Infinity™
Uric Acid Liquid Stable Reagent

PRODUCT SUMMARY

Stability	:	Until Expiry at 2 - 8°C
Linear Range	:	0.03-1.5 mmol/L (0.5-25.2 mg/dL)
Specimen Type	:	Serum or Urine
Method	:	Enzymatic Endpoint
Reagent Preparation	:	Supplied ready to use.

IVD

SYMBOLS IN PRODUCT LABELLING

EC REP	Authorized Representative		Temperature Limitation
IVD	For in vitro diagnostic use		Use by/Expiration Date
LOT	Batch code/Lot number		CAUTION. CONSULT INSTRUCTIONS FOR USE.
REF	Catalogue number		Manufactured by
	Consult instructions for use		

INTENDED USE
This reagent is intended for the in vitro quantitative determination of Uric Acid in human serum or urine.

CLINICAL SIGNIFICANCE
Uric acid is a metabolite of purines, nucleic acids and nucleoproteins: consequently, abnormal levels may be indicative of a disorder in the metabolism of these substances. Hyperuricaemia may be observed in renal dysfunction, gout, leukemia, polycythaemia, atherosclerosis, diabetes, hypothyroidism, or in some genetic diseases. Decreased levels are present in patients with Wilson's Disease. [1, 2, 3]

METHODOLOGY
This reagent is based upon the methods of Trivedi and Kabasakalian[4,5] with a modified Trinder[6] peroxide assay using 2,4,6-Tribromo-3-hydroxy benzoic acid (TBHB).

The series of reactions involved in the assay system is as follows:

1. $\text{Uric Acid} + O_2 + H_2O \xrightarrow{\textit{Uricase}} \text{Allantoin} + CO_2 + H_2O_2$

2. $2H_2O_2 + \text{4-AAP} + \text{TBHB} \xrightarrow{\textit{Peroxidase}} \text{Quinoneimine} + H_2O$

1. Uric Acid is oxidised to allantoin by uricase with the production of H_2O_2.
2. The peroxide reacts with 4-aminoantipyrine (4-AAP) and TBHB in the presence of peroxidase to yield a quinoneimine dye. The resulting change in absorbance at 520nm (520-550nm) is proportional to uric acid concentration in the sample.

REAGENT COMPOSITION

Active Ingredients	Concentration
4-Aminoantipyrine	0.5 mmol/L
TBHB	1.75 mmol/L
Uricase (Bacillus Sp.)	> 120 U/L
Peroxidase (Horseradish)	> 500 U/L
Tris Buffer	50 mmol/L
pH 8.25 ± 0.1 at 20°C.	

WARNING: Do not ingest. Avoid contact with skin and eyes. If spilt thoroughly wash affected areas with water. Reagent contains Sodium Azide which may react with copper or lead plumbing. Flush with plenty of water when disposing. For further information consult the Infinity Uric Acid Liquid Stable Reagent Material Safety Data Sheet.

CAUTION: This product contains animal source material. Handle and dispose of this product as if it were potentially infectious.

REAGENT PREPARATION
Reagent is supplied ready to use.

STABILITY AND STORAGE
When stored refrigerated at 2-8°C the reagent is stable until the expiry date stated on the bottle and kit box label.

Indications of Reagent Deterioration:
- Turbidity;
- Reagent Absorbance >0.5 AU at 520nm; and/or
- Failure to recover control values within the assigned range.

SPECIMEN COLLECTION AND HANDLING
Collection: No special preparation of the patient is required.
Serum: Use non-haemolysed serum.
Urine: It is recommended that 15 mL of 2 mol/L NaOH be added to the collection vessel. Upon receipt of the urine sample, pH should be checked. If the pH is less than 8.0 it should be adjusted with NaOH. A 1:10 dilution of urine is typically required prior to analysis. [7]
Storage: Serum samples are stable for at least 3 days at room temperature (18-25°C) and for at least 6 months frozen.[2] Stabilized urine may be stored at room temperature for 5 days.[7]

ADDITIONAL EQUIPMENT REQUIRED BUT NOT PROVIDED
- If required, pipettes for accurately dispensing measured volumes.
- A clinical chemistry analyzer capable of maintaining constant temperature (37°C) and measuring absorbance at 520 nm.
- Analyzer specific consumables, eg: sample cups.
- Normal and abnormal assayed control material.
- Calibrator or a suitable aqueous standard (see calibration section).

ASSAY PROCEDURE
The following system parameters are recommended. Individual instrument applications are available upon request from the Technical Support Group.

SYSTEM PARAMETERS

Temperature		37°C
Primary Wavelength		520 nm (520-550 nm)
Secondary Wavelength		600 - 660 nm
Assay Type		Endpoint
Direction		Increase
Sample :	Reagent Ratio	1 : 50
eg:	Sample Vol	3 µL
	Reagent Vol	150 µL
Incubation Time		300 Seconds
Reagent Blank Limits	Low	0.0 AU
(520nm, 1cm light path)	High	0.5 AU
Linearity		0.03-1.50 mmol/L (0.5-25.2 mg/dL)
Analytical Sensitivity (520nm, 1cm light path)		0.42 ΔA per mmol/L 0.025ΔA per mg/dL

CALCULATIONS
Results are calculated, usually automatically by the instrument, as follows:

$$\text{Uric Acid} = \frac{\text{Absorbance of Unknown}}{\text{Absorbance of Calibrator}} \times \text{Calibrator Value}$$

Example:
Absorbance of calibrator = 0.302
Absorbance of unknown = 0.071
Value of calibrator = 0.720 mmol/L (12.1 mg/dL)

$$\text{Uric Acid} = \frac{0.071}{0.302} \times 0.720 = 0.16 \text{ mmol/L}$$

$$\text{Uric Acid} = \frac{0.071}{0.302} \times 12.1 = 2.8 \text{ mg/dL}$$

NOTES
1. The reagent and sample volumes may be altered proportionally to accommodate different spectrophotometer requirements.
2. The color development is stable for 15 minutes.
3. Specimens with Uric Acid concentrations greater than 1.50 mmol/L (25.2 mg/dL) should be diluted with saline and reassayed. Multiply results by the dilution factor.

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4. S.I. unit conversion factor: mmol/L x 16.8 = mg/dL.

CALIBRATION

Calibration is required. An aqueous standard or serum based calibrator, with an assigned value traceable to a primary standard (eg NIST or IRMM) is recommended. Standards should not contain formaldehyde or enzyme inhibitors as preservatives. For calibration frequency on automated instruments, refer to the instrument manufacturers specifications.

However, calibration stability is contingent upon optimum instrument performance and the use of reagents which have been stored as recommended in the stability and storage section of this package insert. Recalibration is recommended at anytime if one of the following events occurs:-

- The lot number of reagent changes.
- Preventative maintenance is performed or a critical component is replaced.
- Control values have shifted or are out of range and a new vial of control does not rectify the problem.

QUALITY CONTROL

To ensure adequate quality control, normal and abnormal control with assayed values should be run as unknown samples:-

- At least once per day or as established by the laboratory.
- When a new bottle of reagent is used.
- After preventative maintenance is performed or a critical component is replaced.
- With every calibration.

Control results falling outside the upper or lower limits of the established ranges indicate the assay may be out of control.

The following corrective actions are recommended in such situations:-

- Repeat the same controls.
- If repeated control results are outside the limits, prepare fresh control serum and repeat the test.
- If results are still out of control, recalibrate with fresh calibrator, then repeat the test.
- If results are still out of control, perform a calibration with freshly prepared reagent, then repeat the test.
- If results are still out of control, contact Technical Services or the local distributor.

LIMITATIONS

1. Studies to determine the level of interference from haemoglobin, bilirubin (free and conjugated) and lipaemia were carried out. The following results were obtained:
   Haemoglobin: No interference from haemoglobin up to 424 mg/dL.
   Free Bilirubin: No interference from free bilirubin up to 212 µmol/L (12 mg/dL).
   Conjugated Bilirubin: No interference from conjugated bilirubin up to 212 µmol/L (12 mg/dL).
   Lipaemia: No interference from lipaemia, measured as absorbance at 630nm, up to 1.68 AU.
2. Young DS[8] has published a comprehensive list of drugs and substances which may interfere with this assay.

EXPECTED VALUES [9]

Child:	0.12 - 0.32 mmol/L	2.0 - 5.0 mg/dL
Adult Male:	0.21 - 0.42 mmol/L	3.5 - 7.2 mg/dL
Adult Female:	0.15 - 0.35 mmol/L	2.6 - 6.0 mg/dL
Urine:	1.48 - 4.43 mmol/day	250 - 750 mg/day

The quoted values should serve as a guide only. It is recommended that each Laboratory verify this range or derives a reference interval for the population it serves. [10]

PERFORMANCE DATA

The following data was obtained using the Infinity Uric Acid Liquid Stable Reagent on a well maintained automated clinical chemistry analyzer. Users should establish product performance on their specific analyzer used.

IMPRECISION

Imprecision was evaluated over a period of 20 days using two levels of commercial control and following the NCCLS EP5-T procedure. [11]

		LEVEL I	LEVEL II
Number of data points		80	80
Mean (mmol/L / mg/dL)		0.279 / 4.69	0.603 / 10.13
Within run:	SD (mmol/L / mg/dL)	0.007 / 0.12	0.009 / 0.15
	CV (%)	2.3	1.5
Total:	SD (mmol/L / mg/dL)	0.019 / 0.32	0.021 / 0.35
	CV (%)	6.8	3.4

METHOD COMPARISON

Comparison studies were carried out using a similar commercially available reagent as a reference. Serum and urine samples were assayed in parallel and the results compared by least squares regression. The following statistics were obtained.

Serum:	
Number of sample pairs	60
Range of sample results	0.11-0.61 mmol/L (1.85-10.25 mg/dL)
Mean of reference method results	0.315 mmol/L (5.29 mg/dL)
Mean of Uric Acid results	0.336 mmol/L (5.65 mg/dL)
Slope	0.931
Intercept	0.042 mmol/L (0.71 mg/dL)
Correlation coefficient	0.987
Urine:	
Number of sample pairs	41
Range of sample results	0.48 - 11.7 mmol/L (8.0 - 196 mg/dL)
Mean of reference method results	3.0 mmol/L (49.6 mg/dL)
Mean of Uric Acid results	2.5 mmol/L (42.7 mg/dL)
Slope	0.967
Intercept	-0.32 mmol/L (-5.3 mg/dL)
Correlation coefficient	0.990

LINEARITY

When run as recommended the assay is linear between 0.03 and 1.50 mmol/L (0.5-25.2 mg/dL).

ANALYTICAL SENSITIVITY

When run as recommended the sensitivity of this assay is 0.42 ΔAbs per mmol/L or 0.025 ΔAbs per mg/dL (1cm light path, 520nm).

REFERENCES

1. Searcy R.L., Diagnostic Biochemistry. McGraw-Hill, New York, NY, 1969.
2. Henry R.J, Common C. and Winkelman J.W. (eds), Clinical Chemistry: Principles and Techniques. Harper & Row, Hagerstown, MD, 1974.
3. Balis M. E., Adv. Clin. Chem. 18(213) 1976.
4. Trivedi R., Berta E. and Rebar L., Clin. Chem. 22(1223), 1976.
5. Kabasakalian P. Kalliney S. and Wescott A. Clin. Chem. 19(522) 1973.
6. Trinder P., J. Clin. Pathol. 22(246) 1949.
7. Shephard MD, Mezzachi RD. Clin Biochem Revs 1983; 4:61-7.
8. Young DS. Effects of Drugs on Clinical Laboratory Tests. Third Edition. 1990; 3:360-370.
9. Tietz Textbook of Clinical Chemistry and Molecular Diagnosis (4th Ed.) Burtis, Ashwood & Bruns (Eds), Elsevier Saunders, 2005; 2301.
10. Wachtel M et al, Creation and Verification of Reference Intervals. Laboratory Medicine 1995; 26:593-7.
11. National Committee for Clinical Laboratory Standards. User evaluation of Precision Performance of Clinical Chemistry Devices. NCCLS; 1984, NCCLS Publication EP5-T.

Fisher Diagnostics
a division of Fisher Scientific Company, LLC
a part of Thermo Fisher Scientific Inc.
Middletown, VA 22645-1905 USA
Phone: 800-528-0494
540-869-3200
Fax: 540-869-8132

EC REP WMDE
Bergerweg 18
6085 AT Horn
The Netherlands

JL840768-en (R1)

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Reorder Information

Catalogue No.	Configuration
TR24321	2 x 125 mL