CE IVD

ALT Reagent Kit (Alanine Substrate Method)

Instructions for Use

REF CC1006

PRODUCT NAME

ALT Reagent Kit (Alanine Substrate Method)

PACKAGE SPECIFICATION

R1:1×20 mL	R2:1×10 mL	R1:1×40 mL	R2:1×20 mL
R1:1×60 mL	R2:1×30 mL	R1:2×60 mL	R2:2×30 mL
R1:2×30 mL	R2:2×15 mL	R1:2×40 mL	R2:2×20 mL
R1:2×50 mL	R2:1×50 mL	R1:2×60 mL	R2:1×60 mL
R1:2×60 mL	R2:3×20 mL	R1:2×65 mL	R2:1×70 mL
R1:2×80 mL	R2:1×80 mL	R1:2×120 mL	R2:2×60 mL
R1:3×20 mL	R2:3×10 mL	R1:3×40 mL	R2:3×20 mL
R1:4×40 mL	R2:4×20 mL	R1:4×50 mL	R2:2×50 mL
R1:4×55 mL	R2:2×55 mL	R1:4×60 mL	R2:2×60 mL
R1:4×60 mL	R2:4×30 mL	R1:4×60 mL	R2:6×20 mL
R1:4×65 mL	R2:2×65 mL	R1:4×65 mL	R2:2×70 mL
R1:4×100 mL	R2:2×100 mL	R1:4×653 mL	R2:4×283 mL
R1:2×65 mL	R2:1×65 mL	R1:4×65 mL	R2:2×65 mL
12×72T (R1: 12×16.8 mL R2:12×8.4 mL)			

INTENDED USE

Used for the *in vitro* quantitative determination of alanine aminotransferase activity in human serum and plasma.
Mainly used to assist in the evaluation of liver function. ALT is a sensitive indicator to reflect liver injury, various acute liver injuries (such as acute infectious hepatitis and drug or alcohol poisoning). Serum ALT can be in the clinical symptoms (such as jaundice) before the emergence of a sharp rise and so on, and is generally parallel with the severity of the disease and the recovery; serum ALT may also be elevated in chronic hepatitis, fatty liver, cirrhosis, hepatic stasis, etc. In addition, cholecystitis, cholelithiasis, pancreatitis, myocardial infarction and taking certain drugs (such as chlorpromazine, quinine, salicylic acid preparations, etc.) can be seen in the serum ALT rise. For professional and laboratory use only.

TEST PRINCIPLE

L-alanine + α-ketoglutarate $\xrightarrow{\text{ALT}}$ Glutamic acid + pyruvic acid
Pyruvate + NADH + H $\xrightarrow{\text{LDH}}$ Lactate + NAD
The rate of NADH reduction was measured at 340 nm and ALT viability was calculated.

MAIN COMPONENTS

Kit contetnt	Components in reagents	Concentration
Reagent 1	Tris(Hydroxymethyl)aminomethane Buffer (pH 7.4)	1.2114 g/L
	NADH	0.55 g/L
	Lactate Dehydrogenase	3000 U/L
	Sodium Azide	2 g/L
Reagent 2	L-Alanine	25 g/L
	α-Ketoglutaric Acid	5 g/L
	Sodium Azide	2 g/L

The components in different batches of a multi-component kit are not interchangeable.

STORAGE AND SHELF LIFE

The unopened reagents are stable for a shelf life of 18 months when stored away from direct sunlight at 2-8°C. Opened reagents are stable for 42 days when stored at 2-8°C.
Refer to the label on the reagent kit for the manufacturing date and the expiry date.

APPLICABLE INSTRUMENTS

The kit is applicable to the following instruments: fully automatic biochemistry analyzers from Hitachi High-Tech (Shanghai) International Trading Co., Ltd., models: 7100, 7170, 7180, 7600, LABOSPECT 008 AS, 3100, 3500; fully automatic biochemistry analyzers from Beckman Coulter Commercial Enterprise (China) Co., Ltd., models: DXC800, AU480, AU680, AU5800; fully automatic biochemistry analyzers from Canon Medical Systems (China) Co., Ltd., models: TBA-120FR, TBA-2000FR, TBA-FX8; fully automatic biochemistry analyzers from Shenzhen Mindray Bio-Medical Electronics Co., Ltd., models: BS-420, BS-490, BS-600, BS-800, BS-820, BS-2000; fully automatic biochemistry analyzers from Dirui Industrial Co., Ltd., models: CS-400, CS-600B, CS-1200; fully automatic biochemistry analyzers from Siemens Healthineers Diagnostics (Shanghai) Co. Ltd., models: 1800, 2400, ADVIA Chemistry XPT; fully automatic biochemistry analyzers from Roche Diagnostics (shanghai) Co., Ltd., models: cobas 6000 c 501, cobas 8000 c 502, 701, 702; clinical chemistry analyzers from Getein Biotech, Inc, models: CM-400, CM-430, CM-480, CM-600, CM-630, CM-680, CM-800, CM-830, CM-880, CM-2000, CM-1600, CM-1200, CM-1000; automatic biochemical analyzers from Changchun Blaser Medical Technology Co., LTD, models: BBA-400, BBA-300, BBA-480. If you need the application parameters of the fully automatic biochemistry analyzers, please contact our company.

SAMPLE REQUIREMENTS

1. This test can be used for human serum and plasma samples.
2. Serum and heparin anticoagulant plasma should be separated in time after blood collection to avoid hemolysis.
3. The test results for serum and plasma will not change within 3 days at 15-25°C, 7 days at 2-8°C and 30 days at -20°C.

TEST PROCEDURE

1. Dual reagents are ready for use and no preparation is required.
2. Test conditions: (Different load parameters can be requested based on different testing instruments)

Primary/Secondary Wavelength	340nm/415 nm	**Calibration Type**	Linearity
Sample/R1/R2	15-30/200/100 μL	**Time of mixture of serum + R1**	3 min
Method	Rate method	**Reaction time after addition of R2**	3 min
Calibration Method	Two-point calibration	**Direction of reaction**	Downward

Operating procedures:
Dual Reagent Operation

Substances Added	Blank tubes	Test tubes
Reagent R1	200 μL	200 μL
Distilled water	15-30 μL	-
Sample	-	15-30 μL
Mix and incubate at 37°C for 3 min.		
Reagent R2	100 μL	100 μL
Mix well, incubate at 37°C for 60-90 s, continuously monitor the absorbance change of each tube at the measurement wavelength for 1-3 min, and calculate △A/min for each tube.		

3. Calibration procedure: Randox calibration serum can also be used.
4. Quality control procedure: Select quality control serum from Randox, and its measured value should be within the range of its label claim. If the result deviates from the range, find out the reason according to the steps below:

4.1 Check whether the parameter settings and light source are correct.
4.2 Check whether the cuvettes and sampling probes are clean.
4.3 Check whether water is contaminated, and bacterial growth will cause incorrect results.
4.4 Check reaction temperature.
4.5 Check the expiration date of the kit.

5. Result calculation:

$$\text{ALT viability (U/L)} = \frac{(\Delta A_{assay}/\text{min} - \Delta A_{blank}/\text{min}) \times K}{\text{Total reaction volume (mL)} \times 1000}$$

$$K = \frac{}{\text{Sample volume (mL)} \times \text{millimolar extinction coefficient} \times 1.0}$$

Note: 1000 = conversion factor from U/mL to U/L; 1.0 = cuvette optical diameter; millimolar extinction coefficient = 6.22

REFERENCE RANGE

Reference range for adults is 0-40 U/L
The above reference range is only a guideline. Each laboratory should establish its own reference range.

RESULT INTERPRETATION

Since hemolysis interferes with determination, it should be avoided as much as possible during operation.

LIMITATIONS

There is no interference with measurement when hemoglobin ≤ 500 mg/dL, ascorbic acid ≤ 50 mg/dL, bilirubin ≤ 40 mg/dL, and triglycerides ≤ 1000 mg/dL.

PERFORMANCE CHARACTERISTICS

1. Appearance
Reagent 1 in the kit is a colorless clear liquid, which may contain a small number of insoluble particles that do not affect determination. Reagent 2 is a colorless or slightly yellow clear liquid, which may contain a small number of insoluble particles that do not affect determination.
2. Reagent blank absorbance
2.1 Reagent blank absorbance A_{340nm} should be not less than 1.0.
2.2 Rate of change in absorbance of reagent blanks
The reagent blank absorbance change: $|\Delta A_{340nm}|$ /min should not be greater than 0.004.
3. Accuracy
The relative deviation should not fall outside the range of ± 15.0%.
4. Linear range
For serum sample testing within the reagent linear range of [5, 1000] U/L (37°C):
a) The linear correlation coefficient (r) should not be less than 0.9900;
b) The deviation from linearity should not fall outside the range of ± 15 U/L for testing within the linear range of [5, 100] U/L;
the deviation from linearity should not fall outside the range of ± 10% for testing within the linear range of (100, 1000] U/L;
5. Analytical sensitivity
When a sample has a concentration of 97.4 U/L, its absorbance difference should be ≥ -0.050.
6. Precision
6.1 Within-run precision
Within-run precision should not be more than 5.0%.
6.2 Between-run precision
Between-run precision should not be more than 10.0%.

PRECAUTIONS

1. General precautions
1.1 This product is for *in vitro* diagnostic use only.
1.2 For clinical diagnosis, please make a comprehensive judgment based on the measurements, clinical symptoms and other findings.
1.3 Please use this product according to the IFU.
1.4 The results of the kit are only used as a basis for clinical aid in the diagnosis of various diseases. The clinical diagnosis and management of the patient should take into account his/her signs/symptoms, medical history, other laboratory tests and response to treatment, etc. are considered together.
1.5 Reagents from different manufacturers used to test the same sample may produce different results, which should be considered in conjunction with clinical findings.
2. Precautions for operation
2.1 Please treat the specimens as dangerous substances that may be infected with HIV, HBV, HCV, etc. Please use disposable gloves to avoid or reduce the associated risk for infection.
2.2 If the reagents get into the eyes or mouth, or come into contact with the skin, rinse them quickly and thoroughly with water, and receive medical treatment from a doctor when necessary.
2.3 Avoid direct sunlight during operation.
3. Precautions for use
3.1 Please store the reagents according to the storage method, and avoid freezing. Please do not use frozen reagents whose quality may change.
3.2 Please do not use expired reagents whose test results may be inaccurate.
3.3 Please avoid adding reagents halfway during a test.
3.4 Please avoid direct sunlight during operation.
3.5 Do not use the reagents with visible signs of turbidity or if the absorbance of the reagent blank is less than 1.000.
3.6 Serum and heparin-anticoagulated plasma should be separated promptly after blood collection to avoid hemolysis; do not use hemolyzed samples.
4. Precautions for waste disposal
Samples, waste liquids, etc. are potentially biologically contaminated. Operators should comply with the SOP for laboratory safety and dispose of waste liquids in accordance with local regulations for medical waste, infectious waste, industrial waste, etc.
5. Other precautions
5.1 On a fully automatic biochemistry analyzer, the linearity range is related to the ratio of the amount of a sample to the amount of a reagent and the time of measurement.
5.2 The amounts of the reagent and sample can be changed proportionally according to the requirements of different instruments.
5.3 Please do not use the reagent bottles for other purposes.
5.4 A result calculated with the k value is not as reliable as that obtained using the SRM (calibrator).
5.5 Please do not mix reagents in different batches.

REFERENCE

Shang Hong et al. National clinical testing operation procedures (4th ed.). People's Health Publishing House.2015:279-280.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on ALT Reagent Kit (Alanine Substrate Method) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2021.

Key to symbols used					
	Manufacturer		Use-by date	REF	Catalogue number
	Date of manufacture	LOT	Batch code		Temperature limit
IVD	*In vitro* diagnostic medical device		Keep away from sunlight		Biological risks
	Consult *instructions for use* or consult electronic *instructions for use*		Do not use if package is damaged and consult *instructions for use*	EU REP	Authorized representative
CE	CE mark		This way up		Do not re-use

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