

Intended Use

Pointe Uric Acid Reagent Set is intended for research use only quantitative determination of Uric Acid in urine using the Yumizen C230 and Yumizen C240 analyzers.

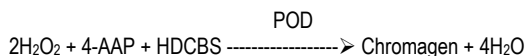
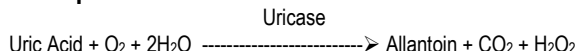
Clinical Significance

The determination of uric acid in urine is useful in determining the cause of hyperuricemia and accessing risk for formation of kidney stones.¹

Test Summary

Uric Acid has been determined by phosphotungstate methods,² variations of the phosphotungstate method³ and iron reduction methods.^{4,5} The above methodologies are influenced by many substances in their procedures as well as many contaminating substances on glassware, etc.⁶ The enzyme Uricase has been widely used for Uric Acid determinations because of its improved specificity.^{7,8} Recently, hydrogen peroxide, a by-product of the Uricase-Uric Acid reaction, has been coupled to other enzymatic reactions to yield a colorimetric end product. The present procedure uses the coupling of 4-aminoantipyrine (4-AAP), 2-Hydroxy-3,5-Dichloro-benzenesulfonate (HDCBS), and hydrogen peroxide in the presence of peroxidase to yield a chromagen measured at 520nm.

Principle



Uric Acid is oxidized by Uricase to allantoin and hydrogen peroxide. HDCBS + 4-AAP + hydrogen peroxide, in the presence of peroxidase, produces a red chromagen that is measured at 520nm. The absorbance at 520nm is proportional to the concentration of Uric Acid in the sample.

Reagent Composition

Uric Acid reagent: 4-AAP >0.2mM, HDCBS 2mM, Uricase (Microbial) >150 U/L, Peroxidase (horseradish) >2,500 U/L, Buffer, pH 8.1 ± 0.1, Non-reactive stabilizers.

Reagent Preparation

The reagent is ready to use.

Reagent Storage and Stability

The reagent set is stored at 2-8°C. Under proper storage the reagent will remain stable until the indicated expiration date.

Precautions

- The reagent should not be used if: The reagent is turbid or contains obvious microbial growth. The reagent blank has an absorbance of 0.500 or greater at 520nm. A pink color is normal for this reagent.
- All specimens and controls should be handled as potentially infectious, using safe laboratory procedures. (NCCLS M29-T2)⁹

Specimen Collection and Storage

- Uric Acid in urine can be stored for up to 4 days at 20-25°C if pH > 8.0.¹⁰
- Collect specimens per NCCLS document GP16-A3.¹¹

Interferences

An extensive list of drugs or other agents interfering with uric acid in urine has been reported by Young, et al¹².

Materials Provided

Uric Acid Reagent

Materials Required but not Provided

- Yumizen C230 / Yumizen C240 Analyzer
- Yumizen C230 / Yumizen C240 Operation manual
- Pointe Chemistry Calibrator, catalog number C7506-50

4. Pointe Human Urine control set, catalog number P7582-CTL

Test Parameters

| | | | |
|----------------|----------|---------------------|-----------|
| Chem: | UA | Chemistry: | Uric Acid |
| Chemistry No.: | 231 | Print Name: | UA |
| Reaction Type: | Endpoint | Reaction Direction: | Positive |
| Pri. Wave: | 510 nm | Sec. Wave: | 670 nm |
| Decimal.: | 0.1 | Samp. Type: | Urine |
| Blank Time: | | Reaction Time: | 35 37 |
| Unit: | mg/dL | Incubation Time: | 0 |

| | Sample Vol. | Aspirated | Diluent | Reagent Vol. | Diluent |
|------------|-------------|-----------|---------|--------------|---------|
| Standard; | 4 | uL | uL | 180 | uL uL |
| Decreased; | | uL | uL | uL | |
| Increased; | | uL | uL | uL | |

| | | | |
|------------------------------|---------------|----------------------|---------------|
| Linearity Range (Standard); | 0.1-100.0 | Linearity Limit: | |
| Linearity Range (Decreased): | | Substrate Depletion: | |
| Linearity Range (Increased): | | Mixed Blank Abs.: | - 40000 40000 |
| R1 Blank Abs.: | - 40000 40000 | On-board Stability: | 30 Day (s) |
| Blank Response | - 40000 40000 | Reagent Alarm Limit: | 10 |
| Twin Chemistry: | | | |

| | | |
|----------------|-----|------|
| Prozone Check: | | |
| Q1: | Q2: | Q3: |
| Q4: | PC: | ABS: |

| | |
|-------------------------|-------|
| Use Qualitative Result: | |
| Range: | Flag: |

| | | | |
|---------------|--------|-------|--|
| Slope Offset: | | | |
| Slope | Offset | Unit | |
| 1 | 0 | mg/dL | |

| | |
|-----------------------|------------------------------|
| Pretreatment: | |
| Pretreat Sample Vol.: | uL Pretreat Reagent Vol.: uL |

| | |
|---------------------------------|-----------------------------------|
| Ref. Range: | |
| Sample Type: Gender: Age Range: | Ref. Range: Critical Range: Unit: |

Calibration Setup Parameters

| | | | | | |
|---------------------|-----------------------------------|------------|-------|-----|----------------|
| Chem: | UA | Calibrator | Conc. | Pos | Lot No. |
| Calibration Setting | | Water | 0.0 | W | |
| Math Model: | Two-Point Linear | Chem Cal | * | * | |
| Factor: Replicates: | 2 | | | | |
| Acceptance Limits | | | | | |
| Cal Time: | | | | | |
| Slope Diff: | SD: | | | | |
| Sensitivity: | Repeatability: | | | | * User Defined |
| Deter Coeff: | | | | | |
| Auto Calib. | <input type="checkbox"/> Cal Time | | | | |

Pointe Uric Acid Reagent Set (UV)

Limitations

1. If the spectrophotometer being used requires a final volume greater than 1.0ml for accurate reading, use 0.075ml (75ul) of sample to 3.0ml of reagent. Perform the test as described above.
2. The procedure described is linear to 100 mg/dl.

Calibration

Use an NIST-traceable calibrator. The procedure should be calibrated according to the instrument manufacturer's calibration instructions. If control results are found to be out of range, the procedure should be re-calibrated.

Calculations (Example)

A = Absorbance

$$\frac{A(\text{Unk})}{A(\text{Std})} \times \text{Conc. of Std (mg/dl)} = \text{Uric Acid (mg/dl)}$$

Example: A (Unk) = 0.126, A (Std) = 0.100, Conc. of Std = 5 mg/dl.

$$\text{Then: } \frac{0.126}{0.100} \times 5 = 6.3 \text{ mg/dl}$$

SI Units (mM/L)

To convert to mM/L, multiply the result (mg/dl) by 10 to convert dl to L and divide by 168 (the molecular weight of Uric Acid).

$$\text{Mg/dl} \times \frac{10}{168} = \text{mM/L} \qquad \text{mg/dl} \times .0595 = \text{mM/L}$$

Example: 6.3mg/dl x .0595 = 0.374mM/L

Quality Control

Urine controls with known normal and abnormal uric acid values should be run routinely to monitor the validity of the reaction. These controls should be run at least with every working shift in which uric acid determinations are performed. It is strongly recommended that each laboratory establish its own frequency of control determination. Quality control requirements should be performed in conformance with local, state, and/or Federal regulations or accreditation requirements.

Expected Values

250-750mg/24 hours¹

It is strongly recommended that each laboratory establish its own normal range.

Performance

1. Assay Range: 0.1 – 100.0 mg/dl
2. Comparison: A study was performed between the Yumizen 200 series analyzers and a similar analyzer and method, resulting in a correlation coefficient of 0.9842 and the regression equation was $y=1.076x-1.45$.
3. Precision: Precision studies were performed using the Yumizen 200 series analyzers following a modification of the guidelines which are contained in NCCLS document EP5-T2.¹³

Within Day (n=20)

| Mean | S.D. | C.V.% |
|------|------|-------|
| 7.8 | 0.31 | 4.0 |
| 19.5 | 0.37 | 1.9 |
| 44.5 | 0.44 | 1.0 |







4. Sensitivity: Limit of blank (LOB): 0.06mg/dl




References

1. Nader Rifai, Andrea Rita Horvath, Carl T. Wittwer. Tietz textbook of clinical chemistry and molecular diagnostics. Sixth Edition. St. Louis : Elsevier, 2018. p. 503. ISBN: 978-0-323-35921-4.
2. Folin, D., Dennis, W., J. Biol. Chem. 13:469 (1913).
3. Caraway, W.T., Clin. Chem. 4:239 (1963).
4. Morin, L.G., J. Clin. Path. 60:691 (1973).
5. Morin, L.G., Clin. Chem. 20:51 (1974).
6. Brochner-Mortenson, K., Medicine 19:161 (1940).

7. Klackar, H.M., J. Biol. Chem. 167:429 (1947).
8. Praetorius, E., Poulson, H., Scand. J. Clin. Invest 5:273 (1953).
9. NCCLS document "Protection of Laboratory Workers from Infectious Disease Transmitted by Blood, Body Fluids, and Tissue", 2nd Ed. (1991).
10. Use of anticoagulants in diagnostic laboratory investigations. WHO publication WHO/DIL/LAB/99.1Rev.2, p.49 (2002).
11. NCCLS. Urinalysis and collection, transportation and preservation of urine specimen; Approved guideline -3rd Edition, NCCLS document GP16-A3 (2009)
12. Young DS. Effects of Drugs on Clinical Laboratory Tests. 4th Edition, Washington, DC, AAC Press (1995) 3: 621-622.
13. NCCLS document "Evaluation of Precision Performance of Clinical Chemistry Devices", 2nd Ed. (1992).

Symbol Key

| | |
|--|--|
|  Use by (YYYY-MM-DD) |  Lot and batch code |
|  Catalog number |  Manufacturer |
|  Temperature limitation |  Consult instructions for use |
| Research use only | |

 12-U7581-120  Manufactured by
HORIBA Instruments Incorporated - Pointe Brand
5449 Research Drive Canton, MI 48188 

Certified to Perform Reagents

The Pointe reagents are certified to be manufactured according to specified parameters. Any Pointe reagent product not meeting specifications through its listed expiration date will be remedied immediately without charge.

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