Glutamate Oxaloacetate Transaminase Assay Kit (GOT/AST)

Method: Aspartic acid substrate method

Cat . No.	Size	Instrument
GB010G	R1: 4×100 ml R2: 2×50 ml	For Hitachi 717 &ShimadzuCL7200/8000
GS011G	R1: 6×60 ml R2: 2×45 ml	For Hitachi 917 &OlympusAU640/400/600
GH011G	R1: 2×50 ml R2: 1×25 ml	For Hitachi 902
GT011G	R1: 5×48 ml R2: 2×30 ml	For TOSHIBA
GX011G	R1: 2×80 ml R2: 2×20 ml	For SYNCHRON CX4-5-7-9/LX20/DXC600-800

INTENDED USE

The Aspartate Aminotransferase (AST) assay is used for the quantitation of aspartate aminotransferase in human serum. This product is suitable for Manual use.

CLINICAL SIGNIFICANCE[1,2]

Aspartate Aminotransferase (AST), also referred to as glutamate oxaloacetate transaminase (GOT), is an enzyme involved in amino acid metabolism. The activity of AST is in the serum is significantly increased during heart, liver, kidney and muscle diseases (tissue injuries, functional disorders). The activity of the enzyme is increased 4-8 hours following a myocardial infarction, reaching its peak in 2-3 days and declining on the fifth and sixth days.

ASSAY PRINCIPLES

Two substrates participate in the reaction catalyzed by AST, L-aspartate and Oxoglutarate. With the help of NADH coenzyme, Malate dehydrogenase (MDH) contained in the reagent catalyses the transformation of Oxalacetate released in the first reaction. The oxido-reductive process of NADH/NAD^+ is indicated by a decrese in absorbance at 340 nm. The Lactate dehydrogenase (LDH) in the medium counteracts the disturbing effect of Pyruvate contained in the sample.

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

$$\text{Oxalacetate}+\text{NADH}+H^+ \xrightarrow{\text{MDH}} \text{Mlactate}+NAD^+ + H_2O$$

REAGENT COMPOSITION

Contents	Concentration of Solutions
Reagent 1 (R1)	
Tris Buffer (pH=8.0)	80 mmol/L
L-aspartate	240 mmol/L
NADH	0.18 mmol/L
Reagent 2 (R2)	
Tris Buffer (pH=5.0)	200 mmol/L
LDH	>600 U/L
MDH	>600 U/L
α-ketoglutarate	12 mmol/L

SAMPLE COLLECTION AND PREPARATION

Serum samples.
Use fresh patient serum samples. Serum samples are stable for a week at 2-8°C.

STABILITY AND PREPARATION OF REAGENTS

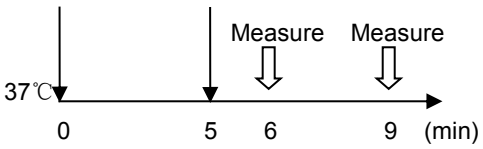
All reagents are ready to use.
Stable up to the expiry date when stored at 2-8℃.

ASSAY PROCEDURE

Test Procedure for Analyzers (HITACHI 917/7170)
Assay Mode: Rate A 20-34
Wave Length (main/sub): 340 nm/405 nm

Sample:10 μl

R1: 200 μl R2: 50 μl



CALIBRATION

Recommend that this assay should be calibrated using Gcell calibration serum, calibration trace to JSCC-TS01. Randox calibration also can be used, Randox calibration choosing method: (IFCC Tris buffer no P5P/IFCC 37℃)

CALCULATION

Calculation using calibration

$$\text{Concentration} = \frac{\triangle A_{sample}/\text{min}}{\triangle A_{calibrator}/\text{min}} \times \text{calibrator value}$$

Calculation using factor

$$\text{AST (U/L)} = \frac{\Delta A/\text{min} \times V_t}{\varepsilon \times V_s \times L} \times 1000 = \Delta A/\text{min} \times K$$

K= 4180

QUALITY CONTROL

Randox Assayed Multisera are recommended for daily quality control. Values obtained should fall within a specified range. If these values fall outside the range, the following steps should be taken:

1. Check instrument settings and light source.
2. Check reaction temperature.
3. Check expiration date of kit and contents.

NORMAL VALUE

	30°C (U/l)	37°C (U/L)
Male	0-25	0-40
Female	0-21	0-31

It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geographical location of the population.

SPECIFIC PERFORMANCE CHARACTERISTICS

Beijing Strong Biotechnologies, Inc.
Add: 5/F Kuang Yi Building, No. 15 Hua Yuan Dong Lu, Haidian District, Beijing 100191 P. R. China
Tel: +86 10 8201 2486 Fax: +86 10 8201 2812

Web: www.bsbe.com.cn Email: jg.tech@bsbe.com.cn

CE version 10 APR 2017

LINEARITY

The method is linear up to 1000 U/L. If the Sample above this concentration should be diluted it with 0.9% NaCl and repeat assay.

PRECISION

The CV of the test should be CV≤10%

Intra assay precision		
N=20	level 1	level 2
Mean(U/L)	33	151
SD	1.02	1.14
CV(%)	3.07	0.75

Inter assay precision			
N=5	Batch 1	Batch 2	Batch 3
Mean(U/L)	32.7	31.7	32.7
$\bar{x}$	32.4		
(Xmax-Xmin)/$\bar{x}$	(32.7-31.7)/32.4*100=3.1%		

INTERFERENCE

The following analyze were tested up to the levels indicated and found not to interfere:

Hemoglobin	400 mg/dl
Intralipid	300 mg/dl
Bilirubin	40 mg/dl
Ascorbic Acid	20 mg/dl

SAFETY PRECAUTIONS AND WARNINGS

1. For in vitro diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.
2. Reagent contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.
3. Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent azide from building up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.
4. Specimens should be treated as potentially infectious (HIV, Hepatitis B virus, Hepatitis C virus, etc.) and handled with appropriate caution.
5. Reagents with different lot numbers should not be interchanged or mixed.

REFERENCES

1. Wroblewski F, La Due J.S: Ann Intern Med. 1956; 45:801.
2. Wroblewski F, La Due J.S: Proc Soc Exp Biol Med 1956; 91:569.

INDEX OF SYMBOLS

	Manufacture
REF	Catalogue Number
LOT	Lot number
	Date of manufacture
	Use by(Expiration date)
IVD	For In-Vitro Diagnostic use only
2℃ 8℃	Stored at 2-8℃
	Attention:See instruction for use
EC REP	Authorized Representative in the European Company

Beijing Strong Biotechnologies, Inc.
Add: 5/F Kuang Yi Building, No. 15 Hua Yuan Dong Lu, Haidian District, Beijing 100191 P. R. China
Tel: +86 10 8201 2486 Fax: +86 10 8201 2812

Web: www.bsbe.com.cn Email: jg.tech@bsbe.com.cn

CE version 10 APR 2017