Uric Acid – Uricasi (Emerson-Trinder)

Instructions for use (IFU)

IVD CE

ORDERING INFORMATION

	Code	Composition
OPEN KONELAB INDIKO	REF B75182562	n° 7 vials x 48 mL (R.A) n° 7 vials x 12 mL (R.B)
	REF B75182563	n° 8 vials x 16 mL (R.A) n° 8 vials x 4 mL (R.B)
CHEMILAB	REF B81180001	n° 2 vials x 32 mL (R.A) n° 2 vials x 8 mL (R.B)
	REF B81180002	n° 8 vials x 32 mL (R.A) n° 8 vials x 8 mL (R.B)

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 context. FOR PROFESSIONAL USE ONLY.

CLINICAL SIGNIFICANCE

Uric acid is the principal 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 OF THE METHOD

Enzymatic method (Uricase) with the detection system Emerson-Trinder.

Uric acid is converted by uricase and hydrogen peroxide which, under the catalytic influence of peroxide (POD), oxidizes compound, reacts with 4-aminophenazone 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.

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

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

Storage and stability

= storage temperature 2-8°C

If stored closed at 2-8 ° C, avoiding direct light, the intact reagents are stable until the expiration date, printed on the label.

Concentrations

Reagent A:			
	Conc.	U.M.	
Good's buffer pH 8.0	70.0	mmol/L	
3,5-diclorophnolsulphonate	2.20	mmol/L	
Ascorbate Oxidase	150	U/L	
Reagent B:			
Good's buffer pH 8.0	70.0	mmol/L	 *GHS08
4-Aminophenazone	0.50	mmol/L	
Uricase	400	U/L	
Peroxidase (POD)	2000	U/L	

*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 protection/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.

Reagents included in the kit

The reagent is described above.

Materials required but not supplied in the kit

Controls, calibrators and pipettes with adequate volume.

PRECAUTIONS and WARNINGS

1. Reagents and waste materials shall be disposed of in accordance with Community waste provisions or national or regional provisions.
2. Reagents may contain non-active components such as preservatives and detergents. The total concentration of these components is below the limits set out in Regulation 1272/2008 EC and subsequent amendments and additions.
3. It is recommended that the reagent be handled in accordance with the rules of good laboratory practice and that appropriate personal protective equipment be used.
4. Do not use the reagent if it is visibly degraded (e.g. presence of corpuscles).
5. All human samples shall be handled and disposed of as potentially infectious material.
6. The kit should only be used by qualified and properly trained technical personnel.
7. Diagnoses shall be carried out exclusively by authorised and qualified personnel.
8. Comply with national directives on occupational safety and quality assurance.
9. Use equipment that complies with current regulations.

Reporting 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.

PROCEDURE

Quality control

Control sera with a known titer of Uric Acid are commercially available for quality control, with values and confidence limits included. Sclavo Diagnostics Normal and pathological control sera are available: Clinicontrol N 5x5mL cod. B35181700 and Clinicontrol A 5x5 mL code B35181701. The values obtained must be within the acceptability range.

Calibration

For calibration use the "Calibrator serum Sclavo" code B35181702.

Traceability

The Uric Acid traceability is reported in the package insert supplied with the "Calibrator Serum".

SAMPLE

Type of sample and storage

Serum or Heparinized-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 four days, if stored at 4-8°C.

PREPARATION OF THE REAGENT

Liquid reagents are ready for use. After opening, the reagents are stable for 30 days if kept closed at a temperature of 2-8°C and protected from direct light. A slight variation in color from batch to batch, does not affect the test results.

Automation

The kit can be used with all automatic analyzers that can meet the operating conditions of the reagent while maintaining the volumetric ratios R1 / R2 / C. Validated applications are available for Sclavo Konelab® - Indiko® and CHEMILAB instruments. Applications not approved by Sclavo Diagnostics do not guarantee the performance of the reagent and must therefore be approved under the responsibility of the user.

MANUAL METHOD

The kit, in Open format, can be used manually through the use of spectrophotometer or photometer with the following parameters:

Reaction conditions

Wavelength (primary):	510 nm
Temperature:	37°C
Reaction	End Point (Increasing reaction)

Technical

Bring the reagents to reaction temperature and operate away from direct light.

	U.M.	Blank	Calibr. Serum	Sample
Reagent A	µL	1000	1000	1000
Calibr. Serum	µL	-	30	-
Sample	µL	-	-	30
Blank	µL	30	-	-

Mix well and let stand for 1 minute at 37°C.

	U.M.	Blank	Calibr. Serum	Sample
Reagent B	µL	250	250	250

Mix, then incubate for 5 minutes at 37°C. Measure the absorbance of sample and calibrator serum against the reagent blank. The colour obtained is stable for about 60 minutes.

The reaction volumes may be varied proportionally without alteration of results.

Sclavo Diagnostics International
Loc. Pian dei Mori, via Po n° 26-28 • 53018 (SI) (Italy)
Phone +39 0577 390 41 • fax +39 0577 390 444
www.sclavodiagnostics.com

Results:

Manual Method

The conversion factor mg/dL- µmoli/L is equal to 59,6.
Calculation of Uric Acid concentration:

$$\frac{\text{O.D. Sample}}{\text{O.D. Calibrator Serum}} \times \text{Calibr.Serum Concentration} = \text{Uric Acid mg/dL}$$

Automation

The results are automatically calculated by the analyzer based on the calibration line. The analyzer automatically performs calibration in accordance with the method protocol. The calibration line is calculated automatically by the different instruments.

REFERENCE RANGE

Serum/Plasma

		Female	Male
Adults	mg/dL (mmol/L)	2.6–6.0 (155–357)	3.5-7.2 (208-428)
Children			
0 – 5 days	mg/dL (mmol/L)	1.9-7.9 (113-470)	1.9-7.9 (113-470)
1 – 4 years	mg/dL (mmol/L)	1.7-5.1 (101-303)	2.2-5.7 (131-340)
5 – 11 years	mg/dL (mmol/L)	3.0-6.4 (178-381)	3.0-6.4 (178-381)
12 – 14 years	mg/dL (mmol/L)	3.2-6.1 (190-363)	3.2-7.4 (190-440)
15 – 17 years	mg/dL (mmol/L)	3.2-6.4 (190-381)	4.5-8.1 (268-482)

Urine

≤800 mg/24h (4.76 mmol/24h) With normal diet
≤600 mg/24h (3.57 mmol/24h) With low-purine diet

Each laboratory must establish its own normal-range values on the basis of its population.

ANALYTICAL CHARACTERISTICS / PERFORMANCE

Linearity

The method is linear up to 25 mg/dL (1487 µmol/L) of Uric Acid. If the value in the sample exceeds the linearity limit of the method, dilute the sample with saline and multiply the result for the dilution factor.

Accuracy-Recovery

Commercial control sera were analyzed with the Uric Acid kit following the guidelines of the CLSI protocol. The data obtained are reported in the following table:

Serum/Plasma

Range	Replicates	Mean	DS	CV%	Recovery
Low	5	3.41	0.04	1.18	105%
High	5	9.51	0.07	0.75	104.5 %

Urine

Range	Replicates	Mean	DS	CV%	Recovery
Low	5	83,6	1,14	1,36	97,4 %
High	5	189	2,38	1,26	90,1 %

Interference

Interference	Limits
Bilirubin	**20 mg/dL**
Triglycerides	**2000 mg/dL**
Haemoglobin	**50 mg/dL**
Ascorbic Acid	**30 mg/dL**

Precision of the method

Accuracy in the series (Within-run precision) – Repeatability					
Range	U.M.	Mean	S.D.	C.V. (%)	No.
Low	mg/dL	5.00	0.25	4.90	30
High	mg/dL	8.10	0.13	1.56	30
Total precision (Within-lab precision)					
Range	U.M.	Mean	S.D.	C.V. (%)	No.
Low	mg/dL	4.92	0.11	2.32	20
High	mg/dL	7.97	0.12	1.49	20

Limit of Sensitivity

The Sensitivity limit has been measured using serial dilutions of high concentrated sera. The smallest detectable concentration is of about 0.30 mg/dL (17.8 µmol/L) of Uric Acid in the conditions established for this test.

Comparison between methods

The method was compared with a similar commercially available method, analyzing 21 human samples. The correlation data between the two methods are reported in the table below.

Parameter	Estimation
Intercept	0.391
Slope	1.063
Correlation Coeff. (R)	0.998

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

REFERENCES

1 **Thomas L. (1998)** Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft;. p. 208-14.
2 **Newman DJ, Price CP. (1999)** Renal function and nitrogen metabolites. In: Burtis CA, Ashwood ER, editors. Tietz ext book of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; p. 1204-70.
3 **Guder WG, Zawta B et al.** The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001.p. 48-9, 52-3.
4 **Newman JD, Price PC. (1999)** Renal function and nitrogen metabolites. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia:W.B Saunders Company; p. 1250.
5 **Clinical Laboratory Standards Institute (CLSI).** User Verification of Performance for Precision and Trueness; Approved Guideline – Second Edition. EP15-A2.
6 **Clinical Laboratory Standards Institute (CLSI).** Evaluation of Precision Performance of Quantitative Measurements Methods; Approved Guideline – Second Edition. EP05-A2.
7 **Clinical Laboratory Standards Institute (CLSI).** Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline – Third Edition. EP09-A3.
8 **Clinical Laboratory Standards Institute (CLSI).** Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures, 2nd Edition – EP17
9 **Clinical Laboratory Standards Institute (CLSI).** Interference Testing in Clinical Chemistry, – Third Edition. - EP07.
10 **Clinical Laboratory Standards Institute (CLSI).** Evaluation of Linearity of Quantitative Measurement Procedures, 2nd Edition - EP06.

REVISION	DATE	CHANGE
Rev.A	01/2023	New Issue for IVDR Regulation (UE) 2017/746 compliance

Sclavo Diagnostics International
Loc. Pian dei Mori, via Po n° 26-28 • 53018 (SI) (Italy)
Phone +39 0577 390 41 • fax +39 0577 390 444
www.sclavodiagnostics.com