Uric Acid – Instructions for use (IFU)

Distributed by: ISE S.r.l. CUSTOMISED SOLUTIONS FOR YOUR LABORATORY

R1: 4 x 50 mL – R2: 4 x 20 mL • REF A-R0100001001

R1: 2 x 18,5 mL – R2: 1 x 18,5 mL • REF R3330000027

IVD CE

INTENDED USE
Product for use in the quantitative determination in vitro of the concentration of the Uric Acid in human urine, serum or plasma. The results of the test must always be interpreted in conjunction with the clinical picture. For professional use only.

CLINICAL SIGNIFICANCE
Uric acid is the principle product of the catabolism of purine, adenosine and guanosine nucleotides. Approximately 400 mg of uric acid are synthesized daily; food intake accounts for a further 300 mg. About 75% of the uric acid excreted is eliminated in the urine. Most of uric acid is secreted in the gastrointestinal tract where it is degraded by bacterial enzymes into allantoin and other compounds. The amount of uric acid present is determined essentially by the life style adopted, e.g. alimentary habits, alcohol consumption, physical activity, assumption of pharmaceutical products may all influence hyperuricemia. Some the most dangerous complications of uricemia include acute and chronic attacks of gout, and pathological conditions related to renal function.

PRINCIPLE
Uric acid is converted by uricase and hydrogen peroxide which, under the catalytic influence of peroxide (POD), oxidizes compound, reacts with 4aminophenazone and 3,5-diclorophenol-sulphonate giving a red coloured compound, whose colour intensity is directly proportional to the uric acid concentration in the tested sample.

$$\text{Uric Acid} + 2H_2O + O_2 \xrightarrow{\text{Uricase}} \text{Allantoin} + CO_2 + 2H_2O_2$$

$$3,5-\text{diclorophenolsulphonate} + 2H_2O_2 + 4\text{-Aminophenazone} \xrightarrow{\text{POD}} \text{Compound dyed}$$

REAGENTS
A-R0100001001 – R1: 4 x 50 mL – R2: 4 x 20 mL
Reagent 1: n° 4 vials x 42,0 mL ready for use
Reagent 2: n° 4 vials x 11,0 mL ready for use
R3330000027 – R1: 2 x 18,5 mL – R2: 1 x 18,5 mL
Reagent 1: n° 2 vials x 16,7 mL ready for use
Reagent 2: n°1 vial x 8,5 mL ready for use

Concentrations:

Reagent 1:			
	Conc.	**U.M.**	
Good's buffer pH 8.0	70.0	mM	
3,5-diclorophnolsulphonate	2.20	mM	
Ascorbate Oxidase	150	U/L	
Sodium azide	14.6	nM	
Reagent 2:			
Good's buffer pH 8.0	70.0	mM	
4-Aminophenazone	0.50	mM	
Uricase	400	U/L	
Peroxidase (POD)	2000	U/L	
Sodium azide	14.6	mM	


*GHS08

*Warning: DANGER – Contains: Disodium tetraborate decahydrate (CAS 1303-96-4)
H360FD - May damage fertility. May damage the unborn child.
P201 - Obtain special instructions before use.
P202 - Do not handle until all safety precautions have been read and understood.
P280 - Wear protective gloves/protective clothing/eye protection/face rotection/hearing protection.
P308+P313 - IF exposed or concerned: Get medical advice/attention.
P501 - Dispose of contents/container in accordance with local/ regional/national/international regulations.

Precautions
In addition to risk indications related to the active components, reagents may contain inactive components such as preservatives and detergents. The total concentration of these components is lower than the limits reported in the EC 1272/2008 Regulation and subsequent amendments and additions. However, it is recommended to handle reagents according to the standards of good laboratory practice.

Reports of serious incidents
In the event of a serious incident in relation to the use of the device, please inform the manufacturer (via your distributor) and the competent authority of the European Union member state where the incident occurred. For other jurisdictions, reporting must be made in accordance with regulatory requirements. Reporting serious incidents helps provide more information about the safety of the diagnostic medical device.

Storage and stability
Store at 2 - 8°C; protect from direct light. When correctly stored, the reagents are stable up the expiry date reported on the label. A slight variation in the composition of the reagent may occur between batches, but this has no effect on the test results. After opening, the vial R1 and R2 are stable 30 days if recapped immediately and protected from contamination, evaporation, direct light and stored at correct temperature.

Reagent Preparation
Liquids reagents ready for use.
After opening the vials are stable up to the expiry date if recapped immediately and protected from contamination.

SAMPLE COLLECTION
Type of sample and storage
Serum or Heparinised-plasma samples should be used. Samples can be stored for 3 days at 20 - 25°C, for 7 days at 4 - 8°C or for 6 months at – 20°C. Urine, collected in 24 hours, must be read within 24 hours, if stored at 4 - 8°C.

Precaution
All human samples must be handled and disposed of as potentially infectious materials.

PROCEDURE
Quality control
Control sera known as Uric Acid are commercially available for quality control, including certificates of analysis showing values and confidence limits. Normal and pathological control sera "Normal control serum" cod. R0400000006 and "Pathological control serum" code R0400000106. The values obtained must be contained within the acceptability range. In case of incorrect results check the following points:
- Cleanliness of glassware.
- Wavelength setting.
- Expiration date of reagents.

Automation
Although this device has been developed and manufactured to be used by manual method and instrumental systems, it can also be used in combination with other instrumental devices that are able to meet the requirements indicated in the paragraph "Reaction conditions / Technique". All applications that are not explicitly approved cannot be guaranteed in terms of performance and will therefore have to be evaluated by the user.

Calibration
For calibration use the "Multicalibrator" code R0300000006. For ISE srl instruments calibration is recommended every 10 days.

Traceability
The Uric Acid value is reported in the package insert supplied with the "Multicalibrator".

Reaction conditions

Wavelength (primary):	510 nm
Wavelength (secondary):	620 nm
Temperature:	37°C
Optical path:	1 cm

Technique - Procedure with Reagent B as starter

	U.M.	**Calib.Serum**	**Sample**	**Blank**
Reagent A	µL	1000	1000	1000
Calib.Serum	µL	30	-	-
Sample	µL	-	30	-
Distilled Water	µL	-	-	30

Miscelare con delicatezza quindi incubare a 37°C per 1 minuto quindi aggiungere:

	U.M.	**Blank**	**Standard**	**Sample**
Reagente B	µL	250	250	250

Stir vigorously and incubate 5 minutes at 37°C. Read the extinction of the sample and calibrator against reactive white. The developed color is stable for about 60 minutes. The reaction volumes can be varied proportionally while the calculation remains unchanged.

Results
The conversion factor mg/dL- humoli/L is equal to 59,6.
The concentration of Uric Acid is obtained through the following formula:

$$\frac{\text{D.O Sample}}{\text{D.O Clib.Serum}} \times \text{Conc.Calib.} = \text{Uric Acid mg/dL}$$

Sclavo Diagnostics International
Via Po 26-28 – Loc. Pian dei Mori – 53018 Sovicille (SI) (Italy)
Phone +39 0577 39041 - Fax +39 0577 390 444

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Reagents included in the kit
The reagent is described above.

Materials required but not supplied in the kit
Calibrators and controls.

NORMAL VALUES
Serum or plasma:
- Males: 3.4 – 7.0 mg/dL (202 - 416 µmol/L)
- Females: 2.4 – 5.7 mg/dL (143 - 339 µmol/L)

Urine collected in 24 hours:
Average value 250 – 750 mg/24 h (1.48 – 4.43 mmol/24 h)
Each laboratory must establish its own normal values on the basis of its local catchment area.

ANALYTICAL CHARACTERISTICS / PERFORMANCE
Linearity
The method is linear up to 20 mg/dL of Uric Acid.

Accuracy-Recovery
Accuracy studies were performed on normal samples to which known amounts of uric acid had been added. The results indicate an accuracy of 90% with linear correlation.

Interference
Bilirubin does not interfere up to concentration of 20 mg/dL. Triglycerides do not interfere up to concentration of 2000 mg/dL. Haemoglobin does not interfere up to concentration of 50 mg/dL. Ascorbate acid does not interfere up to concentration of 30 mg/dL.

Precision

Within-run precision					
Range	U.M.	Mean	S.D.	C.V. (%)	No.
Low	mg/dL	3.76	0.102	2.71%	30
High	mg/dL	10.11	0.186	1.84%	30
Between-run precision					
Range	U.M.	Mean	S.D.	C.V. (%)	No.
Low	mg/dL	3.76	0.125	3.34%	20
High	mg/dL	10.11	0.379	3.75%	20

Sensitivity
At λ 505 nm, the sensitivity in terms of detection limit is 0.29 mg/dL of Uric Acid.

Comparative method
The method was compared with a similar commercial method. Samples tested = No. 46; Y = 0.993x + 0.23; Correlation Coefficient r = 0.979.

Manufacturer:
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Phone +39 0577 39041 - Fax +39 0577 390 444

Distributor:
I.S.E S.r.l.
Via Delle Driadi, 45 – 00133 Roma
Tel.+39 077 4579365; FAX +39 077 4579305
E-mail: info@logotech-ise.com
www.logotech-ise.com

Symbols used in IFU and Packaging	
IVD In vitro diagnostic medical device	Manufacturer
REF Catalogue Number	Instruction for use
LOT Lot Number	Temperature limitation
Expiration date	

References

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2. Barham D, Trinder P: Analyst, 97 142 (1972).
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REVISION	DATE	CHANGE
Rev.A	12/2022	New Issue for IVDR Regulation (UE) 2017/746 compliance