# Bioway Chemistry Reagent Series
# UA Reagent Kit

***Detection of Uric Acid in Human Serum, Plasma or Urine on Chemistry Analyzers***

***Cat. No. R055K11*** ***UA Reagent Kit***

## *SUMMARY OF TEST PROCEDURE*

**Figure 1: Procedure Diagram**

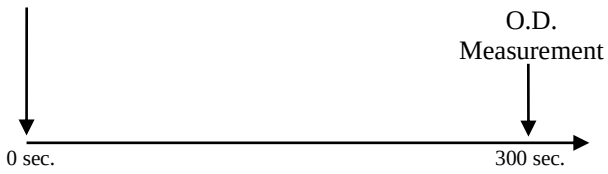


**Table 1: Instrument Parameters***

| | | | |
|---|---|---|---|
| Calibration method | 2-point Linear | Slope of reaction | Increase |
| Testing wavelength | Dλ : 520 nm<br>Sλ : 600 nm | Sample volume | 8 µl |
| Test method | 1 point end | R1 volume | 300 µl |
| Reaction temperature | 37℃ | | |

*Refer to Figure 1 and the package insert for detail

## *INTENDED USE*

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

## *SUMMARY AND EXPLANATION*

Uric acid is a waste product derived from purine metabolism eliminating through the kidneys and gastrointestinal tract. High level serum uric acid may form monosodium urate crystals accumulated inside the bodies and causes gouty arthritis and renal diseases. It also indicates poor kidney and liver function, an increase in nucleoprotein metabolism, such as leukemia and polycythemia.

## *TEST PRINCIPLES*

The Kit utilizes enzymatic reactions to measure the amount of UA (µmol/L) in human serum or plasma.

$$\text{Uric acid} + O_2 + H_2O \xrightarrow{\text{Uricase}} \text{Allatoin} + H_2O_2 + CO_2$$

$$2\,H_2O_2 + \text{4-AAP} + \text{TOOS} \xrightarrow{\text{Peroxidase}} \text{Quinoneimine} + H_2O$$

Uric acid is oxidized in the presence of oxygen and uricase and the produced hydrogen peroxide then reacts with 4-aminoantipyrine (4-AAP) and N-ethyl-N-(hydroxy-3-sulfopropyl)-toluidine (TOOS) to yield quinoneimine which has the highest peak of absorabences at 520nm.

The decrease in absorbance at 520nm is directly proportional to the UA activity in the sample.

## *MATERIALS PROVIDED*

**Reagents:**

| | | |
|---|---|---|
| **R** | Uricase<br>Peroxidase<br>4-AAP<br>TOOS<br>Tris buffer, Ph7.7 | 300 U/L<br>1500 U/L<br>0.45 mmol/L<br>2 mmol/L<br>50 mmol/L |

## *MATERIALS NEEDED BUT NOT PROVIDED*

1. Automated chemistry analyzer
2. UA 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.

## *SPECIMEN COLLECTION AND HANDLING*

Follow standard laboratory procedures to collect blood or serum preventing hemolysis. 10 times diluted urine is also acceptable.
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 7 days.

## *TEST PROCEDURE (see Figure 1)*

Reagent 1 is 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 8 µl of sample and 300 µl of R1; mix well and incubate at 37℃ for 5 minutes.
2. Take optical density measurement.
3. Calculate average Δ A

## *RESULT*

The amount of UA in µmol/L can be obtained by the following calculation:

$$\text{UA (µmol/L)} = \frac{\Delta A\text{test}}{\Delta A\text{standard}} \times \text{standard solution (µmol/L)}$$

Please refer to instrument application if testing under different conditions.

## *EXPECTED VALUES*

Male 208~428 µmol/L
Female 155~357 µmol/L
It is recommended for each laboratory to establish its own expected values

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## *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 UA exceeding the maximum measurement range should be diluted with saline and retested.
4. Avoid high level Vitamin C contaminated in case of getting a lower test result.

## *PERFORMANCE CHARACTERISTICS*

**Linearity**: 0 – 1200 μmol/L (R≥0.990)

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

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

**Interference:** no interference detected for: Unconjugated bilirubin (≦684μmol/L), Ascorbic acid (≦40mg/dl), Bilirubin (≦500mg/dl), Hemoglobin (≦3000NTU), Heparin, EDTA and Sodium Fluoride.

**Reagent Blank Absorbance:** At 520nm wavelength and 10mmoptical diameter, O.D. ≤0.10.

## *REFERENCES*


1. Fossati P. *et al.*, Clin. Chem., 26(2):227 (1980).
2. Morin L.G. *et al.*, J. Clin. Path., 60:691 (1973)
3. Praetorius E. *et al.*, J. Clin. Invest., 5:273 (1953)


Not Intended for Sale in the United States.


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