SyRe Accute

AGAPPE

URIC ACID

4 x 50 mL
12006024

Intended Use
This reagent is intended for *in vitro* quantitative determination of Uric acid in serum, plasma & urine.
Uricase - PAP method
-Linear up to 25 mg/dL

Clinical Significance
Uric acid is the end product of purine metabolism. Uric acid is excreted by the kidneys. Increased levels are found in Gout, arthritis, impaired renal functions & starvation. Decreased levels are found in yellow atrophy of the liver.

Principle
Enzymatic determination of Uric acid according to the following reactions.

$$\text{Uric acid} + 2H_2O + O_2 \xrightarrow{\text{Uricase}} \text{Allantoine} + CO_2 + H_2O_2$$

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

EHSPT: N-Ethyl-N-(2-Hydroxy-3-sulfopropyl)m-Toluidine

Kit Components

Reagent/ Component	Product Code 12006024	Description	
Uric Acid Reagent	4 x 50 mL	EHSPT	0.72 mmol/L
		Phosphate Buffer (pH 7.0)	100 mmol/L
		Ferrocynide	0.03 mmol/L
		Amino -4-antipyrine	0.37 mmol/L
		Peroxidase	≥12000 U/L
		Uricase	≥ 150 U/L
		Sodium Azide	< 0.1%

Risk & Safety
Material Safety data sheets (MSDS) will be provided on request

Reagent Preparation
Uric Acid Reagent is ready to use.

Reagent Storage and Stability
The sealed reagents are stable upto the expiry date stated on the label, when stored at 2-8°C.

Open Vial Stability
Once opened the reagents are stable up to 60 days if contamination is avoided.

On-board Calibration Stability
Calibration is stable for 20 days.

Reagent Deterioration
Turbidity or precipitation in any kit component indicates deterioration and the component must be discarded. Values outside the recommended acceptable range for the Agappe Qualicheck Norm & Path control may also be an indication of reagent instability and associated results are invalid. Sample should be retested using fresh vial of reagent.

Precaution
To avoid contamination, use clean laboratory wares. Close reagent bottles immediately after use. Avoid direct exposure of reagent to light. Do not blow into the reagent bottles.
This reagent is only for IVD use and follow the normal precautions required for handling all laboratory reagents.

Waste Management
Reagents must be disposed off in accordance with local regulations.

Sample
Serum, EDTA or Heparin plasma (Do not use lipemic or hemolysed sample)
Urine (1/10)diluted with distilled water.

Interferences
No interference for
Bilirubin up to 10 mg/dL
Haemoglobin up to 1000 mg/dL

Materials provided
Uric Acid Reagent

Reagents required but not provided
Multicalibrator (Product Code: 11610001), Qualicheck Norm (Product Code: 11601003), Qualicheck Path (Product Code: 11601002)

Unit Conversion

Traditional Unit	SI Unit	Conversion from Traditional to SI
mg/dL	mmol/L	x 0.059

Calibration
Agappe Multicalibrator (Product Code: 11610001) is recommended for calibration of the assay.

Quality Control
It is recommended to use Qualicheck Norm (Product Code: 11601003) or Qualicheck Path (Product Code: 11601002) to verify the performance of the measurement procedure.
Each Laboratory has to establish its own internal quality control scheme and procedures for corrective action if controls do not recover within the acceptable tolerance.

Reference Range
It is recommended that each laboratory should establish its own reference values. The following value may be used as guide line.
Serum / Plasma
Child : 2-5 mg/dL
Adult male : 3.5-7.2 mg/dL
Adult female : 2.6-6 mg/dL
Urine : 250 – 750 mg/24 hr urine.

Results obtained for patient samples are to be correlated with clinical findings of patient for interpretation and diagnosis.

Performance
1. Linearity
The reagent is linear up to 25 mg/dL. If the concentration is greater than linearity (25 mg/dL), dilute the sample with normal saline and repeat the assay. Multiply the result with dilution factor.
2. Comparison
A comparison study has been performed between Agappe reagent and another internationally available reagent yielded a correlation coefficient of r^2= 0.9631 and a regression equation of y = 1.001x.
3. Precision

	Intra Run		Inter Run	
Control	Level 1	Level 2	Level 1	Level 2
n	20	20	20	20
Mean (mg/dL)	4.8	9.6	4.7	9.4
SD	0.15	0.29	0.15	0.26
CV(%)	3.1	3.0	1.56	2.7

Accuracy (mg/dL)		
Control	Expected Value	Measured Value
Control Level 1	4.96 ± 0.75	4.92
Control Level 2	10.0 ± 0.99	9.89
Qualicheck Norm	5.36 ± 0.99	5.39
Qualicheck Path	10.4 ± 1.75	10.29

4. Sensitivity
Lower detection Limit is 0.2 mg/dL

Bibliography

1. Barham,D.,Trider P., Analyst 97,142 (1972)
2. Fossati P., Prencipe L., Berti G., Clin Chem., 26, 227 (1980)
3. Kaplan LA, Pesce AJ., Clinical Chemistry, Mosby Ed. 1989
4. Burtis, Ashwood, Bruns & Saunders : Tietz Text Book of Clinical Chemistry 4th Edition - 2006.

SYMBOLS USED ON THE LABELS

IVD IN VITRO DIAGNOSTIC USE | SEE PACKAGE INSERT FOR PROCEDURE | LOT LOT NUMBER | MANUFACTURER'S ADDRESS | MANUFACTURING DATE | EXPIRY DATE | TEMPERATURE LIMIT

AGAPPE DIAGNOSTICS LTD.
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REV. NO.: ADL/IFU/UAC/40FR/R02
CE ISO 9001:2015
EN ISO 13485:2016

Accute 40 FR Assay Parameter

Page 1	
Test	URIC ACID
Reaction Mode	End
Reference Test ID	**
Test WL	548
Blank WL	660
Test Read Timing	38-40
Blank Read Timing	NA
Sample	5 µL
R1	200 µL
R2	NA
Stirrer	OFF
Cal Mode	std
Page 3	
Calibration Mode	Linear
** Not applicable	
# - Input Programme Number only for sample Blanking parameters	

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