QUANTON BIOLIFE SCIENCES
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UREA (UV) TEST KIT
UV- GLDH Method

QBL/PDS/URU_026

Quantitative determination of Urea in serum / Plasma / Urine
Only for *In Vitro* Diagnostic use

ORDER INFORMATION

REF	Cont.
URU 100	2 X 50 mL
URU 200	4 X 50 mL
URU 125	5 X 25 mL
URU 25	1 X 25 mL

CLINICAL SIGNIFICANCE
Urea is the final result of the metabolism of proteins; It is formed in the liver from their destruction. It can be elevated in blood in: diets with excess of proteins, renal diseases, heart failure, gastrointestinal hemorrhage, dehydration or renal obstruction. Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

Method
"Urease – GLDH": enzymatic UV test

PRINCIPLE
Urea is hydrolysed in the presence of water and urease to produce ammonia and carbon dioxide. The ammonia produced combines with alfa-oxoglutarate and NADH in the presence of glutamate dehydrogenase to yield glutamate and NAD.

REAGENT
Reagent 1 : Buffer reagent
Reagent 2 : Enzyme reagent
Urea Standard : 50 mg/dl

REAGENT PREPARATION
Mix 4 parts (4 ml) of Buffer reagent with 1 part (1 ml) of Enzyme reagent.

REAGENT STORAGE AND STABILITY
The Reagent is stable till expiry when stored at 2 - 8°C.
Store protected from light.

WARNING AND PRECAUTIONS
- For in vitro diagnostic use.
- Do not use components beyond the expiration date.
- Do not mix materials from different kit lot numbers.
- Exercise the normal precautions required for handling all laboratory reagents.
- The reagent contains preservative. Do not swallow. Avoid contact with skin and mucous membranes.
- For detailed information refer Material Safety Data Sheet.

WASTE MANAGEMENT
Please refer to local legal requirements.

MATERIALS REQUIRED BUT NOT PROVIDED
- NaCl solution 9 g/L
- General laboratory equipment

SAMPLE COLLECTION AND PRESERVATION
Serum, heparin plasma or EDTA plasma urine
Dilute urine 1 + 40 with dist. water and multiply results by 50.
Stability: 7 days at 4 – 8°C
1 Year at –20°C
Stability in urine:
2 days at 20 – 25°C
7 days at 4 – 8°C
1 month at –20°C
Discard contaminated specimens! Freeze only once!

ASSAY PROCEDURE
Operating Instructions
- Check reagent inventories at least daily to ensure that quantities are sufficient for the planned work load.
- Bring all reagents, standard and samples to room temperature 18 - 28ºC, prior to analysis.

AUTOMATED PARAMETERS	
Wavelength	340 nm
Measurement	Against distilled water
Reaction	Fixed Time Kinetic
Cuvette	1 cm light path
Reaction Temperature	37°C
Reaction Direction	Decreasing
Sample Volume	10 µl
Working Reagent Volume	1000 µl
Delay/Lag/Time	30 Secs
Interval Time	60 Secs
No. of Readings	01
Blank Absorbance Limit	> 0.8
Low Normal at 37°C	15 mg/dl
High Normal at 37°C	50 mg/dl
Linearity at 37°C	300 mg/dl

MANUAL ASSAY PROCEDURE
Pipette into Test Tubes

	STD	SAMPLE
STANDARD	10 µl	-
SAMPLE	-	10 µl
WORKING REAGENT	1000 µl	1000 µl

- Mix well and read after 30 secs initial absorbance of sample (A1s) and standard (A1std) and start timer simultaneously. Read again, after 60 secs.

SAMPLE DILUTIONS
- This method is linear upto a concentration of 300 mg/dL.
- Dilute samples above this concentration 1:1 with 0.9% saline
- Repeat assay. Multiply the result by 2.

CALCULATION
Serum / Plasma

$$\text{Urea mg/dL} = \frac{\text{Abs.of Sample (AT)}}{\text{Abs.of Standard (AS)}} \times \text{Standard Value (50mg/dL)}$$

Urine

$$\text{Urea mg/dL} = \frac{\text{Abs.of Sample (AT)}}{\text{Abs.of Standard (AS)}} \times \text{Standard Value (50mg/dL)} \times 50$$

CLIBRATORS AND CONTROLS
For the calibration of automated photometric systems the commercially available suitable multi-calibrator is recommended.

The assigned values of **Urea standard** have been made traceable to NIST SRM®-909.

It is recommended to run a normal and a pathological control serum which is commercially available to verify the performance of the measured procedure. The value of controls should fall within the established limit.

Each laboratory should establish corrective action in case of deviations in control recovery.

PERFORMANCE CHARACTERISTICS

WITHIN RUN

Sample	Mean Concentration	SD	CV %
Randox 2	43.96	0.02	0.05%
Randox 3	122.42	0.27	0.22%

RUN TO RUN

Sample	Mean Concentration	SD	CV %
Randox 2	43.95	0.02	0.05%
Randox 3	122.47	0.19	0.16%

LINEARITY

The method is linear upto a concentration of 300 mg/dL. Dilute samples above this concentration 1:1 with 0.9% saline solution and repeat assay. Multiply the result by 2.

Limit of detection: The limit of detection for Urea is 3 mg/dL.

METHOD COMPARISON

A comparison of Paramcare Urea with a commercially available assay (x) using 20 samples gave following results: $R^2 = 0.990$

REFERENCE VALUES

Serum, plasma	15 - 50 mg/dl
Urine	20 - 35 g/24h

The reference values are to be considered as indicative only. Every laboratory should establish its own normal range.

LIMITATION OF THE PROCEDURE

- For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

INTERFERENCE

- Bilirubin: No interference found upto Bilirubin 50 mg/dl.
- Hemoglobin: No interference found upto 400 mg/dL.
- Lipemia: No interference found upto 1000 mg/dL.
- Ascorbic Acid: No interference found upto 50 mg/dL.
- These characteristics have been obtained using an automatic analyzer. Results may vary if a different instrument or a manual procedure is used.

BIBLIOGRAPHY

1. Teitz.N.W.; Fundamentals of clinical chemistry, Philadelphia, W.B. Saunders & Co., Philadelphia, PA, p991 (1976)., Talke H, Schubert GE, Klin Wchers., (1965), 43, 174.

GLOSSARY OF SYMBOL

	Consult Instruction for Use
	Catalog Number
	Store between
	Manufacturer
	Keep away from sunlight

Paramcare Life Sciences Private Limited, G/F-12/13, Evershine-2, Survey No. 307/3/1, Balitha N.H No 48, Vapi, Valsad, Gujarat, 396191.

Quanton Biolife Sciences Private Limited
Anand Mangal Apartment, Behind Axis Bank,
Dak Bunglow Road, Ghatsila, East Singhbhum
Jharkhand - 832303, India
quantoncare@qblsci.com
www.quantonbiolifesciences.com