

Intended Use:

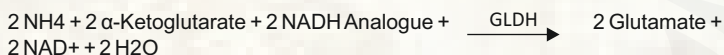
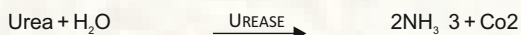
Kit for the quantitative determination of urea in human serum, plasma and urine.

Summary and Explanation

Urea is a metabolic product derived sequentially from the catabolism of either exogenous or endogenous tissue proteins. It is the major nitrogen containing metabolic product of protein catabolism in humans accounting for more than 75% of the non-protein nitrogen eventually excreted. Urea is typically measured in conjunction with creatinine to differentiate between pre-renal and post-renal uraemia. Pre-renal uraemia is observed in cardiac de-compensation, water depletion and increased protein catabolism. Post-renal uraemia is observed in glomerular nephritis, chronic nephritis, polycystic kidney and nephrosclerosis. nt.

Principle of the test:

Urea is converted in the presence of urease to ammonia. Ammonia is then linked with alpha ketoglutarate in the presence of glutamate dehydrogenase (GLDH) with the subsequent conversion of NADH Analogue to an NAD. The rate of NADH Analogue consumption is directly proportional to the urea concentration in the patient sample. Enzymatic determination according to the following reactions:



Reagent Composition:

Component	Ingredients	Concentration in Tests
Reagent 1	TRIS Buffer	pH 7.95
	α-KG	80.0 mmol/l
	ADP	16.0 mmol/l
	Urease	1.00 mmol/l
	GLDH	20000 U/l
	Preservatives and Stabilizers	500 U/l
Reagent 2	α-Ketoglutarate	150 mmol/l
	NADH	1.83 mmol/l
	Preservatives and Stabilizers	
Standard	Urea	8.35 mmol/l

Type of specimen:

Use serum, heparin or EDTA plasma as specimen (do not use ammonium heparin). Collect urine without using preservatives. It is recommended to follow NCCLS procedures (or similar standardised conditions) regarding specimen handling. Specimen should be collected in an appropriate sample container, with proper specimen identification. Serum/plasma should be separated from cells within 2 hours after collection. Stability 4: up to 7 days at 4°C.

Urine should be diluted 1:20 with distilled water. Multiply results obtained by dilution factor. Stability 4: up to 7 days at 4°C

Reagent presentation and stability:

Reagent 1 and 2 are liquid stable and are ready for use.

Test Procedure:

Reagent	S	T
Reagent-1	800 µl	800 µl
Urea Standard (Conc. 50 mg/dl)	10 µl	----
Specimen	----	10 µl
Reagent-2	200 µl	200 µl

Gently mix and immediately aspirate in to the analyzer. Measure the change in Optical Density (ΔOD/min) between 30 Seconds(A1) and 120 seconds (A2) in a Fixed Time Programme at 340 nms

System Parameters:

Reaction Type (Mode)	:	Fixed Time
Reaction Direction	:	Decreasing
Wave Length	:	340 nm
Flow Cell Temp.	:	37°C
Zero Setting with	:	Distilled Water
Delay Time	:	30 Seconds
Measuring Time	:	120 Seconds
Reagent-1 Volume	:	800 µl
Reagent-2 Volume	:	200 µl
Standard / Sample Volume	:	10 µl
Units	:	mg/dl
Standard Concentration	:	50
Linearity	:	350
High Normal	:	50
Low Normal	:	10

CALCULATIONS:

$$(a) \text{ Serum / Plasma Urea in mg/dl} = \frac{\text{Delta Abs. of T}}{\text{Delta Abs. of S}} \times 50$$

$$(b) \text{ Blood Urea Nitrogen (BUN) in mg/dl} = a \times 0.467$$

$$(c) \text{ Urine Urea in gm / 24 hours} = a \times 24\text{hrs urine volume in litres}$$

$$\text{Urine UREA/BUN in gm/24hours} = \text{Conc. of UREA in gm/L} \times 24 \text{ hours Urine Collected in Liters.}$$

Estimation of UREA /BUN in Urine (gm/24 hours) Procedure

Measure and record 24 hrs urine volume collected in liters.
Determine the UREA/ BUN Conc. in mg/dl using High-Q Urea-UV FT Kit

Convert the UREA/BUN Conc. into mg/L by multiplying with factor "10".
Convert the UREA/BUN Conc. from mg/L to gm/L by dividing with "1000".
Multiply the UREA/BUN conc. which is in gm/L with 24 hrs urine collected in liters to get the UREA/BUN Conc. in gm/24hrs.



Precision and Reproducibility:

Serum
Reproducibility was determined using human samples and controls between day (n = 20). The following results were obtained:

Sample	Within run		
	Mean mg/dl	SD mg/dl	CV %
Sample 1	39.61	0.88	2.21
Sample 2	90.95	5.65	6.21
Sample 3	139.78	1.95	1.40

Sample	Between day		
	Mean mg/dl	SD mg/dl	CV %
Sample 1	39.85	1.52	3.81
Sample 2	89.48	3.47	3.87
Sample 3	140.20	5.27	3.76

References:

Chaney, A.L. and Marbach, E.P. (1962) Clin. Chem. 8, 130

Tietz NW. Fundamentals of Clinical Chemistry Philadelphia, Pa: WB Saunders Co 1976:991

Ordering information

Cat No	Pack Size	Presentation
P-URE (E)-100	4 x 25 ml	Two Liquid Reagents and Standard
P-URE (E)-250	10 x 25 ml	
















Product Features

- Liquid Stable, Ready to use Two Reagents.
- Incorporates 5 th Gen NADH Analogue.
- 150 Seconds Fixed Time Assay (30 Sec Delay + 120 Sec Measuring)
- Linearity 350 mg/dl
- Measuring Wavelength 340 nms
- Aqueous Urea Standrad provided (Standrad Conc: 50 mg/dl)
- BUN values can be estimated
- Serum/ Heparinized or EDTA Plasma/ Diluted Urine as specimens
- Available as multipurpose reagents and dedicated system packs



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Biotech**
A game changer in IVD

Symbols used with IVD devices

	Date of manufacture		Manufactured by
	In vitro diagnostic device		Keep away from sunlight
	Do not freeze		This way up
	Use by (yyyy-mm-dd or mm/yyyy)		Reagent
	Calibrator Material		Batch code
	Temperature limitation (store at)		Control
	Consult instructions for use		Keep dry Keep away from rain
	Catalog Number		

eIFU Indicator



Pariksha's world inside
SCAN TO EXPLORE MORE

Manufactured in India by :
Pariksha Biotech Pvt Ltd,
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