

Alanine aminotransferase, aspartate aminotransferase, albumin test card (dry chemical method)

Instructions for Use

Product Name

Common name: Alanine aminotransferase, aspartate aminotransferase, albumin test card (dry chemical method)

Package Specification

Model	DiaCard-6
Specification	10 pcs/box, 20 pcs/box, 50 pcs/box

Intended Use

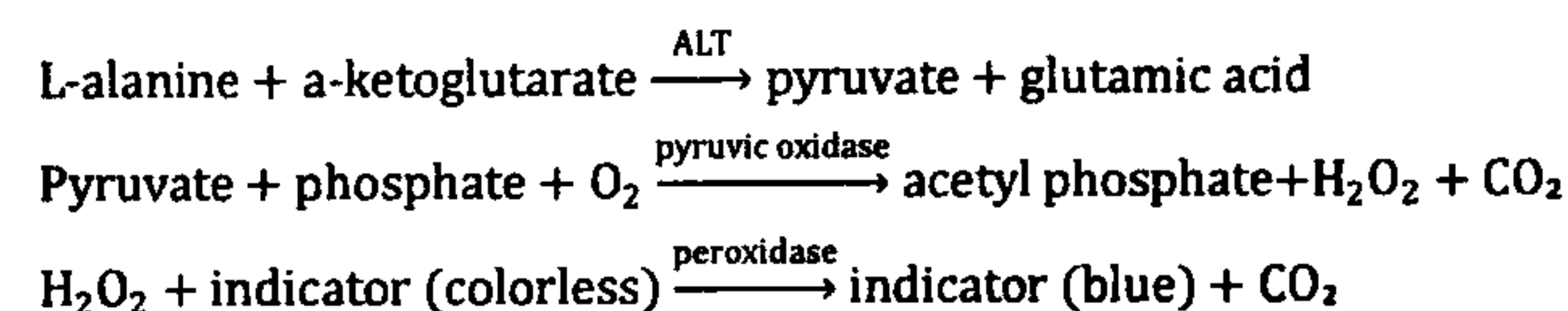
It is intended to be used for in vitro quantitative detection of alanine aminotransferase, aspartate aminotransferase, and albumin in human whole blood.

Test Principle

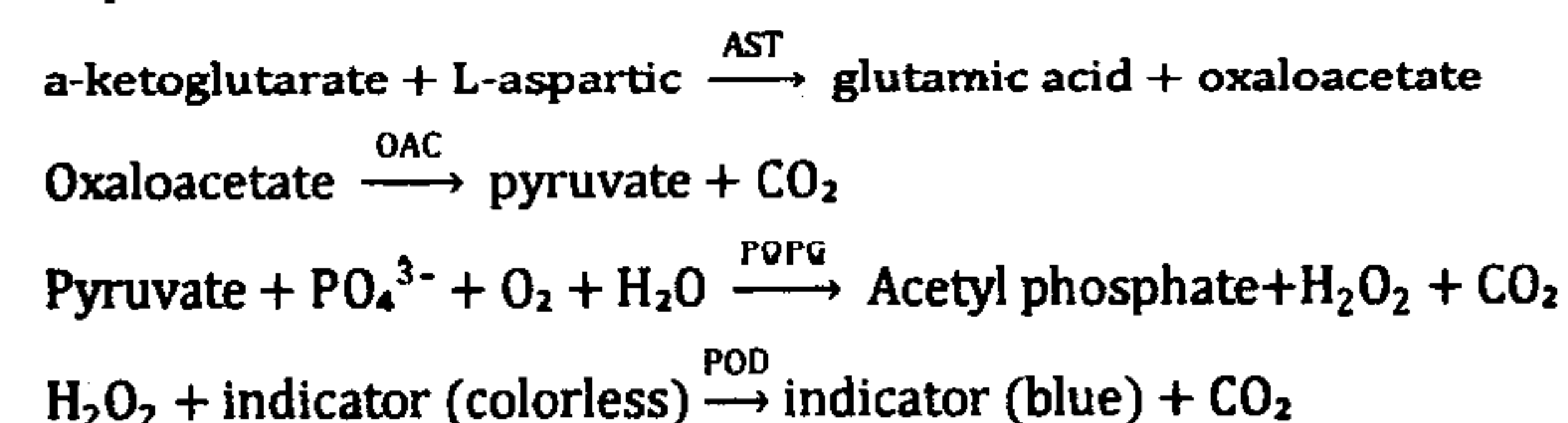
After adding appropriate amount of blood specimen to the test card, the alanine aminotransferase and aspartate aminotransferase in the specimen react with the enzymes and chemicals in the reaction layer through the diffusion layer and produce color changes. Under acidic conditions, albumin reacts with bromocresol green to form a blue-green complex. The color changes produced is proportional to the concentration. Then the analyzer uses the reflection method to read the results and calculates the content of the substance to be measured.

The reaction equation is as follows:

Alanine aminotransferase:



Aspartate aminotransferase:



Albumin:



Main Composition

- Each alanine aminotransferase, aspartate aminotransferase, albumin test card contains the following reagent components:

Name	Content	Name	Content
L-Alanine	5%	Oxaloacetate decarboxylase	1.5U
a-ketoglutarate	1%	Pyruvate oxidase	1.3U
L-Aspartic acid	5%	Peroxidase	5U
MAOS	0.8%	4-aminoantipyrine	0.4%
Bromocresol green	0.12mg		

- code chip
The code chip contains specific batch number of test card for checking the test card batch number.

Storage Conditions and Expiry Date

- The test card should be sealed and stored at 2°C~30°C, and its period of validity is 12 months.
- Test card must be stored in the original packaging. Use the test card immediately after taking out from package.
- Refer to the packaging or label for the manufacture date and expiration date.

Applicable Analyzer

The test card is applicable to Compass2000-1, Compass2000-2, Compass2000-3 dry biochemical analyzer produced by Jiangsu Konsung Bio-Medical Science And Technology Co., Ltd.

Specimen Requirements

- Applicable blood samples include whole blood and serum.
- If the sample contains anticoagulant, only whole blood anticoagulated by heparin can be used.
- The whole blood should be tested as soon as possible after collection. For storage, it can be stored at 2°C~8°C for 48 hours.
- The serum sample can be stored for 7 days at 2°C~8°C, and stored for one month at -20°C. Do not freeze or melt it repeatedly.

Test Method

- Prepare the required items: dry biochemical analyzer and other required items.
- Read this instructions for use of the dry biochemical analyzer carefully and be familiar with the operation of the analyzer.
- Check whether the code chip is consistent with the information on the test card label.
- Place the test card to the correct position of the analyzer and add 45μl sample.
- The analyzer starts the test, and the result is displayed on the analyzer screen after the test is completed.
- The analyzer starts the test, and the result is displayed on the analyzer screen after reacting at 37°C for 3 minutes.

Reference intervals

Alanine aminotransferase:	female 10 U/L -40U/L
	Male 10 U/L -50U/L
Aspartate aminotransferase:	female 13 U/L -35U/L
	Male 15 U/L -40U/L
Albumin:	40-55g/L (4.0g/dL -5.5g/dL)

It is recommended that each laboratory establish its own reference range according to the actual situation.

Test Result

The dry biochemical analyzer automatically test the test card with blood specimen, and the alanine aminotransferase and aspartate aminotransferase are showed in U/L and albumin in g/L.

Limitation of Test Method

- Diagnosis and treatment should not rely solely on the test result. Clinical history and other laboratory tests should be considered.
- Other factors may also cause inaccuracy of test results, such as technical factors, misoperation, etc.

3. The test card showed no significant interference at the following concentrations of interfering substances: plasma free hemoglobin $\leq 10\text{mg/dL}$, bilirubin $\leq 60\text{mg/dL}$, triglyceride $\leq 100\text{mg/dL}$, ascorbic acid $\leq 5\text{mg/dL}$, and ammonia ion $\leq 400\mu\text{mol/L}$.












Performance Specification

1. Repeatability
- 1) The CV of alanine aminotransferase $\leq 7.5\%$.
 - 2) The CV of aspartate aminotransferase $\leq 7.5\%$.
 - 3) The CV of albumin $\leq 7.5\%$.
2. Linearity
- | Test item | Linearity Range | Correlation requirements |
|----------------------------|-----------------------------|--------------------------|
| Alanine aminotransferase | 10~800 U/L | $r \geq 0.9900$ |
| Aspartate aminotransferase | 10~800 U/L | $r \geq 0.9900$ |
| Albumin | 10~60 g/L
(1.0~6.0 g/dL) | $r \geq 0.9900$ |
3. Precision
- 1) Relative bias of alanine aminotransferase $\leq \pm 10\%$
 - 2) Relative bias of aspartate aminotransferase $\leq \pm 10\%$
 - 3) Relative bias of albumin $\leq \pm 10\%$
4. Inter-batch difference
- 1) Alanine aminotransferase deviation $\leq 10\%$
 - 2) Aspartate aminotransferase deviation $\leq 10\%$
 - 3) Albumin deviation $\leq 10\%$

Notes

- 1. This product is for In Vitro Diagnostic use only;
- 2. Use the product prior to the expiration date.
- 3. During the operation, the blood sample should be dripped into the test card at one time. If the amount of blood dripped on the test card is insufficient, a new test card and fresh blood sample should be used for testing.
- 4. This product is for single-use only. Always handle blood specimens with care as they may be infectious. Consult local environment authorities for proper disposal. Always wear protective gloves when handling blood specimens and test cards with specimen.

Symbol and Explanation

Symbol	Explanation
	In vitro diagnostic medical device
	Consult instructions for use
	Caution
	Batch code
	Date of manufacture
	Manufacturer
	Temperature limit
	Use-by date
	Do not reuse
	CE mark
	Authorized representative in the European community

Bibliography

- 1. Shang Hong, Wang Yusan, Shen Ziyu, etc. National Clinical Laboratory Procedures [M]. 4th edition. Beijing: People's Medical Publishing House, 2014: 279-283.
- 2. WS/T404.1-2012 Reference intervals for common clinical biochemical tests - Part 1: Serum alanine aminotransferase aspartate aminotransferase, alkaline phosphatase and Y-glutamyltransferase; WS/T404.1-2012 Reference intervals for common clinical biochemistry tests - Part 2: Serum total protein and albumin.



Jiangsu Konsung Bio-Medical Science And Technology Co., Ltd.
NO.8, Shengchang West Road, Danyang Development Zone,
Jiangsu Province, 212300, P.R.China



Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537, Hamburg, Germany

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