TECO DIAGNOSTICS
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AST (SGOT)
KINETIC METHOD
TC MATRIX-160/240

INTENDED USE
For the quantitative determination of aspartate aminotransferase activity in serum or plasma on TC Matrix analyzer.

SUMMARY AND EXPLANATION OF THE TEST
Aspartate aminotransferase (AST) catalyzes the transfer of the amino group from aspartic acid to α-ketoglutaric acid. This enzyme is found in practically every tissue of the body, including red blood cells. It is in particularly high concentration in the liver, heart and skeletal muscles. Acute destruction of tissue results in the release of AST into the blood stream. Following myocardial infarction there is a significant increase in serum AST activity in about 6 to 8 hours with peak values reached after 48 to 60 hours, however, serum ALT activity remains within normal limits or only marginally increased. In hepatitis and other forms of liver disease associated with hepatic necrosis, both AST and ALT are elevated. Elevated levels of serum AST activity are also observed in infectious mononucleosis, muscular dystrophy, dermatomyositis, and in other forms of muscle and liver injury.
The method presented here is an UV-Kinetic method based on the rate of NADH oxidation in a coupled malic dehydrogenase reaction
The TC Matrix System automatically proportions the appropriate sample and reagent volumes into the cuvette. The system monitors the change in absorbance at 340 nanometers. This change in absorbance is directly proportional to the activity of aspartate aminotransferase in the sample and is used by the TC Matrix System to calculate and express aspartate aminotransferase activity.

$$\text{L-aspartate} + \alpha\text{-ketoglutarate} \xrightarrow{\text{AST}} \text{Oxaloacetate} + \text{L-glutamate}$$

$$\text{Oxaloacetate} + \text{NADH} + H^+ \xrightarrow{\text{MDH}} \text{L-malate} + NAD^+ + H_2O$$

REAGENT PREPARATION
No preparation is required.

REAGENT COMPOSITION
a-Ketoglutarate: 16 mmol/L
Malate dehydrogenase (MDH):>600 IU/L
L-Aspartate: 218 mmol/L
NADH: 0.18mmol/L
Also non-reactive chemicals for optimal system performance.

REAGENT STORAGE AND STABILITY
Aspartate Aminotransferase Reagent stored unopened at 2ºC to 8ºC is stable until the expiration date shown on the bottle label. Once opened, Aspartate Aminotransferase Reagent is stable for 14 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, plasma. For serum, blood is drawn into a tube which does not contain anticoagulant and is allowed to clot. The serum is then separated from the clot. Serum should be removed within 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.
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 manual for further instructions on calibrating the instrument

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

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

INTERFERENCE
1. Samples showing evidence of hemolysis should not be used.
2. Pyruvate may cause elevated results at a level of 4 mg/dL.
3. Lipemic samples >3+ should be ultra-centrifuged and the analysis performed on the infranate.
4. On this method, refer to the work of Young for a review of drug and comprehensive list of substances which have an effect on Aspartate Aminotransferase level.

EXPECTED VALUE
10 - 42 IU/L or 0.2 to 0.7 µkat/L

PROCEDURES
Settings for TC-Matrix 160

Test Name:	AST(SGOT)	R1:	120
Full Name:	Aspartate Aminotransferase	R2:	25
Pri. Wave:	340 nm	Sample volume:	10.0
Sec. Wave:	700 nm	Calibration Type:	2 point linear
Assay/ Point:	Kinetic	K Value:	/
Start - End:	14 - 21	Point:	2
Decimal place:	1	Blank Type:	Water
Unit:	U/L	Point 0 (Blank) Con.:	0.0
Linearity Range:	2.0000 - 750.0000	Point 1 (STD) Con.:	Standard/
Correlation Factor:	1.0000 - 0.0000		Calibrator

Settings for TC-Matrix 240

Test Name:	AST(SGOT)	R1:	120
Full Name:	Aspartate Aminotransferase	R2:	25
Pri. Wave:	340 nm	Sample volume:	7.0
Sec. Wave:	700 nm	Calibration Type:	2 point linear
Assay/ Point:	Kinetic	K Value:	/
Start - End:	20 - 27	Point:	2
Decimal place:	1	Blank Type:	Water
Unit:	U/L	Point 0 (Blank) Con.:	0.0
Linearity Range:	2.0000 - 750.0000	Point 1 (STD) Con.:	Standard/
Correlation Factor:	1.0000 - 0.0000		Calibrator

PERFORMANCE CHARACTERISTICS

Analytical Range: 2-750 IU/L

For Aspartate Aminotransferase analyte by Aspartate Aminotransferase Reagent on TC Matrix System, this method has been demonstrated to be linear from 2-750 IU/L

Accuracy: Comparison study was performed on TC Matrix System from 40 samples. Beckman Coulter Aspartate Aminotransferase Reagent was used to compare with Aspartate Aminotransferase Reagent. The results of this study in yield a correlation coefficient of 0.99 with a regression equation of y=0.99X -2.1.

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

Sample	Sample 1	Sample 2
N	25	25
Mean (mg/dl)	42	197
Standard Deviation (mg/dl)	2.2	8.1
Coefficient of Variation (%)	5.9	4.7

Run-Day precision for Aspartate Aminotransferase 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)	42	196
Standard Deviation (mg/dl)	2.4	8.3
Coefficient of Variation (%)	6.0	4.7

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.

REFERENCES:

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