TECO DIAGNOSTICS
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URIC ACID
ENZYMATIC METHOD
TC MATRIX-160/240

INTENDED USE
For the quantitative determination of uric acid in serum or plasma on TC Matrix analyzers.

SUMMARY AND EXPLANATION OF THE TEST
Uric acid is the end-product of urine metabolism in humans. It circulates and is filtered from the blood by the glomentuli. The determination of serum uric acid for detecting hyperuricemia is helpful in the diagnosis of gout, increased metabolism of nucleoproteins such as in leukemia and polycythemia. Serum uric acid levels also increase with decreased renal function, diabetic ketosis, shock, alcoholism, and starvation.
Uric Acid is converted by uricase into allantoin and hydrogen peroxides. The hydrogen peroxide initiates the coupling of 4-aminoantipyrine to 3,5-dichloro-2-hydroxybenzene sulfonic acid (DHBS) to form the chromogen, which is measured at 505 nm, and which is proportional to the amount of hydrogen peroxide generated from uric acid.
The TC Matrix System automatically proportions the appropriate sample and reagent volumes into the cuvette. The system monitors the change in absorbance at 700 nanometers. This change in absorbance is directly proportional to the concentration of uric acid in the sample and is used by the TC Matrix System to calculate and express the uric acid concentration.

$$\text{Uric acid} + O_2 + 2H_2O \xrightarrow{\text{Uricase}} \text{Allantoin} + CO_2 + H_2O_2$$

$$2H_2O + \text{4-Aminoantipyrine} + \text{DHBS} \xrightarrow{\text{Peroxidase}} \text{Chromogen} + 4H_2O$$

REAGENT PREPARATION
No preparation is required.

REAGENT COMPOSITION
Uricase: 240u/L
4-Aminoantipyrine: 0.85mmol/L
3.5-dichloro-2-hydroxybenzene sulfonate (DHBS): 3.4mmol/L
Horseradish peroxidase: 960 IU/L
Also, non-reactive chemicals for optimal system performance.

REAGENT STORAGE AND STABILITY
Unopened Uric Acid Reagent, stored at 2ºC to 8ºC, is stable until the expiration date shown on the bottle label.

SPECIMEN COLLECTION AND HANDLING
1. The test can be performed on serum and plasma. For serum, blood is drawn into a tube which does not contain anticoagulant and it is allowed to clot. The serum is then separated from the clot. A maximum limit of two hours from the time of collection is recommended.

2. Separated serum or plasma should not remain at room temperature longer than 8 hours. If assays are not completed within 8 hours, serum and plasma should be stored at 2ºC to 8ºC. If assays are not completed within 48 hours, or the separated sample is to be stored beyond 48 hours, samples should be frozen at -15ºC to -20ºC. Frozen samples should be thawed only once. Analyte deterioration may occur in samples that are repeatedly frozen and thawed.

3. For plasma, add whole blood directly into a tube containing anticoagulant. Acceptable anticoagulants are listed in the "LIMITATIONS" section.

CALIBRATION
1. Calibrator required: TECO MULTI Calibrator. (not provided)
2. The system must have a valid calibration in memory before controls or patient samples can be run.
3. The TC Matrix system will automatically perform checks on the calibration and produce data at the end of calibration.

Note: Refer to the TC Matrix 160 manual for further instructions on calibrating the instrument

MATERIALS NEEDED BUT NOT SUPPLIED WITH REAGENT KIT
TECO MULTI Calibrator
At least two levels of control material.

LIMITATIONS
1. The anticoagulants EDTA, Potassium Oxalate, Sodium Fluoride and Sodium Citrate were found to be incompatible with this method.
2. The anticoagulants Ammonium Heparin, Lithium Heparin and Sodium Heparin were found to be compatible with this method.

INTERFERENCE
1. Bilirubin and ascorbic acid can result in falsely depressed uric acid levels.
2. Lipemic samples may cause falsely elevated uric acid levels.
3. Collection tubes containing formaldehyde as a preservative must be avoided.
4. On this method, refer to the work of Young[10] for a review of drug and comprehensive list of substances effect on Uric Acid level.

EXPECTED VALUE
1.5 to 7.0 mg/dL
It is strongly recommended that each laboratory establish its own normal range.

PROCEDURES
Settings for TC-Matrix 160

Test Name:	UA	R1:	150
Full Name:	Uric Acid	R2:	0
Pri. Wave:	505 nm	Sample Volume:	3
Sec. wave:	700 nm	Calibration Type:	2 point linear
Assay/Point:	1 Point End	K value:	/
Start-End:	1 - 10	Point:	2
Decimal Place:	1	Blank Type-	Reagent
Unit:	mg/dl	Point (0) Blank Con.:	0.0
Linearity Range:	1.000– 20.000	Point (1) STD. Con.:	Standard/ Calibration
Correlation Factor: 1.0000-0.0000			

Settings for TC-Matrix 240

Test Name:	UA	R1:	150
Full Name:	Uric Acid	R2:	0
Pri. Wave:	505 nm	Sample Volume:	3
Sec. wave:	700 nm	Calibration Type:	2 point linear
Assay/Point:	1 Point End	K value:	/
Start-End:	1 - 25	Point:	2
Decimal Place:	1	Blank Type-	Reagent
Unit:	mg/dl	Point (0) Blank Con.:	0.0
Linearity Range:	1.000– 20.000	Point (1) STD. Con.:	Standard/ Calibration
Correlation Factor: 1.0000-0.0000			

PERFORMANCE CHARACTERISTICS

Analytical Range: 1 - 20 mg/dL

For uric acid analyte by Uric Acid Reagent on TC Matrix System, this method has been demonstrated to be linear from 1- 20 mg/dL

Accuracy: Comparison study was performed on TC Matrix System from 40 samples. Beckman Coulter Uric Acid Reagent was used to compare with Uric Acid Reagent. The results of this study in yield a correlation coefficient of 0.98 with a regression equation of y=0.95X +1.2.

Precision: Within Run precision for Uric Acid Reagent Set was determined following a modification of NCCLS EP5-A. Two commercial human serum were assayed on Beckman CX System for 25 times.

Sample	Sample 1	Sample 2
N	25	25
Mean (mg/dl)	5.9	9.7
Standard Deviation	0.17	0.22
Coefficient of Variation	3.0	2.1

Run-Day precision for Uric Acid Reagent was determined following a modification of NCCLS EP5-A. Two commercial human serum were assayed on TC Matrix Systems five times per day for five days for the total of 25 values.

Sample	Sample 1	Sample 2
N	25	25
Mean (mg/dl)	5.9	9.7
Standard Deviation	0.17	0.19
Coefficient of Variation	3.1	2.3

PRECAUTIONS

1. For in vitro diagnostic use only.
2. Since all specimens are potentially infectious, they should be handled with appropriate precautions and practices in accordance with Biosafety level 2 as recommended by USA NIH manual Biosafety in Microbiological and Biomedical Laboratories, and in accordance with National or local regulations related to the safety precautions of such materials.
3. Each laboratory has to perform the quality control test to assure the results being reliable before running the specimen tests.

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Manufactured by:

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