Uric Acid Kit

CliniQuant – FSR

Uricase - Trinder, End Point (TOOS)

Meril Diagnostics

IVD For *in vitro* diagnostic use
Read this pack insert thoroughly before use

REF	Pack Size	R1 Uric acid Reagent	R2 Uric Acid Standard
URCFSR-01	4 x 10ml	4 x 10ml	1 x 5ml
URCFSR-02	4 x 50ml	4 x 50ml	1 x 5ml
URCFSR-03	10 x 50ml	10 x 50ml	2 x 5ml

INTENDED USE

This reagent is intended for quantitative determination of Uric Acid concentration in human serum or plasma and urine.

CLINICAL SIGNIFICANCE

Hyperuricemia is most commonly defined by serum or plasma uric acid concentrations greater than 7.0 mg/dl. The quantification of uric acid is an aid in diagnosis of gout, decreased renal function, diabetes, tumor, genetic diseases.

PRINCIPLE OF THE METHOD

Uric acid in sample is oxidized to allantoin in presence of enzyme uricase and H_2O_2 is generated. The H_2O_2 reacts with TOOS and 4-aminoantipyrine in the presence of peroxidase to form a purple complex. The intensity of color formed is proportional to the uric acid concentration.

$$\text{Uric acid} + O_2 + H_2O \xrightarrow{\text{Uricase}} \text{Allantoin} + CO_2 + H_2O_2$$

$$\text{TOOS} + 4\text{AAP} + 2H_2O_2 \xrightarrow{\text{Peroxidase}} \text{Purple complex} + 4H_2O$$

KIT COMPONENTS

Composition

R1 - Uric Acid Reagent : Pipes buffer pH 7.5 50 mmol/l, TOOS 2.0 mmol/l, 4-aminoantipyrine 3 mmol/l, uricase > 200 U/l, POD > 2000 U/l, and stabilizers.

R2 - Uric Acid Standard : 6.0 mg/dl, Uric acid 60 mg/l, Sodium azide 0.1%

MATERIALS REQUIRED BUT NOT PROVIDED

Laboratory instrumentation, Spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi automated, calibrated micropipettes, glass or high quality polystyrene cuvettes, test tube/ rack, heating bath, controls, saline.

REAGENT PREPARATION, STORAGE & STABILITY

Reagent is ready to use. Keep away from direct light sources.

Stability: up to expiration date on labels at 2-8 °C.

Stability since first opening of vials: preferable within 60 days at 2-8 °C.

REAGENT DETERIORATION

1. Discard any turbid reagent or reagent absorbance exceeds 0.3 at 546 nm against distilled water.
2. Keep the Standard vial plugged after use, in order to avoid deterioration.

WARNINGS AND PRECAUTIONS

1. Reagent may contain some non-reactive and preservative components. It is recommended to handle carefully, avoiding contact with skin and ingestion.
2. Specimens should be considered infectious and handled appropriately.
3. Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

SPECIMEN

Use fresh unhemolysed serum or heparinised plasma. Avoid use of EDTA and fluoride as anticoagulants. Serum / plasma is stable for 7 days at 2-8°C and 1 month at -20°C.

Dilute urine samples 1:10 with deionized water and multiply results by ten.

Programme Parameter for MERILYZER CliniQuant

Reading Mode	End Point
Standard Conc.	6.0 (mg/dl)
Filter - 1 (nm)	546
Filter - 2 (nm)	670
Temperature	37 °C
Volume (µl)	500
Delay Time (Sec)	5
Reaction Direction	Increase
Reference Low	2.5
Reference High	7.2
Linearity Limit	25

CE
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TEST PROCEDURE

Dispense	Blank	Standard	Sample
Reagent 1	1ml	1ml	1ml
Distilled water	25 µl	-	-
Standard	-	25 µl	-
Sample	-	-	25 µl
Mix, incubate for 5 min at 37°C. Read absorbance of standard (As) and samples (Ax) against reagent blank.			

RESULT CALCULATION

Serum/plasma:

Uric Acid mg/dl = Ax/As x Concentration of Standard

Random urine sample:

Uric acid mg/dl = Ax/As x concentration of Standard x10

24 hours urine sample (uric acid mg/24h): Ax/As x concentration of Standard x 10 x urine volume

SI conversion factor: 1 mg/dl x 59.48 = 1 µmol/l

EXPECTED VALUES

Men: 3.6 – 7.2 mg/dl OR 214 – 428 µmol/l

Women: 2.5 – 6.8 mg/dl OR 149 – 404 µmol/l

24h urine: 250 – 750 mg/24h OR 1.5 – 4.5 mmol/24h

It is recommended that each laboratory verifies this range or derives reference interval for the population it serves.

QUALITY CONTROL AND CALIBRATION

It is recommended to perform internal quality control with assayed normal (BioNorm) and assayed abnormal (BioPath), to confirm the validity of the test and assure the accuracy of patient result.

Using the recommended Calibrator (BioCal) or the Standard included, calibrate the assay:

a. When using a new reagent or lot

b. When QC values are out of range

PERFORMANCE CHARACTERISTICS

1. Linearity

The linearity is up to 25 mg/dl or 1487 µmol/l.

2. Sensitivity/ Limit of detection (LOD)

The limit of detection is 0.2 mg/dl.

The limit of quantification is 0.6 mg/dl.

3. Interferences

No interference has been observed for the following

Hemoglobin up to 50 mg/l; Bilirubin up to 16 mg/dl

Triglycerides up to 1000 mg/dl

4. Precision

Intra-assay precision

	Mean	SD	CV
n = 20	mg/dl	mg/dl	%
sample 1	5.37	0.02	0.32
sample 2	11.84	0.02	0.2

Inter-assay precision

	Mean	SD	CV
n = 20	mg/dl	mg/dl	%
sample 1	5.05	0.23	4.55
sample 2	12.08	0.51	4.20

5. Methods Comparison

Comparison was done between reference Uric acid Reagent and CliniQuant - FSR Uric acid Reagent (test)

N = 20 $y = 0.984x - 0.124$

$r^2 = 0.995$

LIMITATIONS

Samples with values above 25 mg/dl should be diluted with 0.9% saline, re-run and multiply results by the dilution factor.

WASTE DISPOSAL

This product is made to be used in professional laboratories. Please consult local regulations for correct waste disposal.

REFERENCES

1. Burtis, C.A., Ashwood, E.R., editors. Tietz Textbook of Clinical Chemistry. 2nd ed. Philadelphia, W.B. Saunders Company, 1994, p. 1539 – 1542.

2. Data on file: Meril Diagnostics.

IFU/URCFSR01/01

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Symbols used on Meril Diagnostics labels:

REF	Catalogue No.		Attention See Instruction for Use
LOT	Batch No.	IVD	*In vitro* Diagnostics
	Expiry Date		Consult Instruction for Use
	Manufacturer		Storage Temperature
	Keep Dry		Keep Away from Sunlight
	Manufacturing Date		Do not use if package is damaged
EC REP	Authorized European Representative in the European Community		