URIC ACID (SINGLE REAGENT)

Cat. No.	Pack Name	Packaging (Content)
BLT00062	UA SINGLE 200	R1: 4 x 50 ml, R2 standard: 1 x 5 ml

EN

CE IVD

INTENDED USE
Diagnostic reagent for quantitative *in vitro* determination of Uric Acid in human serum, plasma and urine.

CLINICAL SIGNIFICANCE
Uric acid is a metabolite of purines, nucleic acids and nucleoproteins, consequently, abnormal levels may be indicative of a disorder in the metabolism of these substances. Hyperuricaemia may be observed in renal dysfunction, gout, leukemia, polycythaemia, atherosclerosis, diabetes and hypothyroidism. Decreased levels are present in patients with Wilson's Disease.

PRINCIPLE
The series of reactions involved in the assay system is as follows:

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

$$\text{DHBS} + 4\text{AAP} + 2H_2O_2 \xrightarrow{\text{Peroxidase}} \text{Quinoneimine dye} + 4H_2O$$

1. Uric acid is oxidised to allantoin by uricase with the production of H_2O_2.
2. The peroxide reacts with 4-aminoantipyrine (4-AAP) and DHBS in the presence of peroxidase to yield a quinoneimine dye. The absorbance of this dye at 505 nm is proportional to uric acid concentration in the sample.

REAGENT COMPOSITION
R1

Pipes Buffer (pH 7.0)	50 mmol/l
DHBS	0.50 mmol/l
Uricase	≥ 0.32 kU/l
Peroxidase	≥1.0 kU/l
4-Aminoantipyrine	0.31 mmol/l
R2 standard	See bottle label

REAGENT PREPARATION
Reagent is liquid, ready to use.

STABILITY AND STORAGE
The unopened reagents are stable till the expiry date stated on the bottle and kit label when stored at 2–8°C.

SPECIMEN COLLECTION AND HANDLING
Use unheamolytic serum or plasma (heparin, EDTA) or urine.
It is recommended to follow NCCLS procedures (or similar standardized conditions).
Stability

in serum / plasma:	3 days	at 20–25°C
	7 days	at 4–8 °C
	6 months	at -20°C
in urine:	4 days	at 20–25°C

For the determination in urine use 24 hours specimen. To prevent the precipitation of uric acid add 15 ml 5 mol/l NaOH into the urine collector to ensure urine pH > 8. Dilute urine samples in 1+9 ratio with distilled water and multiply results by 10. Discard contaminated specimens.

CALIBRATION
Calibration with the standard included in the kit or the calibrator XL MULTICAL, Cat. No. XSYS0034 is recommended.

QUALITY CONTROL
For quality control ERBA NORM, Cat. No. BLT00080 and ERBA PATH, Cat. No. BLT00081 are recommended.

UNIT CONVERSION
mg/dl x 60 = µmol/l

EXPECTED VALUES [9]
Serum:
Adult:

Male:	3.5 – 7.2 mg/dl
Female:	2.6 – 6.0 mg/dl

Urine, 24 h:

average diet:	250 – 750 mg/dl
high-purine diet:	< 1000 mg/dl
low-purine diet:	< 480 mg/dl
purine-free diet:	< 420 mg/dl

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

PERFORMANCE DATA
Data contained within this section is representative of performance on ERBA XL systems. Data obtained in your laboratory may differ from these values.

Limit of quantification:	0.49 mg/dl
Linearity:	25 mg/dl
Measuring range:	0.49 – 25 mg/dl

PRECISION

Intra-assay precision Within run (n=20)	Mean (mg/dl)	SD (mg/dl)	CV (%)
Sample 1	11.852	0.142	1.20
Sample 2	8.946	0.165	1.85

Inter-assay precision Run to run (n=20)	Mean (mg/dl)	SD (mg/dl)	CV (%)
Sample 1	11.653	0.375	3.22
Sample 2	5.011	0.181	3.61

COMPARISON
A comparison between XL-Systems Uric Acid (y) and a commercially available test (x) using 40 samples gave following results:
y = 1.166 x + 0.21 mg/dl
r = 0.999

INTERFERENCES
Following substances do not interfere:
haemoglobin up to 10 g/l, bilirubin up to 40 mg/dl, triglycerides up to 2000 mg/dl.

WARNING AND PRECAUTIONS
For *in vitro* diagnostic use. To be handled by entitled and professionally educated person.
Reagent of the kit is not classified like dangerous but contains less than 0.1% sodium azide - classified as very toxic and dangerous substance for the environment.

WASTE MANAGEMENT
Please refer to local legal requirements.

ASSAY PROCEDURE
Wavelength: 505/670 nm
Cuvette: 1 cm

	Reagent blank	Standard (Calibr.)	Sample
Reagent 1	1.00 ml	1.00 ml	1.00 ml
Sample	-	-	0.025 ml
Standard (Calibr.)	-	0.025 ml	-
Distilled water	0.025 ml	-	-

Mix and incubate 5 min. at 37 °C. Measure absorbance of the sample A_{sam} and standard A_{st} at 505/670 nm against reagent blank.

CALCULATION
$$\text{Uric Acid (mg/dl)} = \frac{\Delta A_{sam}}{\Delta A_{st}} \times C_{st}$$

C_{st} = standard (calibrator) concentration

Applications for automatic analysers are available on request.

ASSAY PARAMETERS FOR PHOTOMETERS

Mode	End Point
Wavelength 1 (nm)	505
Wavelength 2 (nm)	670
Sample Volume (µl)	12.5/25
Reagent Volume (µl)	500/1000
Incubation time (min.)	10
Incubation temp. (°C)	37
Normal Low (mg/dl)	3.5
Normal High (mg/dl)	7.2
Linearity Low (mg/dl)	0.49
Linearity High (mg/dl)	25
Concentration of Standard	See bottle label
Blank with	Reagent
Absorbance limit (max.)	0.2
Units	mg/dl

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SYMBOLS USED ON LABELS

REF Catalogue Number	Manufacturer	See Instruction for Use
LOT Lot Number	CE Mark - Device comply with the Directive 98/79/EC	Storage Temperature
Expiry Date	IVD In Vitro Diagnostics	CONT Content

QUALITY SYSTEM CERTIFIED
ISO 9001 ISO 13485

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