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

ORDER INFORMATION

REF	Cont.
LURE 100	2 X 50 mL
LURE 200	2 X 100 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

Colorimetric test.

PRINCIPLE

The Berthelot reaction has long been used for the measurement of urea and ammonia. The present method is a modified Berthelot Method. The Urea colorimetric procedure is a modification of the Berthelot reaction. Urea is converted to ammonium by the use of urease. Ammonium ion then reacts with a mixture of salicylate, sodium nitroprusside and hypochlorite to yield a blue-green chromophore. The intensity of the color formed is proportional to the urea concentration in the sample.

REAGENT

Reagent I : Buffer reagent
Reagent II : Enzyme reagent
Reagent III : Color developer (Hypochlorite solution)
Urea Standard : 50mg/dl (8.33 mmol/L)

REAGENT PREPARATION

The Reagent is ready to use.

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 - 28°C, prior to analysis.

AUTOMATED PARAMETERS	
Wavelength	578 nm
Cuvette	1 cm light path
Reaction Temperature	37°C
Measurement	Against Reagent Blank
Reaction Type	End Point
Sample Volume	10 µl
Reagent Volume	1.1 ml + 1.0 ml
Incubation	5 min. + 5 min.
Blank Absorbance Limit	< 0.200
Low Normal	15 mg/dl (2.49 mmol/L)
High Normal	50 mg/dl (8.33 mmol/L)
Linearity	200 mg/dl (33.32 mmol/L)

MANUAL ASSAY PROCEDURE

Pipette into Test Tubes

	BLANK	STD	SAMPLE
REAGENT I	1000 µl	1000 µl	1000 µl
REAGENT II	100 µl	100 µl	100 µl
STANDARD	-	10 µl	-
SAMPLE	-	-	10 µl
Mix well and incubate for 5 mins at 37°C or 10 mins at R.T.			
REAGENT III	1000 µl	1000 µl	1000 µl
Mix well and incubate for 5 mins at 37°C or 10 mins at R.T.			

- Measure the absorbance (AS) of standard, (AT) of test against reagent blank at 578 nm.

SAMPLE DILUTIONS

- This method is linear upto a concentration of 200 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

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

CALIBRATORS 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 %
Level 1	11.68	0.40	3.40%
Level 2	50.50	1.54	3.05%

RUN TO RUN

Sample	Mean Concentration	SD	CV %
Level 1	11.82	0.37	3.10%
Level 2	50.86	1.54	3.03%

LINEARITY

The method is linear upto a concentration of 200 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 Accucare Urea with a commercially available assay (x) using 20 samples gave following results: $R^2 = 0.9900$

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	LOT	Lot Number
REF	Catalog Number		Date of Manufacturing
	Store between		Use By or Expiration Date
	Manufacturer	IVD	For *in vitro* Diagnostic use only
	Keep away from sunlight	CONT	Content of the kit

LAB-CARE DIAGNOSTICS (INDIA) PVT. LTD.
C1 Type, Shed No.: 3225, Chemical Zone,
GIDC Sarigam – 396155, Dist. Valsad, Gujarat, India.
Tel.: +91 22 2554 2109 /1558
Email: accucare@labcarediagnostics.com;
Website: www.labcarediagnostics.com

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