LIQUIZYME

UREA

(NED method)

Code	Product Name	Pack Size
LS029A	Liquizyme Urea (NED method)	100 ml

BEACON

Intended Use

Diagnostic reagent for quantitative in vitro determination of Urea in human serum and plasma.

Clinical Significance

Urea is the end product of protein metabolism. it is synthesized in the liver from the ammonia produced by the catabolism of amino acid. it is transported by the blood to the kidney from where it is excreted. Incresed levels are found in renal disease, urinary obstructions, shock, congestive heart failure and burns. Decresed levels are found in liver failure and pregnancy.

Principle

Urea is an acidic medium condenses with o -phthalaldehyde and nepthy! Ethylene Diamine to form a colored complex. The rate of formation of this complex is measured as an increase in absorbance in a fix time which is proportional to the urea concentration in the sample.

Reagent Composition

Reagent 1 : OPA Reagent

OPA : >1 mmol/l

Reagent 2 : NED Reagent

NED : >1 mmol/l

Reagent 3 : Urea Standard : 50 mg/dl

Ready to use

Materials Required But Not Provided

- Clean & Dry container.
- Laboratory Glass Pipettes or Micropipettes & Tips
- Colorimeter or Bio-Chemistry Analyzer.

Reagent Preparation

Reagent is liquid, ready to use.

Stability And Storage

The unopened reagents are stable till the expiry date stated on the bottle and kit label when stored at +2-+8°C.

Specimen Collection And Handling

Use unheamolytic serum or plasma (heparin, EDTA) and urine. It is recommended to follow NCCLS procedures (or similar standardized conditions).

Stability

5 days : at +2 – +8°C

Discard contaminated specimens.

Calibration

Calibration with the Urea standard provided in the kit is recommended.

Quality Control

It's recommended to run normal and abnormal control sera to validate reagent performance.

Expected Values

Serum : 15 - 50 mg/dl

It is recommended that each laboratory verify this range or derives reference interval for the population it serves.

Performance Data

Data contained within this section is representative of performance on Beacon system. Data obtained in your laboratory may differ from these values.

Limit of quantification : 1 mg/dl
Linearity : 200 mg/dl
Measuring range : 1 – 200 mg/dl

Precision

Intra-assay precision Within run (n=20)	Mean (mg/dl)	SD (mg/dl)	CV (%)
Sample 1	47.45	1.15	2.42
Sample 2	124.90	1.74	1.40

Inter-assay precision Run to run (n=20)	Mean (mg/dl)	SD (mg/dl)	CV (%)
Sample 1	64.8	1.37	2.12

Comparison

A comparison between Urea (y) and a commercially available test (x) using 20 samples gave following results:

y = 0.9615x - 1.0117

r = 0.999

Warning And Precautions

For in vitro diagnostic use. To be handled by entitled and professionally educated person.

Waste Management

Please refer to local legal requirements.

Assay Procedure

Wavelength : 505 nm
Cuvette : 1 cm

Addition Sequence	Standard	Sample
Reagent 1	1000 µl	1000 µl
Standard	50 µl	-
Sample	-	50 µl
Reagent 2	500 µl	500 µl

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Mix well and read the intial absorbamce A_1 for the standard and test after exactly 60 second. Read another absorbance A_2 of the standard and test exactly 60 seconds later at 505 nm. Calculate the change in absorbance for both standard and test

Calculation

$$\text{Urea (mg/dl)} = \frac{\text{Abs. T}}{\text{Abs. S}} \times 50$$

Assay Parameters For Photometers

Mode	Fixed Time
Wavelength 1 (nm)	505
Sample Volume (µl)	50
Reagent 1	1000 µl
Reagent 2	500 µl
Lag time (sec.)	60
Real time (sec.)	60
Incubation temp. (°C)	37
Normal Low (mg/dl)	15
Normal High (mg/dl)	50
Linearity Low (mg/dl)	1
Linearity High (mg/dl)	200
Standard Concentration	50 mg/dl
Unit	mg/dl

References

1. Cornall, A. G., Bardawill, C. J., David, M. M.: J. Biol. Chem. 177, 751, 1949.
2. Doumas, B.T., Bayse, D.D.akol.: Clin. Chem. 27, 1642, 1981.
3. Chromy, V., Fischer, J.: Clin. Chem. 23, 754, 1977.
4. Chromy, V., Fischer, J., Voznieek, J.: Z. Med. Labor.-Diagn. 21, 333, 1980.
5. Tietz Textbook of Clinical Chemistry and Molecular diagnostics. Burtis, C.A.,
6. Ashwood, E.R., Bruns, D.E.; 5th edition, WB Saunders.

Symbols Used On Labels

REF	Catalogue Number		Manufacturer
	See Instruction for Use	LOT	Lot Number
CONT	Content		Storage Temperature
	Expiry Date	IVD	In Vitro Diagnostics

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