

# Bioway Chemistry Reagent Series

## The Serum Aspartate Transaminase Reagent Kit

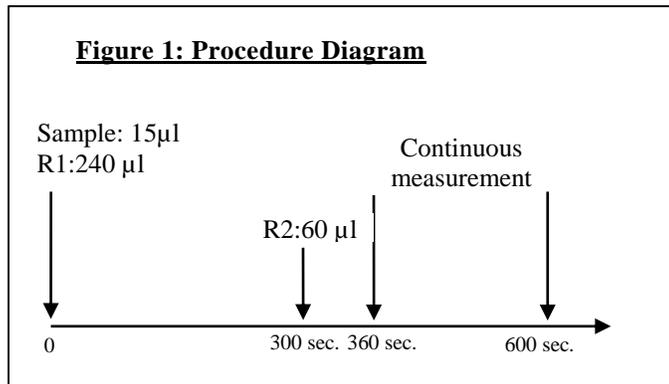
Detection of Aspartate Transaminase in Human Serum or Plasma on Chemistry Analyzers



Cat. No. R012K11

The Serum AST Reagent Kit

### SUMMARY OF TEST PROCEDURE



**Table 1: Instrument Parameters\***

Calibration method	linear	Slope of reaction	Decreased
Wavelength	Dλ : 340 nm Sλ : 415 nm	Sample volume	15 µl
F factor	3376	R1 volume	240 µl
Reaction temperature	37°C	R2 volume	60 µl

\*Refer to Figure 1 and the package insert for detail

### INTENDED USE

**Bioway Chemistry Reagent Series S Reagent Kit** (the Kit) is an assay intended for *in vitro* quantitative detection of aspartate transaminase in human serum or plasma on automated clinical chemistry analyzers.

### SUMMARY AND EXPLANATION

There are several alternative names of aspartate transaminase, including glutamic oxaloacetic transaminase or aspartate aminotransferase. It is one of a group of enzymes which catalyzes the interconversion of amino acids and keto acids by transferring amino groups. The enzyme is widely distributed in human tissues but found mainly in the heart and liver. It is part of diagnostic tests for liver function, myocardial infarction, acute pancreatitis, acute hemolytic anemia and acute renal disease. Serum values may increase 15 to 20 times than normal levels and it is roughly proportional to the degree of tissue damage.

### TEST PRINCIPLES

It is a two-stage biochemical reaction for aspartate transaminase detection. In the beginning, Aspartate transaminase catalyzes the transamination of L-aspartate and α-Oxoglutarate, producing L-glutamate and oxalacetate. Then by the catalysis of malate dehydrogenase, oxaloacetate is reduced to L-malate. The process is quantified by measuring the absorbances at 340 nm in a kinetic fashion.



The rate of increase in absorbance at 340 nm is directly proportional to the AST activity in the sample.

### MATERIALS PROVIDED

#### Reagents:

<b>R1</b>	Tris buffer, pH 7.65 MDH LDH	50 mmol/L ≥ 3000 U/L 6500 U/L
<b>R2</b>	α-Oxoglutarate L-Aspartate NADH Sodium azide	14 mmol/L 210 mmol/L 0.18 mmol/L 1 g/L

### MATERIALS NEEDED BUT NOT PROVIDED

1. Sample collection tube for applicable instrument

2. AST calibrator set and control set (commercially available)

### INSTRUMENT

The Kit is applicable on most automated chemistry analyzers. Refer to specific instrument application for suggested settings.

### STORAGE AND STABILITY

Store the reagents at 2-8°C. Avoid direct sunlight. The Kit is stable through the expiration date when stored properly. R1 and R2 reagents are stable for 1 month at 2-8°C after opening.

### PRECAUTIONS

1. The Kit is for *in vitro* diagnostic use only. Not for use in humans or animals.
2. The instructions must be followed to obtain accurate results.
3. Do not use the reagents beyond the expiration date.
4. Treat all specimens as infectious. Proper handling and disposal procedures of specimens and test materials should be strictly followed.
5. Reagents contain sodium azide as preservative; avoid contact with skin and eyes, flush with copious amounts of water when disposing.

### SPECIMEN COLLECTION AND HANDLING

Follow standard laboratory procedures to collect specimens avoiding hemolysis.

The Test can be performed with human serum, EDTA-treated or heparinized plasma. **Please do not use oxalic acid due to the interference of inhibiting AST activity.**

It is recommended to perform test immediately after sample collection. If the test cannot be done immediately

### TEST PROCEDURE (see Figure 1)

Reagent 1 and 2 are liquid stable ready-to-use, no preparation needed.

**Calibration:** Recommend using commercially available calibrator set for optimal results.

**Test procedure:** see Figure 1 and Table 1 for instrument parameter setup. Refer to specific instrument application for suggested setting.

1. Add 15 µl of sample and 240 µl of R1; mix well and incubate at 37°C for 5 minutes.
2. Add 60µl of R2; mix well and incubate at 37°C for 1 minute.
3. Take continuous optical density measurement for 4 minutes.
4. Calculate average Δ A /min

### RESULT

# Bioway Chemistry Reagent Series

## The Serum Aspartate Transaminase Reagent Kit

Detection of Aspartate Transaminase in Human Serum or Plasma on Chemistry Analyzers



The AST activity in U/L can be obtained by the following calculation:

$$\text{AST (U/L)} = (\Delta A_{\text{test}} / \text{min} - \Delta A_{\text{blank}} / \text{min}) \times \text{factor (F)}$$

The calculation factor for UV spectrophotometer is 3376 when the optical path is 10 mm. Please refer to instrument application if testing under different conditions.

### EXPECTED VALUES

8~40 U/L

It is recommended for each laboratory to establish its own expected values

### QUALITY CONTROL

Using commercially available controls with known concentration is recommended before each batch of tests to ensure the test is properly performed and all reagents and the instrument are functional as specified.

### LIMITATIONS

1. The Kit is for *in vitro* use on automated chemistry analyzers only.
2. Anticoagulants containing citrate should not be used.
3. The test result is affected by bilirubin and blood lipids.
4. Results obtained using the Kit should not be used as the only basis for a definite diagnosis.
5. Samples with ALP exceeding the maximum measurement range should be diluted with saline and retested.

### PERFORMANCE CHARACTERISTICS

**Linearity:** 0~400 U/L (R $\geq$ 0.99)

**Accuracy:** relative deviation 90~110%;

**Precision:** Within Run: CV $\leq$ 4%;  
Run-to-Run: CV $\leq$ 5%

**Reagent Blank Absorbance:** at 340nm wavelength and 10 mm optical diameter, O.D.  $\geq$ 0.90

### REFERENCES

1. National Committee for Clinical Laboratory Standards, Procedures for the Handling and Processing of Blood
2. Specimens, Approved Guideline, NCCLS publication H18-A, Villanova, PA (1990).
3. Tietz, N. W., Clinical Guide to Laboratory Tests, 2nd Edition, W. B. Saunders, Philadelphia, PA (1990).

Not Intended for Sale in the United States.

Pointe Biotech (Nanjing) Co., Ltd.

No.85,Xingmin South Road, Jiang Ning District, Nanjing,P.R.China 211100

Tel:86-25-52425019,

Fax:86-25-52424836

[info@biowaydx.com](mailto:info@biowaydx.com)

