

Intended Use

For the quantitative determination of Uric Acid in serum using the Yumizen C560 analyzer. **Rx Only.**

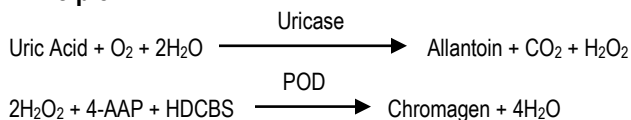
Clinical Significance

The determination of uric acid in serum is most commonly performed for the diagnosis of gout. Increased uric acid levels are also found in leukemia, polycythemia, familial idiopathic hyperuricemia, and conditions associated with decreased renal function.

Test Summary

Uric Acid has been determined by phosphotungstate methods,¹ variations of the phosphotungstate method² and iron reduction methods.^{3,4} The above methodologies are influenced by many substances in their procedures as well as many contaminating substances on glassware, etc.⁵ The enzyme Uricase has been widely used for Uric Acid determinations because of its improved specificity.^{6,7} 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. Manufacturer studies have shown reagent is stable for 30 days once placed in the refrigerated reagent carousel (2-10°C), however reagent stability may vary based on individual laboratory conditions.

Precautions and Hazards

1. This reagent set is for in vitro diagnostic use only.
2. 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.
3. All specimens and controls should be handled as potentially infectious, using safe laboratory procedures. (NCCLS M29-T2)⁸

Hazards:

Hazard Classifications: Specific target organ toxicity, single exposure; Respiratory tract irritation (Category 3)

Hazard Statements: H335: May cause respiratory irritation

Precautionary Statements: **Prevention:** P261: Avoid breathing dust/fume/gas/mist/vapors/spray. P271: Use only in a well-ventilated area

Response: P304+P340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. P312: Call a POISON CENTER or doctor/physician if you feel unwell. **Storage:** P403 + P233: Store in a well-ventilated place. Keep container tightly closed. **Disposal:**

P501: Dispose of contents into sewer system after diluting with large volumes of water, if in accordance with local regulations. **Refer to the Safety Data Sheet for this product (SDS-U7581) available by calling 1-734-487-8300.**



Signal Word: Warning

Specimen Collection and Storage

1. Unhemolyzed serum is recommended.
2. Uric Acid in serum is stable for three days at 2-8°C and up to six months when frozen.⁹
3. Collect specimens per NCCLS document H4-A3.¹⁰

Interferences

1. Elevated ascorbic acid levels can result in falsely depressed uric acid values.
2. Lipemic samples may cause falsely elevated uric acid levels.
3. Hemoglobin to 78.7 mg/dl has been demonstrated to have a negligible effect (<10%) on uric acid values. Hemoglobin greater than 100 mg/dl may cause falsely elevated uric acid values.
4. Bilirubin to 30 mg/dl has been demonstrated to have a negligible effect (<10%) on uric acid results using this method.
5. See Young, et al¹¹ for other interfering substances.

Materials Provided

Uric Acid Reagent

Materials Required but not Provided

1. Yumizen C560 Analyzer
2. Yumizen C560 Operation manual

Pointe Uric Acid Reagent Set

3. Pointe Chemistry Calibrator, catalog number C7506-50
4. Pointe Chemistry control, catalog number C7592-100

Limitations

1. The procedure described is linear to 20 mg/dl. Samples with values exceeding 20 mg/dl should be diluted 1:1 with saline, re-assayed, and the results multiplied by two.
2. Lipemic samples will give falsely elevated results and a serum blank must be run.

Calibration

Use Pointe Chemistry Calibrator (Catalog Number C7506-50). The procedure should be calibrated according to the instrument manufacturer's calibration instructions. If control results are found to be out of range, the test may need to be re-calibrated. Under typical operating conditions manufacturer calibration stability studies have shown the calibration curve will be stable for at least 14 days.

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).

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

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

Quality Control

Serum 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

2.5 - 7.7mg/dl⁹

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

Performance

1. Assay Range: 0.0 – 20.0 mg/dl
2. Correlation: A study was performed between the Yumizen C560 and a similar analyzer using this method, resulting in the following:

Method	Uric Acid
N	100
Mean Uric Acid (mg/dL)	8.20
Range (mg/dL)	0.2-19.8
Standard Deviation	4.58
Regression Analysis	y = 0.988x – 0.01
Correlation Coefficient	0.9977

3. Precision: Precision studies were performed following a modification of the guidelines contained in the NCCLS document EP5-T2.¹²

Sample	Within Day		
	LOW	MID	HIGH
N	20	20	20
Mean	4.89	9.06	16.34
Standard Deviation	0.04	0.05	0.05
Coefficient of Variation (%)	0.7%	0.5%	0.3%

Sample	Day to Day		
	LOW	MID	HIGH
N	40	40	40
Mean	4.77	9.00	16.44
Standard Deviation	0.16	0.25	0.46
Coefficient of Variation (%)	3.4%	2.8%	2.8%

4. Sensitivity: 2SD limit of detection (95% Conf) = 0.0 mg/dL

References

1. Folin, D., Dennis, W., J. Biol. Chem. 13:469 (1913).
2. Caraway, W.T., Clin. Chem. 4:239 (1963).
3. Morin, L.G., J. Clin. Path. 60:691 (1973).
4. Morin, L.G., Clin. Chem. 20:51 (1974).
5. Brochner-Mortenson, K., Medicine 19:161 (1940).
6. Klackar, H.M., J. Biol. Chem. 167:429 (1947).
7. Praetorius, E., Poulson, H., Scand. J. Clin. Invest 5:273 (1953).
8. NCCLS document "Protection of Laboratory Workers from Infectious Disease Transmitted by Blood, Body Fluids, and Tissue", 2nd Ed. (1991).
9. Henry, R.J., Clinical Chemistry: Principles and Technics, 2nd Ed., Hagerstown (MD), Harper & Row, pp. 531 & 541 (1974).
10. NCCLS document "Procedures for the Collection of Diagnostic Blood Specimens by Skin Puncture", 3rd Ed. (1991).
11. Young, D.S., et al. Clin. Chem. 21:1D (1975).
12. NCCLS document "Evaluation of Precision Performance of Clinical Chemistry Devices", 2nd Ed. (1992).

CHEMISTRY PARAMETERS

Chem:	URIC	No.:	231	Sample Type:	Serum
Chemistry:	Uric Acid			Print Name:	URIC
Reaction Type:	End Point			Reaction Direction:	Positive
Pri Wave:	505			Sec Wave:	660
Unit:	mg/dL			Decimal:	0.1
Blank Time:	10	12		Reaction Time:	80 82
	Sample Vol.	Aspirated	Diluent	Reagent Vol.	Diluent
Standard:	2.7 ul	-- ul	-- ul	R1: 120 ul	-- ul
Decreased:	-- ul	-- ul	-- ul	R2: -- ul	-- ul
Increased:	-- ul	-- ul	-- ul	R3: -- ul	-- ul
	<input type="checkbox"/> Sample Blank	<input checked="" type="checkbox"/> Auto Rerun		R4: -- ul	-- ul
<u>Slope/Offset Adjustment</u>					
	Slope: 1	Offset: 0			

Linearity Range (Standard)	0	20	Linearity Limit:
Linearity Range (Decreased)	---	---	Substrate Depletion:
Linearity Range (Increased)	---	---	Mixed Blank Abs:
R1 Blank Abs:	---	---	Uncapping Time
Blank Response:	---	---	Reagent Alarm Limit:
Twin Chemistry:			<input type="checkbox"/> Enzyme Linear Extension
<input type="checkbox"/> Prozone Check		<input type="checkbox"/> Rate Check	<input type="checkbox"/> Antigen Addition
Q1:	Q2:	Q3:	Q4:
PC:	ABS:		

Pointe Uric Acid Reagent Set

CALIBRATION PARAMETERS

Calibrator Definition						
Calibrator:	*	Lot No.:	*			
Exp Date:	*					
Carousel		Pos				
Sample Carousel 1	*					
Sample Carousel 2						
Sample Carousel 3						
Reagent/Calibration						
<u>Calibrator</u>	<u>Pos</u>	<u>Lot No</u>	<u>Exp Date</u>	<u>Chem</u>	<u>Conc</u>	<u>Unit</u>
Water	W	*	*	URIC	0	mg/dL
Chemistry Calibrator	*	*	*	URIC	*	mg/dL
Calibration Setup						
Chem:	URIC					
Calibration Settings						
Math Model:	Two-Point Linear					
Factor:		Replicates:	2			
Acceptance Limits						
Cal Time:	336	Hour				
Slope Diff:	---	SD:	---			
Sensitivity :	---	Repeatability:	---			
Deter Coeff:	---					
Auto Calib.						
<input type="checkbox"/> Bottle Changed	<input type="checkbox"/> Lot Changed	<input type="checkbox"/> Cal Time				

It is recommended that two levels of control material be assayed daily.
* Indicates user defined parameter.

REF 14-U7581-160



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



Certified Performance Guarantee

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.

Manufactured by HORIBA Instruments Incorporated – Pointe Brand
5449 Research Drive, Canton, MI 48188

European Authorized Representative:
Obelis s.a.

Boulevard Général Wahis 53
1030 Brussels, BELGIUM

Tel: (32)2.732.59.54 Fax:(32)2.732.60.03 email: mail@obelis.net



Symbol Key



Use by (YYYY-MM-DD)



Lot and batch code



Catalog number



Manufacturer



Temperature limitation



Consult instructions for use



In vitro diagnostic medical device **Rx Only:** Prescription Use Only