

## LYPHOZYME

### UREA (BERTHELOT METHOD)



**BEACON**

| Code   | Product Name   | Pack Size |
|--------|----------------|-----------|
| LP007A | Lyphozyme Urea | 100 ml    |
| LP007B | Lyphozyme Urea | 200 ml    |
| LP007C | Lyphozyme Urea | 500 ml    |
| LP007E | Lyphozyme Urea | 1000 ml   |

#### Intended Use

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

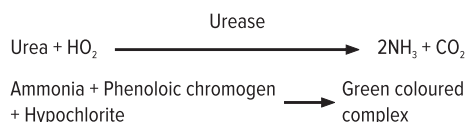
#### Clinical Significance

Urea is the end product of the protein metabolism. It is synthesized in the liver from the ammonia produced by the catabolism of amino acids. It is transported by the blood to the kidneys from where it is excreted. Increased levels are found in renal diseases, urinary obstructions, shock, congestive heart failure and burns. Decreased levels are found in liver failure and pregnancy.

#### Principle

Urease hydrolyzes urea to ammonia and CO<sub>2</sub>. The ammonia further reacts with a phenolic chromogen and hypochlorite to form a green coloured complex. Intensity of the colour formed is directly proportional to the amount of urea present in the sample.

#### Reaction:



#### Reagent Composition

##### Reagent 1 : Urea Enzyme Reagent

Buffer : <100 mmol/l  
Urease : > 5 kU

##### Reagent 2 : Urea Chromogen Reagent

Sodium hypochlorite : Q.S

##### Reagent 3 : Urea Standard : 40 mg/dl

Ready to use

#### Reagent Preparation

Reagent is liquid, ready to use.

#### Materials Required But Not Provided

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

#### Samples

Serum, plasma, Urine. Dilute urine specimen 1 + 49 with distilled water before the assay (results x 50). Urea is reported to be stable in serum for 5 days at 2-8°C.

#### Preparation of Reagent & Stability

Bring all the reagent to room temperature.

#### Working Reagent

- Dissolve the enzyme reagent (Reagent 1) in Deionised water as per volume indicated on the vial.
- Reagent 2 - is ready to use. Allow the reagents to stand for 5 minutes at R.T for equilibration.
- Store the kit at 2°-8 °C away from light.
- Working reagent - after reconstitution is stable for 75 days when stored at 2 - 8°C.
- Reagent 2 - Once open is stable for six months when stored At 2-8 °C.

#### Stability And Storage

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

#### Specimen Collection And Handling

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

#### Stability In Serum :

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 / Plasma : 10 - 50 mg/dl  
Urine : 15 - 30 mg/24 hrs

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 : 300 mg/dl

Measuring range : 1 – 300 mg/dl

#### Precision

| Intra-assay precision<br>Within run (n=20) | Mean<br>(mg/dl) | SD<br>(mg/dl) | CV<br>(%) |
|--|-----------------|---------------|-----------|
| Sample 1                                   | 23              | 0.79          | 3.46      |
| Sample 2                                   | 120             | 1.49          | 1.24      |

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| Inter-assay precision<br>Run to run (n=20) | Mean<br>(mg/dl) | SD<br>(mg/dl) | CV<br>(%) |
|--|-----------------|---------------|-----------|
| Sample 1                                   | 35              | 0.98          | 2.82      |

#### Comparison

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

$$y = 0.979x - 0.104$$

$$r = 0.993$$

#### Interferences

- Lipemia (intralipid 20 g/L) does not interfere.
- Bilirubin (40 mg/dL) does not interfere Hemoglobin (>2 g/L) may affect the results.
- Other drugs and substances may interfere.

#### 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.

#### Procedure:

(S) and Test (T):

| Addition Sequence                         | Reagent Blank | Standard | Sample  |
|---|---------------|----------|---------|
| Working Reagent                           | 1000 µl       | 1000 µl  | 1000 µl |
| Standard                                  | -             | 10 µl    | -       |
| Sample                                    | -             | -        | 10 µl   |
| Mix and incubate 5 min. At 37°C. Then add |               |          |         |
| Chromogen Reagent                         | 1000 µl       | 1000 µl  | 1000 µl |

Mix and incubate for 5 minutes at 37°C. Measure the absorbance of standard (Abs. S) and test (Abs. T) against reagent blank at 630 nm within 60 minutes.

#### Calculation

$$\text{Urea (mg/dl)} = \frac{\text{Abs. of T}}{\text{Abs. of C}} \times 40$$

#### Assay Parameters For Photometers

| Mode                   | End point |
|------------------------|-----------|
| Wavelength 1 (nm)      | 630       |
| Sample Volume (µl)     | 10        |
| Reagent Volume (µl)    | 1000      |
| Incubation time (min.) | 5 + 5     |
| Incubation temp. (°C)  | 37        |
| Normal Low (mg/dl)     | 10        |
| Normal High (mg/dl)    | 50        |
| Linearity Low (mg/dl)  | 1         |
| Linearity High (mg/dl) | 300       |
| Standard Concentration | 40 mg/dl  |
| Blank with             | Reagent   |
| Unit                   | mg/dl     |

#### References

1. Leonard, P. L., Persaud, J., Motwani, R.: Clin. Chim. Acta 35, 409, 1971.
2. Tietz Textbook of Clinical Chemistry and Molecular diagnostics. Burtis, C.A., Ashwood, E.R., Bruns, D.E.; 5th edition, WB Saunders Company, 2012.

#### Symbols Used On Labels



Catalogue  
Number



Manufacturer



See Instruction  
for Use



Lot Number



Content



Storage Temperature



Expiry Date



In Vitro Diagnostics



BEA/24/URB/LP/IFU-02

22/04/2022