SyRe Accute

AGAPPE

UREA U V

4 x 50/2 x 30 mL
12006023

Intended Use
This reagent is intended for *in vitro* quantitative determination of urea in serum, plasma & urine.
-Urease / GLDH methodology
-Linear up to 300 mg/dL

Clinical Significance
Proteins cannot be stored in human body, so excess should be broken down. Amino acids which form the components of proteins break down to give ammonia. This is toxic & so through a series of chemical reactions (urea cycle) non toxic urea is produced & this is released into the blood which is filtered in the kidney & excreted in the urine.
Elevated levels are seen during increased protein breakdown, dehydration, vomiting, and diarrhea. Also seen in any kind of renal disorder like Glomerular nephritis, chronic nephritis & nephritic syndrome.

Principle

$$\text{Urea} + H_2O \xrightarrow{\text{urease}} 2NH_3 + CO_2$$

$$2NH_4^+ + 2\alpha\text{-ketoglutarate} + 2NADH \xrightarrow{GLDH} 2L\text{-Glutamate} + 2NAD^+ + 2H_2O$$

Kit Components

Reagent/ Component	Product Code 12006023	Description	
Urea U V R1	4 x 50 mL	Buffer (pH 7.6)	100 mmol/L
		ADP	0.7 mmol/L
		α-ketoglutarate	9.0 mmol/L
Urea U V R2	2 x 30 mL	GLDH	≥1100 U/L
		Urease	≥6500 U/L
		NADH	0.25 mmol/L
		2-Oxoglutarate	5 mmol/L

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

Reagent Preparation
Urea U V R1 & R2 Reagents are 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,Plasma (Do not use lipemic or hemolysed sample) - Do not use anticoagulants containing fluorides and ammonium ions.
Urine - Diluted to 1/100 with distilled water. Multiply the result with dilution factor.

Interferences
No interference for

Bilirubin up to	20 mg/dL
Ascorbic acid up to	50 mg/dL
Haemoglobin up to	1000 mg/dL

Materials provided
Urea U V R1 & R2 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 0.1665

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 : 10-50 mg/dL
Urine : 20-35 gm/24 hr
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 300 mg/dL. If the concentration is greater than linearity (300 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= 0.9828 and a regression equation of y = 0.9706x.
3. Precision

	Intra Run		Inter Run	
Control	Level 1	Level 2	Level 1	Level 2
n	20	20	20	20
Mean (mg/dL)	36	96	35.8	96.1
SD	1.2	2.0	1.0	2.4
CV(%)	3.3	2.08	2.7	2.4

Accuracy (mg/dL)		
Control	Expected Value	Measured Value
Control Level 1	32.6 ± 9.8	32.3
Control Level 2	102 ± 23	103
Qualicheck Norm	40 ± 8.42	41.6
Qualicheck Path	126 ± 18	127.3

4. Sensitivity
Lower detection Limit is 1 mg/dL

Bibliography

1. Talke, H. and Schubert G.E.Kiln-Wocchsr 43: 174 (1965)
2. Kassirer,J.P.,New Eng. J.Med. 285,385 (1971)

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/UUV/40FR/R01
CE ISO 9001:2015
EN ISO 13485:2016

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Accute 40 FR Assay Parameter

Page 1	
Test	UREA U.V
Reaction Mode	Rate
Reference Test ID	**
Test WL	340
Blank WL	NA
Test Read Timing	36-42
Blank Read Timing	NA
Sample	3 µL
R1	200 µL
R2	50 µL
Stirrer	ON
Cal Mode	std
Page 3	
Calibration Mode	Linear
** Not applicable	
# - Input Programme Number only for sample Blanking parameters	

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