ENVOY® 500 AST REAGENT KIT

ELITechGroup
CLINICAL SYSTEMS

Product no. 55250

For *in vitro* diagnostic use

☛CAUTION : Federal Law restricts this device to sale by or on the order of a licensed healthcare practitioner (Rx ONLY)

☛INTENDED USE

Envoy® 500 AST Reagent is for the quantitative determination of aspartate aminotransferase (AST) in serum and plasma on Envoy 500 Series Analyzers. Aspartate aminotransferase is also known as aspartate transaminase and glutamate oxaloacetate transaminase (GOT).

SUMMARY [1,2]

Aspartate transaminase is distributed throughout all body tissues and is present in high concentrations in the heart, liver, skeletal muscle, kidney, and pancreas. Elevated serum AST activities are indicative of tissue damage without being specific to a particular organ.

AST catalyzes the transamination of L-aspartate and α-ketoglutarate to produce oxaloacetate and L-glutamate. Oxaloacetate is subsequently reduced by malate dehydrogenase (MDH) to L-malate with the simultaneous oxidation of NADH to NAD. Lactate dehydrogenase is present to suppress endogenous reactions.

$$\text{L-Aspartate} + \alpha\text{-Ketoglutarate} \xrightarrow{\text{AST}} \text{Oxaloacetate} + \text{L-Glutamate}$$

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

NADH absorbs at 340 nm. As the concentration of NADH decreases, the absorbance at this wavelength decreases as well. The Envoy measures the rate of this decrease at 340 nm to calculate the activity of AST in the original sample.

REAGENTS

COMPOSITION

The Envoy 500 AST Reagent 1 and Reagent 2 are combined by the Envoy 500 Analyzer. The combined reagent contains 240 mmol/L L-aspartate, 15.6 mmol/L α-ketoglutarate, ≥ 0.30 mmol/L NADH, ≥ 7 kU/L Lactate dehydrogenase (lactobacillus), ≥ 1 kU/L Malate dehydrogenase (porcine), tris buffer, and other ingredients.

☛WARNINGS AND PRECAUTIONS

- This reagent is for professional *in vitro* diagnostic use only.
- Reagent 2 is classified as hazardous.

WARNING. Causes serious eye irritation. Wear protective gloves/ protective clothing/ eye protection/ face protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

- For more information, refer to Safety Data Sheet (SDS).
- Take normal precautions and adhere to good laboratory practice.
- Use clean or single use laboratory equipment only to avoid contaminations.
- These reagents contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of the reagent always flush with copious amounts of water to prevent azide buildup.
- Dispose of contents in accordance with all local, state and federal regulations.

PREPARATION

Both AST Reagent 1 and Reagent 2 are ready for use on the Envoy 500 Analyzer as packaged.

☛STORAGE AND STABILITY

Store these reagents at 2 to 8 °C and protected from light. Do not freeze. Unopened reagents are stable to the expiration dates on the bottle labels. Open reagents are stable for 28 days onboard the Envoy 500 Analyzer.

SPECIMENS [1,2]

COLLECTION AND STORAGE

Fresh unhemolyzed serum is the preferred specimen. Heparinized plasma is also acceptable. Do not assay hemolyzed specimens or whole blood as red blood cells contain high levels of AST.

Collect specimens by venipuncture according to accepted clinical protocol. Separate the serum or plasma sample from the cells as soon as possible. Clarify excessively lipemic samples by ultracentrifugation before analysis.

For best results, use only fresh specimens. Specimens may be stored at 4° C for 1 to 3 days with only a minimal loss of AST activity.
If specimens must be kept for longer periods, they should be frozen at -15 to -20 °C.

COMPATIBLE ADDITIVES

Acceptable chemical preservatives are sodium, lithium and ammonium heparin. Do not use other chemical additives.

INTERFERING SUBSTANCES

Lipemia and bilirubin interfere with this test. For additional information, refer to the section on Interfering Substances under Performance Characteristics.

PROCEDURE

☛MATERIALS PROVIDED

The Envoy 500 AST Reagent Kit includes the following components:

8 x 44.9 mL boats of Envoy 500 AST Reagent 1
8 x 12.0 mL bottles of Envoy 500 AST Reagent 2

MATERIALS REQUIRED BUT NOT PROVIDED

- Envoy Serum Controls (product no. 55131)
- Normal Saline.

REAGENT INSTALLATION AND USE

Program the instrument using the application parameters and programming instructions provided at the end of this Instructions For Use.

Refer to the Operator Manual for additional information on installing reagents, programming the analyzer, and running samples and controls.

The Envoy 500 AST Reagent is ready to use as packaged. Small bottles may become separated from large boats during shipping. If this occurs, snap the small bottles back onto the large reagent boats before continuing.

Do not remove the caps from the bottles until you are ready to install the reagent on the analyzer. Before installing, mix the reagents by inverting the reagent boat several times. Record the installation date on the label and insert the unit into the designated position on the reagent tray. Let the reagents equilibrate on the instrument for at least 30 minutes before use.

CALIBRATION

Envoy 500 AST Reagent does not require calibration. Results are automatically calculated from the absorptivity of NADH.

QUALITY CONTROL

Quality control requirements should be established in accordance with local, state and/or federal regulations or accreditation requirements. Assay at least two levels of serum control daily. Serum Controls for Envoy 500 level 1 and level 2 may be used. Controls should also be assayed after maintaining the instrument and after loading a new reagent unit.

Controls may be assayed more frequently based on laboratory workflow and the discretion of the user.

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CALCULATIONS

All calculations are performed by the instrument.

LIMITATIONS

Do not analyze hemolyzed specimens or whole blood. Any chemical additive not listed under Chemical Compatibility may bias results. Do not report results outside of the usable range shown below. Refer to the Interfering Substances section for possible sources of chemical interference.

PERFORMANCE CHARACTERISTICS

USABLE RANGE

The linear range for this assay is listed below. Specimens that exceed the upper limit of this range should be diluted with normal saline and reanalyzed. Multiply the results of diluted specimens by the appropriate dilution factors.

Range	Conventional Units	SI Units
Default	5 to 650 U/L	0.09 to 11.1 µkat/L
Hyperactive	500 to 1,300 U/L	8.5 to 22.1 µkat/L

EXPECTED VALUES [1]

Published AST reference ranges for adults are listed below. Use these ranges only as guides. Each laboratory should establish its own reference ranges.

Reference Range	Conventional Units	SI Units
Serum/Plasma	5 to 34 U/L	0.09 to 0.58 µkat/L

DETECTION LIMIT AND SENSITIVITY

The detection limit for this application is 5 U/L (0.09 µkat/L). This limit was established by assaying normal saline thirty times on an Envoy 500 Analyzer in a single analytical run. The detection limit was calculated as the mean value plus two times the standard deviation, which were 2.8 and 1.0 U/L respectively.

An absorbance change of 0.001 A/min on the Envoy 500 Analyzer corresponds to a change in AST activity of approximately 2.5 U/L (0.04 µkat/L).

METHOD COMPARISON

Ninety serum and 60 plasma specimens from individual adult patients were assayed for AST using an Envoy 500 Analyzer and another commercially available method. Results were compared by least squares and Passing - Bablok regression, and the following statistics were obtained.

Serum / Plasma Comparison

n = 150 range = 6 to 129 U/L

Least Squares Regression
- Envoy 500 = -2.0 U/L + 0.984 x Competitive Method
- 95% CI slope: 0.954 to 1.013
- 95% CI y-intercept: -2.894 to -1.063
- $s_{(y.x)}$ = 3.22 U/L r = 0.984

Passing - Bablok Regression
- Envoy 500 = - 2.0 U/L + 1.000 x Competitive Method
- 95% CI slope: 0.970 to 1.000
- 95% CI y-intercept: -2.000 to -1.485

PRECISION [3]

Three serum controls were each assayed in triplicate twice per day over 10 days on the Envoy 500 Analyzer. Three additional controls were assayed as hyperactive samples. Estimates of within run and total imprecision are calculated as described in NCCLS publication EP3-T.

Precision of AST Recoveries in U/L

Range			Within Run		Total	
Sample	n	mean	1SD	%CV	1SD	%CV
Default						
Serum 1	60	22	1.2	5.7%	1.3	6.1%
Serum 2	60	354	4.3	1.2%	4.8	1.4%
Serum 3	60	698	6.9	1.0%	7.3	1.0%
Hyperactive						
Serum 1	59	798	14.0	1.8%	16.0	2.0%
Serum 2	60	1029	11.1	1.1%	13.9	1.3%
Serum 3	58	1127	10.6	0.9%	19.6	1.7%

INTERFERING SUBSTANCES

Effects of icterus and lipemia are shown through the assay of pools spiked with ditaurobilirubin and Intralipid®, 20% solution. Observed biases are shown below.

Other substances can affect AST results. For additional information, refer to *Effects of Drugs on Clinical Laboratory Tests*[4] and *Effects of Preanalytical Variables on Clinical Laboratory Tests*[5].

Effects of Common Substances on AST Recoveries

Interferant	Concentration*	Changes in Recoveries
Ditaurobilirubin	24 mg/dL	not significant† at 27 U/L +5.2 at 110 U/L
	40 mg/dL	not significant† at 27 U/L +7.7 at 110 U/L
Intralipid 20% solution	400 mg/dL	No result‡

* Refers to bilirubin and/or triglyceride concentration

† No change greater than 4 U/L was observed

‡ Excessive lipemia can suppress results due to high absorbance

☛REFERENCES

1. Burtis C A, Ashwood E R, Eds. *Tietz Textbook of Clinical Chemistry, Third Edition* W.B. Saunders Company: Philadelphia, PA, 1999.
2. Kaplan L A, Pesce A J, Eds. *Methods in Clinical Chemistry; Theory Analysisand Correlation*,Third Edition Mosby Inc. St. Louis, MO. 1996.
3. *Tentative Guidelines for Manufacturers for Establishing Performance Claims for Clinical Chemical Methods, Replication Experiment* NCCLS Publication: Vol. 2 No. 20. Villanova, PA, 1982.
4. Young D S, *Effects of Drugs on Clinical Laboratory Tests: Fifth Edition* AACC Press: Washington, DC, 2000.
5. Young D S, *Effects of Preanalytical Variables on Clinical Laboratory Tests: Second Edition* AACC Press: Washington, DC, 1997.

☛GLOSSARY OF SYMBOLS

CONT	Contents		Manufacturer	REF	Catalog No.
LOT	Batch Code		See instruction for use		Use by
OPENED	Date opened / Installation date	IVD	*In vitro* diagnostic device		Temperature Limitation
STAB DAYS	Number of days onboard stability	R1	Reagent 1	R2	Reagent 2

☛ : Modification from previous version

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APPLICATION PARAMETERS

PRIMARY PARAMETERS

Code	AST
Bar-Code	Active
Code for Bar-Code	305
Test Methodology	IFCC Modified
Method	Kinetic
Kind of Process	With factor
1st Filter	340
2nd Filter	700
Reaction direction	Decreasing

REAGENTS

Number of reagents	2
Reagent 1 Volume µL	245
Concentrated	Inactive
Reagent 2 Volume µL	55
Concentrated	Inactive

SAMPLE

	Serum	Urine
Name	AST	
Sample µL	20	N/A
Pre-Dilution 1:	1	N/A
Post-Dilution 1:	2	N/A

TIMES

Sample Starter	Inactive
Delay Time	0
Reading Time	210
Reagent 1 Incubation Time	60
Reagent 2 Incubation Time	60

CHECK PARAMETERS

Reagent Limit (mABS)	1550
Curve Acceptance (%)	100

RE-RUN SERUM

Test Limit (Conc)	650
Low Test Limit (Conc)	0
Initial ABS (mABS)	2999
Final ABS (mABS)	250
Max ABS Delta (mABS)	375
Prozone Check	Inactive

Normal Range	Min	Max
Man	[User defined]	
Woman	[User defined]	
Child	[User defined]	

Re-run hyperactive	Active
Re-run pathological	Inactive

RE-RUN URINE

Test Limit (Conc)	N/A
Low Test Limit	N/A
Initial ABS (mABS)	N/A
Final ABS (mABS)	N/A
Max ABS Delta (mABS)	N/A
Prozone Check	Inactive

Normal Range	Min	Max
Man	N/A	
Woman	N/A	
Child	N/A	

Re-run hyperactive	Active
Re-run pathological	Inactive

SECONDARY PARAMETERS

1st Unit Serum	U/L
2nd Unit Serum	Inactive
1st Unit Urine	N/A
2nd Unit Urine	Inactive
Dynamic Blank	Inactive
Needle washes	[From Settings Table]
Cuvette washes	[From Settings Table]
Special washes	[From Settings Table]
Instrumental Factor	1.000
Shift	0.000
Reagent Blank	Every day
Decimals	0

STANDARD PARAMETERS

Reagent ABS	[Determined by Envoy]
Factor	2540

PROGRAMMING INSTRUCTIONS

Detailed instructions for programming reagent parameters are provided in the Envoy 500 Operator Manual and Envoy 500 Settings Table.

If the Envoy 500 Analyzer is not pre-programmed, an AST code must first be added before the parameters can be entered. On the menu bar, select «Test → Test Directory.» A new window will open up listing all the codes for the tests that are installed on the instrument. Click on the «New Code» button, type «AST» into the Code field and select «Save.»

To program the application parameters, check the box next to the code for the AST test, and select the «Parameters» button located at the bottom of the window. To program standard information, click the «Standards» button located at the bottom of the window.

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