TECO DIAGNOSTICS
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CREATININE TEST
KINETIC METHOD
TC-MATRIX-240/480

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

SUMMARY AND EXPLANATION OF THE TEST
Creatinine is excreted as a waste product by the kidneys. Increased serum creatinine levels usually indicate impairment of renal function. Creatinine appears in the glomerular filtrate and is not reabsorbed by the tubule. Hence, any condition that reduces the glomerular filtration rate will result in the increase of creatinine concentration in plasma. Since the excrete rate of creatinine is relatively constant and its production rate is not influenced by protein catabolism or other external factors, the concentration of creatinine in serum is a good measure of renal glomerular function.

Creatinine Reagent is used to measure the creatinine concentration by a modified rate Jaffe method. In the reaction, creatinine combines with picric acid in an alkaline solution to form a creatinine-picrate complex. The TC Matrix System automatically proportions the appropriate sample and reagent volumes into the cuvette. The system monitors the change in absorbance at 520 nanometers. This change in absorbance is directly proportional to the concentration of creatinine in the sample and is used by the TC Matrix System to calculate and express the creatinine concentration.

$$\text{Creatinine + picric acid} \xrightarrow{\text{Alkali}} \text{Creatinine-picrate (reddish colored complex)}$$

REAGENT PREPARATION
No preparation is required.

REAGENT COMPOSITION
Picric Acid: 8.1 mmol/L
Also non-reactive chemicals for optimal system performance.

REAGENT STORAGE AND STABILITY
Teco Creatinine Reagent stored unopened at room temperature is stable until the expiration date shown on the bottle label. Once the bottle is opened, Teco Creatinine Reagent is stable for 30 days, or until the expiration date on the bottle label, whichever occurs first.
DO NOT FREEZE.

SPECIMEN COLLECTION AND HANDLING
1. The test can be performed on serum or plasma. For serum, blood is drawn into a tube which does not contain anticoagulant and the blood 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
Calibration stability is 30 days. Calibration stability depends on the application characteristics and cooling capacity of the autoanalyzer used.

At least two level controls must be run once in every 24 hours. Each laboratory should determine its own quality control scheme and procedures. If quality control results are not within acceptable limits, calibration is required

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

MATERIALS NEEDED BUT NOT SUPPLIED
Creatinine Calibrator/Standard
At least two levels of control material.

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

INTERFERENCE
1. Hemoglobin levels up to 500 mg/dl, Triglyceride levels up to 1000 mg/dl and Bilirubin levels up to 30 mg/dl were found to exhibit negligible interference.
2. Lipemic samples >3+ should be ultra-centrifuged and the analysis performed on the infranate.
3. On this method, refer to the work of Young[10] for a review of drug and comprehensive list of substances effect on creatinine level.

EXPECTED VALUE
0.6 -1.3 mg/dL or 53 to 115µmol/L

PROCEDURES
Settings for TC-Matrix 240/480

Test Name:	CREA-P	R1:	120
Full Name:	Creatinine	R2:	25
Pri. Wave:	505 nm	Sample volume:	12
Sec. Wave:	700 nm	Calibration Type:	Multi-point linear
Assay/ Point:	Fixed time	K Value:	/
Start - End:	20 - 27	Point:	3
Decimal place:	2	Blank Type:	Water
Unit:	mg/dL	Point 0 (Blank) Con.:	0.0
Linearity Range:	0.2000 - 15.000	Point 1 (STD) Con.:	Calibrator/ standard
Correlation Factor:	1.0000 - 0.0000	Point 2 (STD) Con :	Calibrator/ standard

PERFORMANCE CHARACTERISTICS
Analytical Range: 0.2 - 15 mg/dL
For Creatinine analyte by Teco Creatinine Reagent on TC Matrix System, this method has been demonstrated to be linear from 0.2-15 mg/dL

Accuracy: Comparison study was performed on TC Matrix System from 40 samples. Beckman Coulter Creatinine reagent was used to compare with Creatinine Reagent. The results of this study in yield a

correlation coefficient of 0.99 with a regression equation of y=0.99X - 6.4.

Precision: Within Run precision for Creatinine Reagent Set was determined following a modification of NCCLS EP5-A.Two commercial human serum samples were assayed on TC Matrix System 25 times.

Sample	Sample 1	Sample 2
N	25	25
Mean (mg/dl)	1.5	5.4
Standard Deviation (mg/dl)	0.7	0.7
Coefficient of Variation (%)	10.5	7.8

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

Sample	Sample 1	Sample 2
N	25	25
Mean (mg/dl)	1.5	5.4
Standard Deviation (mg/dl)	0.8	0.6
Coefficient of Variation (%)	10.2	7.7

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.
4. Recommended to test alone.

REFERENCES:

1. Jaffe M. 1886. Z Physiol Chem. 10:391-400.
2. Wolf P.L. et.al.1972. Methods and Techniques in Clin Chem. Wiley-Interscience, New York.
3. Tietz, N.W., Specimen Collection and Processing; Sources of Biological Variation," Textbook of Clinical Chemistry, 2nd Edition, W.B. Saunders, Philadelphia, PA (1994).
4. National Committee for Clinical Laboratory Standards. Approved Guideline, NCCLS publication C28-A, Villanova, PA (1994).
5. Henry, J. B., ed., Clinical Diagnostics and Management by Laboratory Methods, 18th Edition, W.B. Saunders, Philadelphia.
6. Tietz, N.W., ed., Clinical Guide to Laboratory Tests, 2nd Edition, W.B. Saunders, Philadelphia, PA (1990).
7. National Committee for Clinical Laboratory Standards, Method Comparison and Bias Estimation Using Patient Samples; Tentative Guideline, NCCLS Publication EP9-T, Villanova, PA (1993).
8. National Committee for Clinical Laboratory Standards, Precision Performance of Clinical Chemistry Devices; Tentative Guideline, 2nd Edition, NCCLS publication EP5-T2, Villanova, PA (1992).
9. National Committee for Clinical Laboratory Standards, National Evaluation Protocols for Interference Testing, Evaluation Protocol Number 7, Vol. 4, No, June 1984.
10. Young, D.S., Effects of Drugs on Clinical Laboratory Tests, 3rd. Ed., AACC Press, Washington DC, 1990, 3-104 thru 3-106.

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Manufactured by:

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