# Bioway Chemistry Reagent Series
# The Serum BUN Reagent Kit

***Detection of Blood Urea Nitrogen in Human Serum or Plasma on Chemistry Analyzers***

***Cat. No. R013K11*** ***The Serum BUN Reagent Kit***

## *SUMMARY OF TEST PROCEDURE*

**Figure 1: Procedure Diagram**

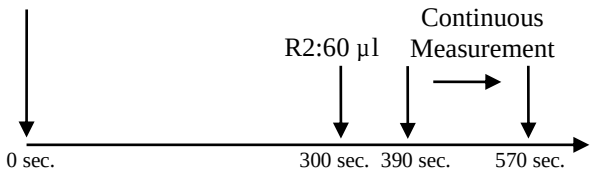


**Table 1: Instrument Parameters***

| | | | |
|---|---|---|---|
| Calibration method | 2-point Linear | Slope of reaction | Decrease |
| Testing wavelength | Dλ : 340 nm<br>Sλ : 405 nm | Sample volume | 6 µl |
| Test method | Rate Method | R1 volume | 240 µl |
| Reaction temperature | 37℃ | R2 volume | 60 µl |

*Refer to Figure 1 and the package insert for detail

## *INTENDED USE*

***Bioway Chemistry Reagent Series*** **BUN Reagent Kit** (the Kit) is an assay intended for *in vitro* quantitative detection of Blood Urea Nitrogen in human serum or plasma on automated clinical chemistry analyzers.

## *SUMMARY AND EXPLANATION*

Urea is major waste product of protein catabolism. It is synthesized in the liver and makes more than half of non-protein nitrogen fraction of the blood. It is then filtered through renal glomeruli into urine and be eliminated from the body. BUN measurements are used in the diagnosis and treatment of renal and metabolic disorders. The concentration of blood urea nitrogen is over or beyond the normal range due to the acute glomerulonephritis, chronic nephritis, polycystic kidney, tubular necrosis, cardiac decompensation, eating disorders or water depletion. Serum urea nitogen and serum creatinine detections are usually performed together in clinical purposes.

## *TEST PRINCIPLES*

The Kit utilizes enzymatic and kinetic reactions to measure the amount of BUN (mmol/L) in human serum or plasma.

$$\text{Urea} + H_2O \xrightarrow{\text{Urease}} 2NH_3 + CO_2$$

$$NH_3 + \alpha\text{-Ketoglutarate} + NADH + H^+ \xrightarrow{\text{GLDH}} \text{Glutamic acid} + NAD^+ + H_2O$$

Urea is converted to ammonia and carbon dioxide by the catalysis of urease. Then the liberated ammonia produced is utilized by glutamic dehydrogenase (GLDH) to convert α-ketoglutarate to glutamic acid, with the concomitant conversion of NADH to $NAD^+$. The process is quantified by measuring the absorabances at 340 nm in a kinetic fashion.

The rate of decrease in absorbance at 340 nm is directly proportional to the BUN activity in the sample.

## *MATERIALS PROVIDED*

**Reagents:**

| | | |
|---|---|---|
| **R1** | Tris buffer, pH8.0<br>NADH<br>GLDH<br>α-Ketoglutarate<br>Sodium azide | 100 mmol/L<br>0.18 mmol/L<br>800 U/L<br>7.5 mmol/L<br>1 g/L |
| **R2** | Urease<br>Sodium azide | 9000 U/L<br>1 g/L |

## *MATERIALS NEEDED BUT NOT PROVIDED*

1. Automated chemistry analyzer
2. BUN control set (commercially available)

## *INSTRUMENT*

The Kit is applicable on most automated chemistry analyzers. Refer to specific instrument application for suggested settings.

## *STORAGE AND STABILITY*

Store the reagents at 2-8℃. Avoid direct sunlight. The Kit is stable through the expiration date when stored properly. The reagent is stable for 1 month at 2-8℃ after opening.

## *PRECAUTIONS*

1. The Kit is for *in vitro* diagnostic use only. Not for use in humans or animals.
2. The instructions must be followed to obtain accurate results.
3. Do not use the reagents beyond the expiration date.
4. Treat all specimens as infectious. Proper handling and disposal procedures of specimens and test materials should be strictly followed.
5. Reagents contain sodium azide as preservative; avoid contact with skin and eyes, flush with copious amounts of water when disposing.

## *SPECIMEN COLLECTION AND HANDLING*

Follow standard laboratory procedures to collect blood or serum preventing hemolysis. 20 times diluted urine is also acceptable. **Do not use fluoride or ammonium ion containing anticoagulants.**
It is recommended to perform test immediately after sample collection. If the test cannot be done immediately, specimens may be stored at 2~8℃ for 3~5 days.

## *TEST PROCEDURE (see Figure 1)*

Reagent 1 and 2 are liquid stable ready-to-use, no preparation needed.

**Calibration:** Recommend using included Bioway calibrator set for optimal results.

**Test procedure**: see Figure 1 and Table 1 for instrument parameter setup. Refer to specific instrument application for suggested setting.

1. Add 6 µl of sample and 240 µl of R1; mix well and incubate at 37℃ for 5 minutes.
2. Add 60µl of R2; mix well and incubate at 37℃ for 1.5 minutes.
3. Take continuous optical density measurement for 3 minutes.
4. Calculate average Δ A /min

Bioway Chemistry Reagent Series

# The Serum BUN Reagent Kit

***Detection of Blood Urea Nitrogen in Human Serum or Plasma on Chemistry Analyzers***

## *RESULT*

The amount of BUN in mmol/L can be obtained by the following calculation:

$$\text{BUN (mmol/L)} = \frac{\Delta A\text{test} / \text{min}}{\Delta A\text{standard} / \text{min}} \times \text{standard solution (mmol/L)}$$

Please refer to instrument application if testing under different conditions.

## *EXPECTED VALUES*

2.9~8.2 mmol/L
It is recommended for each laboratory to establish its own expected values

## *QUALITY CONTROL*

Using commercially available controls with known concentration is recommended before each batch of tests to ensure the test is properly performed and all reagents and the instrument are functional as specified.

## *LIMITATIONS*

1. The Kit is for *in vitro* use on automated chemistry analyzers only.
2. The test result from the Kit should not be used as the only basis for definite diagnosis.
3. Samples with BUN exceeding the maximum measurement range should be diluted with saline and retested.
4. The opened reagent is easy to be contaminated by ammonia in the environment. Be sure to keep it in a clean space and run out as soon as possible.

## *PERFORMANCE CHARACTERISTICS*

**Linearity**: 0 – 33.7 mmol/L (R≥0.990)

**Accuracy**: Bias proportion 90%~110%

**Precision**: Within Run: CV≤4%;
Run-to-Run: CV≤5%

## *REFERENCES*


1. Gentzkow C. J. *et al.*, J. Biol. Chem., 143:513 (1952).
2. Fawcett J. K. *et al.*, J. Clin. Path. 13:156 (1960)
3. Talke *et al.*, 43:174 (1965)


Not Intended for Sale in the United States.


Pointe Biotech (Nanjing) Co., Ltd.

No.85,Xingmin South Road, Jiang Ning District, Nanjing,P.R.China 211100
Tel:86-25-52425019,
Fax:86-25-52424836
info@biowaydx.com