 – 550) nm
Temperature: 25°C, 30°C or 37°C
Optical path: 1 cm light path.

	Blank	**Calibrator (Cal)**	**Sample**
Working Reagent	1000 µl	1000 µl	1000 µl
Sample	----	----	20 µl
Calibrator (Cal)	----	20 µl	----
Gently mix and Incubate at 37°C for 5 minutes or at 15 - 25°C for 15 minutes. Measure the Optical Density (OD).			

	Blank	**Calibrator**	**Sample**
Reagent 1	1000 µl	1000 µl	1000 µl
Sample	----	----	20 µl
Calibrator	----	20 µl	----
Reagent 2	200 µl	200 µl	200 µl
Gently mix and Incubate at 37°C for 5 minutes or at 15 - 25°C for 15 minutes. Measure the Optical Density (OD).			

Calibration:
Using recommended Calibrator, calibrate the assay:
- When using a new reagent kit or changing lot number.
- Following preventive maintenance or replacement of a critical part of the photometer used.
- When Quality Controls are out of range.

Quality Control:
All clinical laboratories should establish an Internal Quality Control program. Verify instrument and reagent performance with recommended controls or similar. The values obtained for QC should fall within manufacturer's acceptable ranges or should be established according to the Laboratory's QC program.

Controls should be assayed:
- Prior reporting patient results.
- Following any maintenance procedure on the photometer used.
- At intervals established by the Laboratory Q.C. Programme.

CALCULATION:

$$\text{Concentration of Uric Acid} = \frac{OD_{Sample}}{OD_{Calibrator}} \times \text{Concentration Calibrator}$$

*Photometer must be blanked with the reagent blank. (Conversion factor: Qty in µmol/l = 59.5 x Qty in mg/dl).

EXPECTED VALUES: [1]

Uric Acid in Serum	*µmol/l*	*mg/dl*
Child	120 - 320	2.02 – 5.38
Men	210 - 420	3.53 – 7.06
Women	150 - 350	2.52 – 5.88

Each laboratory should establish its own reference range. Uric acid results should always be reviewed with the patient's medical examination and history.

PERFORMANCE CHARACTERISTICS:

Performance results can vary with the instrument used. Data obtained in each individual laboratory may differ from these values.

Linearity:
Linear up to 1160 µmol/l.
For samples with a higher concentration, dilute 1:1 with 0.9% NaCl (9g/l) and re-assay. Multiply result by 2.

Interfering substances:
Bilirubin (mixed isomers): Less than 10% interference up to 600 µmol/l Bilirubin.
Haemolysis: Less than 10% interference up to 1.25 g/l Haemoglobin.
Lipemia: Less than 10% interference up to 1.25 g/l Intralipid.

Sensitivity:
The Lowest Detectable Level was estimated at 0.7 µmol/l.

Precision:

Within Run N = 20	Mean *(µmol/l)*	*SD*	*% CV*	*Between Run N = 20*	Mean *(µmol/l)*	*SD*	*% CV*
Level 1	269	5.37	2.00	Level 1	275	8.19	2.98
Level 2	648	11.86	1.83	Level 2	637	8.83	1.38

Method Comparison:
Using 50 samples, a comparison, between this Uric Acid test (y) and another commercially available test (x), gave the following results:

y = 1.002x + 7.087	r = 0.999	Sample range: 153 to 904 µmol/l

BIBLIOGRAPHY:

1. Burtis CA, Ashwood ER. Tietz Fund. Of Clin. Chem. 5th ed. 30-54, 422-426 and 1015. &
2. Thelfeld, W. et al (1973) Dtsh. Med. Wschr., 98:380.
3. Tietz NW, ed. Clinical Guide to Laboratory test, 3rd ed. Philadelphia, Pa: Saunders; 1995; 624-626.

SYMBOLS:

The following symbols are used in the labelling of Glenbio Ltd. systems:

IVD In Vitro Diagnostics
REF Catalogue No
LOT Batch Code
CONT Content
REAG Reagent
STD Aqueous Standard
CE CE Mark - Device comply with the Directives 98/79/EC
Storage temperature
Consult Instruction for Use
Expiry Date (Last day of the month)
Manufactured By

GLENBIO LTD
10 Kilbegs Road, Antrim, Co. Antrim, BT41 4NN
Tel/Fax: +44(0)2879659842
Email: info@glenbio.com
Web: www.glenbio.com

EC REP GLENBIO IRELAND LTD
17b Fota Business Park, Carrigtwohill, Co. Cork,
T45 PK77, Ireland

Revision: 08 Issued on: 27 July 2021