Sinocare

Package Insert for Alanine Aminotransferase/ Aspartate Aminotransferase/Total Bilirubin/Albumin Reagent Kit

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【Product Name】
Alanine Aminotransferase/Aspartate Aminotransferase/Total Bilirubin/Albumin Reagent Kit
(Abbreviation: ALT/AST/TB/ALB)

【Package Size】
Specification A: 15 tests/kit, 30 tests/kit, 50 tests/kit.
Specification B: 15 tests/kit, 30 tests/kit, 50 tests/kit.

【Intended Use】
The Alanine Aminotransferase/Aspartate Aminotransferase/Total Bilirubin/Albumin Reagent Kit is intended to quantitatively determine the activity of alanine aminotransferase (ALT) and aspartate aminotransferase (AST) and concentration of total bilirubin (TB) and albumin (ALB) concentration in human serum. Clinically, it is mainly used for auxiliary diagnosis of liver diseases.
ALT and AST are sensitive indicators of liver cell damage and liver injury degree. The AST concentration elevates continuously and goes beyond ALT concentration usually indicates severe liver damage and is a sign of aggravation of chronic disease.
TB is the total value of direct bilirubin and indirect bilirubin. Clinically, it is mainly used to diagnose whether the liver disease or biliary tract is in abnormal state.
ALB is produced by liver. When there is severe hepatosis (such as liver cirrhosis), liver’ s ability to produce albumin is greatly decreased, resulting in the decrease of serum albumin concentration.

【Test Principle】
ALT: Alanine aminotransferase catalyzes the migration of amino group from L-Alanine, generating pyruvic acid and L-glutamate. Pyruvic acid reacts with NADH under the catalysis of Lactate dehydrogenase, generating lactic acid and NAD+. The activity of ALT can be calculated by measuring the descent rate of absorbance at 340 nm.
AST: Aspartate aminotransferase catalyzes the transfer of amino group from Aspartic acid to α -ketoglutarate, forming L-glutamate and oxaloacetic acid. Under the catalyzing of malate dehydrogenase, the formed oxaloacetic acid is converted into L-malate and NAD+ in the

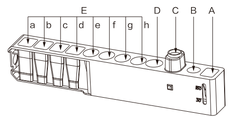
presence of NADH. The activity of AST can be calculated by measuring the descent rate of absorbance at 340 nm.
TB: Sulfanilic acid is diazotized into diazocompound after reacting with nitrite, which can combine with various bilirubin in the presence of catalyst and form azobilirubin, which is then converted into azopigment under acidic condition. The concentration of total bilirubin can be calculated by measuring the variation of absorbance at 546 nm.
ALB: The albumin in serum sample combines with Bromocresol green when PH=4.2 and form green compound, which turns the solution into green from yellow. The concentration of ALB can be calculated by measuring the variation of absorbance at 630 nm.

【Composition】
Specification A: Mainly consists of reagent cartridge, tip and control material.
Specification B: Mainly consists of reagent cartridge and tip.
The cartridge consists of reagent chambers and reagents, diluent/cleaning fluid chamber and diluent/cleaning fluid, sample chamber, dilution chamber and tip rack.
The main constituents of the reagents and control materials are:

Reagent		Constituent	Concentration
ALT	Reagent R1	TRIS buffer	5.0 mmol/L ~ 20.0 mmol/L
		Lactic dehydrogenase	1.0 KU/L ~ 2.0 KU/L
	Reagent R2	β -NADH	0.2 g/L ~ 0.5 g/L
		α -Ketoglutaric acid disodium salt	15.0 g/L ~ 25.0 g/L
AST	Reagent R1	L-Alanine	45.0 g/L ~ 75.0 g/L
		β -NADH	0.2 g/L ~ 0.5 g/L
		Potassium L-Aspartate	30.0 g/L ~ 55.0 g/L
		Malate dehydrogenase	0.2 KU/L ~ 0.5 KU/L
		Sodium azide	0.1 g/L ~ 0.5 g/L
	Reagent R2	α -Ketoglutaric acid disodium salt	25.0 g/L ~ 40.0 g/L
		Sodium azide	0.5 g/L ~ 1.5 g/L

Reagent		Constituent	Concentration
TB	Reagent R1	Sulfanilic acid	7.0 g/L ~ 9.0 g/L
		Surfactant	0.5 g/L ~ 1.5 g/L
	Reagent R2	Hydrochloric acid	50.0mmol/L ~ 150.0mmol/L
		Sodium nitrite	0.5 g/L ~ 1.5 g/L
ALB	Reagent R	Succinic acid	40.0mmol/L ~ 60.0mmol/L
		Bromocresol green (BCG)	0.1 g/L ~ 0.3 g/L
		Surfactant	2.0 g/L ~ 5.0 g/L
Control Material		Buffer	Certain amount
		Human serum/plasma	20 % ~ 100 %
		Alanine aminotransferase, aspartate aminotransferase, bilirubin, human serum albumin	Certain amount

The illustration of the reagent cartridge is shown below:



Note: Please do not touch the ‘E: reagents’ area of the reagent cartridge during the whole test process, or the test result may be affected.

Component	Function
A: Sample chamber	Sample loading area
B: Dilution chamber	For mixing the sample and diluent in proportion
C: Tip rack	For placing the tip
D: Diluent/cleaning fluid chamber	Contains diluent/cleaning fluid
E: Reagents	a: Contains ALB reagent
	b: Contains ALT reagent R1
	c: Contains AST reagent R1
	d: Contains TB reagent R1
	e: Contains diluent/cleaning fluid
	f: Contains ALT reagent R2
	g: Contains AST reagent R2
	h: Contains TB reagent R2

Note: The pictures are for reference only, please take the actual product as the standard.

Different packaging sizes and specifications are shown below:

Specification		Contents
Specification A	15 tests/kit	Reagent cartridge (x15), tip (x35), control material level 1 (1mL), control material level 2 (1mL) (each including a bottle of lyophilized powder and a bottle of reconstitution diluent)
	30 tests/kit	Reagent cartridge (x30), tip (x65), control material level 1 (1mL), control material level 2 (1mL) (each including a bottle of lyophilized powder and a bottle of reconstitution diluent)
	50 tests/kit	Reagent cartridge (x50), tip (x105), control material level 1 (1mL), control material level 2 (1mL) (each including a bottle of lyophilized powder and a bottle of reconstitution diluent)

Specification		Contents
Specification B	15 tests/kit	Reagent cartridge (x15), tip (x35)
	30 tests/kit	Reagent cartridge (x30), tip (x65)
	50 tests/kit	Reagent cartridge (x50), tip (x105)

The reagent cartridges and control materials of different lot are incompatible.

【Storage Conditions & Expiry date】

Product	Expired by	Storage Conditions
Reagent cartridge	2 hours	Room temperature. Before testing, please equilibrate the reagent cartridge to room temperature. (Avoid bright light exposure) Cartridges cannot be returned to the refrigerator once they had been at room temperature.
	12 months	2~8℃.

Product		Expired by		Storage Conditions
Control Material	TB	Opened and reconstituted	7 days	2~8℃.
			14 days	-15 ~ -25℃. The control material can only be frozen once.
		Unopened	12 months	2~8℃.
	ALT/ AST/ ALB	Opened and reconstituted	14 days	2~8℃.
			28 days	-15 ~ -25℃. The control material can only be frozen once.
		Unopened	12 months	2~8℃.

Check the label on the packing box for manufacture date, expiry date and QC range.

【Applicable device】
The Portable Automatic Multi-function Analyzer manufactured by Changsha Sinocare Inc..

【Sample Requirements】
1, Sample size: ≥150 μ L.
2, Sample type: serum. After collecting blood sample, please process the sample following the procedures written on the blood collection tube. Avoid sample where hemolysis, turbidity or high lipemia exists.
3, The sample can be stored at room temperature for 8 hours, or at 2~8℃ for 4 days. Please equilibrate the sample to room temperature and blend well before testing.
4, No significant interference is observed in the test result of sample that contains:

Potential Interfering Substance	Test Item	Highest concentration at which no interference was observed
Hemoglobin	ALT/AST/TB/ALB	120 mg/dL
Ascorbic acid		6 mg/dL
Cholesterol		13 mmol/L
Intralipid		400 mg/dL
Intralipid	ALT/AST/ALB	900 mg/dL
Total bilirubin	ALB	600 μM
Total bilirubin	ALT	350 μM
Total bilirubin	AST	300 μM

Note: substances may interfere with the test results if they:
1. Are not included in the list;
2. Are included in the list, but the concentrations exceed the specified value forementioned.

【Test Method】
Auxiliary materials required: disposable rubber gloves;

1. Sample Test

a) Test environment
Temperature: 15 °C −30 °C
Relative Humidity: 25%−85%
Please perform the test under prescribed conditions, or incorrect results may be obtained.

b) Sample Test Procedure
Startup and equilibrate the analyzer. Open the package of the reagent kit, take out the reagent cartridge, and equilibrate to room temperature. Avoid bright light exposure.
Place the tip into the tip rack. Add at least 150 μL sample into the sample chamber. Insert the reagent cartridge into the cartridge holder. Touch 'Test' and input test information, then start testing. The test result will display when the test completes. Take out the used reagent cartridge to finish the test.
Test report: the test result of ALT/AST is reported in the form of activity (unit: U/L); the test result of TB is reported in the form of concentration (unit: μ mol/L,mg/dL or mg/L); the test result of ALB is reported in the form of concentration (unit: g/L,mg/dL,mg/L or g/dL).

2. Quality control

The control material of Alanine Aminotransferase/Aspartate Aminotransferase/Total Bilirubin/Albumin Reagent Kit is intended for the quality control of the reagent kit and the applicable devices.
Please carry out QC test periodically to inspect whether the system is working normally and provides valid test results.

a) Dissolving of control material
Equilibrate the lyophilized powder to room temperature. Slightly shake off the reconstitution diluent on the bottle wall and cap. Open

the powder bottle carefully, so that the lyophilized powder does not spray out. Pour the reconstitution diluent into the powder bottle, cap the bottle with rubber plug. Place the bottle at room temperature for 10 – 15 minutes, and turn the bottle upside down gently until the powder is fully dissolved. The dissolved control material should be equilibrated to room temperature and blend well before each use.

b) QC test
For QC test procedure, please refer to the sample test procedure. The test result should be within the QC range. If the QC test result exceeds the QC range, please follow the steps below:
Check if the test item of reagent cartridge and control material matches;
Check if the lot number of reagent cartridge and control material matches;
Check if the reagent cartridge and control material are not expired;
Check if the reagent cartridge and tip are clean;
If the problem still persists after excluding the factors above, please contact local distributor or Changsha Sinocare Inc.

c) Frequency of QC test
Carry out QC test whenever:
Having doubts about the test result;
Using the reagent kit from different transportation lot;
Using the reagent kit from different lot;
There is any anomaly on the analyzer.
WARNING! Treat used reagent cartridges, tips and control material as a biological risk. Please follow the national/local rules and regulations when disposing them.

【Reference Interval】
ALT: male: 9.0 U/L – 50.0 U/L, female: 7.0 U/L – 40.0 U/L;
Reference: WS/T 404.1−2012 Reference intervals for common clinical biochemistry tests.
AST: male: 15.0 U/L – 40.0 U/L, female: 13.0 U/L – 35.0 U/L;
Reference: WS/T 404.1−2012 Reference intervals for common clinical biochemistry tests.
TB: 3.4 μmol/L – 17.1 μmol/L(0.20 mg/dL − 1.00 mg/dL or 1.99 mg/L −10.00 mg/L); Reference: SHANG Hong, WANG Yu−san, SHEN Zi−yu, etc.; National guide to clinical laboratory procedures【S】. 4th Edition. Beijing: People's medical publishing house.
ALB: 40.0 g/L – 55.0 g/L(4000.0 mg/dL − 5500.0 mg/dL,40000 mg/L − 55000 mg/L or 4.00 g/dL − 5.50 g/dL); Reference: WS/T 404.2−2012 Reference intervals for common clinical biochemistry tests.
It is suggested that the laboratories establish their own reference intervals due to the differences in region, race, gender and age.

【Explanation of Test Results】
The review and analysis of the test result should be done by specialists. The reference interval may vary due to the differences in region, race, gender and age, if a test result is doubtful or is not consistent with clinical symptoms, please retest the sample or verify the accuracy of the result in other ways. If the test result exceeds or falls short of the measurement range, please do not retest with diluted samples.
The mean values and the corresponding QC ranges were derived from replicate analyses and are specific for this lot of product. Data from the Portable Automatic Multi−function Analyzer is included in the determination of some ranges. All tests were performed by the manufacturer laboratories using manufacturer supported reagents and a representative sampling of this lot of product. It is recommended that each laboratory establish its own acceptable ranges

provided as guides, Laboratory established ranges may vary from those listed during the life of this control. If the result of QC test is not within the QC range specified on the outer package of the reagent kit, please perform a new test. If the result is still out of the range, please contact Changsha Sinocare Inc. customer service center or local distributor.

【Limitations of Test Method】
1. The Alanine Aminotransferase/Aspartate Aminotransferase/Total Bilirubin/Albumin Reagent Kit is only applicable for the matching analyzer specified in **【Applicable device】**.
2. The test results are only for clinical reference. The clinical diagnosis and treatment of the patients should take into account their symptoms and signs, medical history, other laboratory tests and therapeutic responses.

【Performance Characteristics】

1. Linearity

Test Item	Linearity
ALT	For【4.0, 600.0】U/L, correlative coefficient (r) ≥ 0.990
AST	For【4.0, 600.0】U/L, correlative coefficient (r) ≥ 0.990
TB	For【1.7, 600.0】μ mol/L([0.10, 35.08] mg/dL or [1.00, 350.82] mg/L), correlative coefficient (r) ≥ 0.990
ALB	For【10.0, 60.0】g/L([1000.0, 6000.0] mg/dL,[10000, 60000] mg/L or [1.00, 6.00] g/dL), correlative coefficient (r) ≥ 0.990; For【10.0, 20.0】g/L([1000.0, 2000.0] mg/dL,[10000, 20000] mg/L or [1.00, 2.00] g/dL), the absolute deviation does not exceed ± 4.0 g/L(400.0 mg/dL,4000 mg/L or 0.40 g/dL); For (20.0, 60.0】g/L((2000.0, 6000.0] mg/dL,(20000, 60000] mg/L or (2.00, 6.00] g/dL), the relative deviation does not exceed ± 10.0 %.

2. Analytical sensitivity

Test Item	Analytical sensitivity
ALT	For 30.0 U/L sample concentration, the absolute value of the variation rate of absorbance |ΔA/min| ≥ 0.004.
AST	For 130.0 U/L sample concentration, the absolute value of the variation rate of absorbance |ΔA/min| ≥ 0.025.
TB	For 10.0 μ mol/L(0.58 mg/dL or 5.85 mg/L)sample concentration, the absolute value of the variation of absorbance |ΔA| ≥ 0.010.
ALB	For 40.0 g/L(4000.0 mg/dL,40000 mg/L or 4.00 g/dL)sample concentration, the absolute value of the variation of absorbance |ΔA| ≥ 0.300.

3. Accuracy/Trueness

Test Item	Indicator	Value
ALT	Trueness	Relative deviation does not exceed ± 15.0 %.
AST		Relative deviation does not exceed ± 15.0 %.
TB	Accuracy	Relative deviation does not exceed ± 10.0 %.
ALB		Relative deviation does not exceed ± 10.0 %.

4. Intra-assay precision
CV ≤ 5.0%.

5. Inter-assay precision
R ≤ 10.0%.

【Cautions】
1. This product is for in vitro diagnostic use only. Please take protective measures during operation (e.g.: wearing mask, gloves, etc.). Once contact with eyes or skin, wash immediately with water; go to the hospital if swallow by mistake;
2. Please do not use expired reagent kits;
3. Please treat used or expired reagent kits as medical waste when disposing them;
4. The reagent cartridges and tips are disposable, please do not reuse;
5. The QC test is valid only when .the reagent cartridges and control materials are from the same lot;
6. The control material contains human−derived serum/plasma, please treat it as potential source of infection;
7. Expired control material is not applicable for the QC test of corresponding test item;
8. Please examine the appearance of the reagent cartridges before testing. If there is any damage on the reagent cartridge, discard and perform the test with a new one;
9. Before testing, please read this package insert and the user manual of the applicable device carefully;
10. Testing should be performed by professionally trained staff working in certified laboratories or clinics at which the sample is taken by qualified medical personnel.

【Explanation of symbols】

Symbol	Title of Symbol
IVD	In vitro diagnostic medical device
	Consult instructions for use
2℃ 8℃	Store at 2−8℃
LOT	Lot number
	Date of manufacture
	Use−by date,expiry date
	Do not re−use
	Keep away from sunlight
	Keep dry
	Manufacturer
	Biological risks
EC REP	Authorized representative in the European Community
CE	CE marking

【References】

1. Reference: SHANG Hong, WANG Yu−san, SHEN Zi−yu, etc.; National guide to clinical laboratory procedures【S】. 4th Edition. Beijing: People's medical publishing house, 2015:301.
2. Reference: WS/T 404.1−2012 Reference intervals for common clinical biochemistry tests, part 1: ALT, AST, ALP and GGT.
3. Reference: WS/T 404.2−2012 Reference intervals for common clinical biochemistry tests, part 2: TB, ALB.

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Sinocare三诺			
公司名称	三诺生物传感股份有限公司	须符合HSF检测	
文件名称	英文谷丙转氨酶谷草转氨酶总胆红素白蛋白检测试剂盒(速率法终点法)CE版说明书	文件编号	C-37200398
文件版本	A.4	物料编码	37200461
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制作材料	70克双胶纸 4折页 风琴折 双面印刷 (印刷之前请去掉虚线)	单位	毫米（mm）

文件版本	变更时间	变更说明	变更人
A.4	2022/05/18	应ECR202111018 历史图纸变更，源文件正确，PDF与转曲文件错误需修改	张瑶
A.3	2021/12/22	ECR202110002要求：添加切换单位	张瑶
A.2	2021/04/28	ECR202104013要求：欧代变更	黎辉雄

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