URIC ACID

Diagnostic reagent for determination of Uric acid concentration.

Liquid. Mono Reagent. Store at 2°C - 8°C. For in Vitro Diagnostic Use. Do not freeze

Ref No	Pack	Ref No	Pack	Ref No	Pack	Ref No	Pack
A2340	5 x 100 mL	DM2340	990 Tests	BY2340	6364 Tests	K2341	4545 Tests
A2341	5 x 50 mL	R2340	1111 Tests	BY2341	4545 Tests	M2340	3030 Tests
A2342	5 x 25 mL	R2341	370 Tests	N2340	1136 Tests	M2341	1212 Tests
T2340	5294 Tests	S2340	2462 Tests	N2341	636 Tests	L2340	5000 Tests
T2341	1471 Tests	S2341	1846 Tests	K2340	6364 Tests	L2341	2667 Tests

INTENDED USE

The test is applied for the quantitative determination of uric acid in serum or plasma.

TEST PRINCIPLE

Uric acid in the sample originates, by means of the coupled reactions described below, a coloured complex that can be measured by spectrophotometry.

$$\text{Uric acid} + O_2 + 2\,H_2O \xrightarrow{\text{Alantoin uricase}} CO_2 + H_2O_2$$

$$2\,H_2O_2 + 4\text{-Aminoantipyrine} + \text{DCFS} \xrightarrow{\text{Peroxidase}} \text{Quinoneimine} + 4\,H_2O$$

TEST PARAMETERS

Method	: Colorimetric, Endpoint, Trinder, Increasing Reaction, Enzymatic
Wavelength	: 520 ± 10 nm
Temperature	: 37°C
Sample	: Serum,Plasma,Urine (dilute urine 1:10 with physiological saline) Don't use EDTA.
Linearity	: 1 mg/dL - 25 mg/dL

REAGENT COMPOSITION

Phosphate	≤ 120 mmol/L,
Detergent	≤ 1.8 g/L,
Dichlorophenolsulfonate	≤ 4.4 mmol/L,
Uricase	> 0.12 U/mL,
Ascorbate oxidase	> 5 U/mL,
Peroxidase	> 1 U/mL,
4-aminoantipyrine	≤ 0.6 mmol/L,
pH 7.8.	

REAGENT PREPARATION

Reagent is ready for use.

REAGENT STABILITY AND STORAGE

Stability of the reagent is up to expiration date on labels at 2-8°C.
Stability of first opening vials is more than 60 days at 2-8°C.

On board stability is strongly related to auto analyzers cooling specification and carry-over values.

SAMPLE

Serum, plasma heparinate and urine are collected by standard procedures. Oxalate, citrate and fluoride could yeld a small decrease of uric acid. Uric acid is stable 7 days at 2-8°C, 3 days at 20-25°C and 6 month at -20°C.

Dilute urine sample 1:10 with deionized water.

TEST PROCEDURE

Sample Start

There have many ready application procedures dedicated to different kind of photometers and ready manual working process can be supplied on request.

There have many ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied on request.

CALCULATION

Serum/plasma sample:
Uric acid mg/dL = Ax/As x 6 (standard value)

Random urine sample:
Uric acid mg/dL = Ax/As x 6 x 10
(standard value and dilution)

24 hours urine sample (uric acid mg/24h):
Uric acid mg/24h = Ax/As x 6 x 10 x diuresis (dL)

(standard value, dilution and diuresis in dL)

Unit Conversion

mg/dL x 59.4 =µmol/L

REFERENCE INTERVAL (NORMAL VALUES) (Based on CLSI C28-P Document)*

Serum/plasma samples:

Men	: 3.5 - 7.2 mg/dL
Women	: 2.6 - 6 mg/dL
24h urine	: 250 - 750 mg/24h

*It is recommended that each laboratory establish its own reference range.

QUALITY CONTROL AND CALIBRATION

All control sera with uric acid values determined by this method can be used. We recommend:

"ARCON N", Assayed Control Serum Normal
Cat.No. A3910

"ARCON P", Assayed Control Serum Abnormal
Cat.No. A3920

The assay requires the use of a Uric Standard or a Uric Calibrator. We recommend:
ARCHEM Standard
Cat.No. A2340S (6 mg/dL)

Any commercially available Standard or Calibrator suitable for this method may be used.

*Calibration Stability: It is strongly depend of application to auto analyzers and auto analyzers specification. Calibration stability is 20 days.

*Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

Quality control is recommended every morning. Calibration is not recommended if QC control values are acceptable. Reagent should be calibrated after lot changes.

PERFORMANCE CHARACTERISTICS

Low linearity: 1 mg/dL

High Linearity: The method is linear up to 25 mg/dL.

If the value is exceeded, it is suggested to dilute sample 1+9 with saline and to repeat the test, multiplying the result by 10.

Linearity may considerably vary depending on the instrument used.

Precision Studies (Based on CLSI EP5 Doc.):

Repeatibility (within run) (Intra-assay)

Mean conc.	SD	CV	n
4.60 mg/dL	0.04	0.90%	10
10.72 mg/dL	0.04	0.40%	10

Reproducibility (run to run) (Inter-assay)

Mean conc.	SD	CV	n
4.57 mg/dL	0.04	0.90%	20
10.72 mg/dL	0.11	1.00%	20

Sensitivity (LOD) (Based on CLSI EP17 document): The limit of detection is 0.16 mg/dL.

Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagents. Details of the comparison experiments are available on request.

Interferences: No interference was observed by the presence of:

Hemoglobin	≤ 150 mg/dL
Bilirubin	≤ 12 mg/dL

Lipids interference is observed

Methods comparison: A comparison between Bioanalytic and a commercially available product gave the following results:

Uric acid T FL Bioanalytic = x
Uric acid competitor = y
n = 104
$y = 0.976x - 0.026$ mg/dl $r^2 = 0.99$

These performance characteristics have been obtained using an analyzer. Results may vary, if a different instrument or a manual procedure is used.

NOTES

1. For in vitro diagnostic use only. Do not pipette by mouth. Avoid contact with skin and mucous membranes.
2. All the calibrators, controls and some reagents must be considered as human & animal sample, so potentially infectious; all the protection actions must be applied to avoid any potential biological risk.
3. Material safety data sheet will be supplied on request.
4. Exercise the normal precautions required for handling laboratory reagents.
5. After measurements are taken, reagent bottles should cap and kept at 2-8°C. Caps of the reagents bottles cannot be used between two different kind of reagent and between R1 & R2.
6. Reagents with different lot numbers should not be interchanged or mixed.
7. The linearity limit depends on the sample to reagent ratio.

PRECAUTIONS AND WASTE DISPOSAL

This product is made to be used in professional laboratories and by professional operators. Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.
R36/38 : Irritating to eyes and skin.
S20/21 : When using, do not eat, drink or smoke.
S26 : In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S28 : After contact with skin wash immediately with plenty of water.
S36/37/39: Wear suitable protective clothing, gloves and eye/face protection.
S45 : In case of accident or if you feel unwell, seek medical advice immediately.
S56 : Dispose of this material and its container at hazardous or special waste collection point.
S57 : Use appropriate container to avoid environmental contamination.
S61 : Avoid release in environment. Refer to special instructions/safety data sheets.
Please consult local regulations for a correct waste disposal.

ABBREVIATIONS

CLSI : Clinical and Laboratory Standards Institute
CV% : Coefficient of Variation Percentage
EP : Evaluation Protocols
GLP : Good Laboratory Practice
IU : International Unit
mA : miliabsorbance
mL : mililiter
NCCLS : National Committee for Clinical Laboratory Standards
QC : Quality Control

REFERENCES

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SYMBOLS

IVD	Only for invitro diagnostic use
LOT	Lot of manufacturing
R1	Reagent 1
CONC	Concentration
INGRED	Reagent Ingredients
REF	Reference Number (Catalog No)
SN	Serial Number
	Expiration date
	Storage temperature interval
	Read the directions
	Biological risk

CE

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