Alanine aminotransferase Assay Kit (GPT/ALT)

Method: Alanine Substrate Method

Cat .No	Package Size	Analyzer
EGS001G	R1: 6×60 ml R2: 2×45 ml	For Hitachi917 &OlympusAU640/400/600
EGB000G	R1: 4×100 ml R2: 2×50 ml	For Hitachi 717 &ShimadzuCL7200/8000
EGH001G	R1: 2×50 ml R2: 1×25 ml	For Hitachi902
EGD001G	R1: 24×4.3ml R2: 6×4.3 ml	For Siemens Dupont/Siemens Behring Series
EGALT460 BS	R1: 2×20 ml R2: 1×20 ml	For Mindray BS120/180/190/200/220/230/240/430/460/830
EGGALT	R1: 2×50 ml R2: 1×25 ml	For Semi Auto Analyzer

INTENDED USE

For in vitro quantitative of alanine aminotransferase in human serum.

CLINICAL SIGNIFICANCE

Alanine aminotransferase is a sensitive indicator of liver cell damage. In the acute phase of various hepatitis, various liver diseases and various liver cell necrosis caused by many drugs can be significantly increased. Liver diseases and liver diseases caused by other diseases can cause alanine aminotransferase to increase in varying degrees.

ASSAY PRINCIPLES

The absorbance of NADH was continuously monitored at 340nm, and the rate of decrease was proportional to the activity of ALT in the sample.

$$\text{L-alanine} + \alpha\text{-ketoglutarate} \xrightarrow{\text{ALT}} \text{pyruvate} + \text{L-glutamate}$$

$$\text{pyruvate} + \text{NADH} + \text{H}^+ \xrightarrow{\text{LDH}} \text{L-lactate} + \text{NAD}^+ + \text{H}_2\text{O}$$

$$\text{Endogenous pyruvate} + \text{NADH} \xrightarrow{\text{LDH}} \text{L-lactate} + \text{NAD}^+$$

REAGENT COMPOSITION

Contents	Concentration
Reagent 1 (R1)	
TrisBuffer L-alanine LDH NADH	>10 mmol/L >50 mmol/L ≥1200 U/L >0.18 mmol/L
Reagent 2 (R2)	
α-ketoglutarate	15 mmol/L

STABILITY AND PREPARATION OF REAGENTS

1. Stable up to the expiry date when the reagent is sealed and stored in dark at 2-8 ℃. Cover immediately after use.
2.The production date and expiry date are shown on the label.
3.Once opened, the reagents are stable for 28 days when refrigerated on the analyzer or refrigerator.
4. The single working solution could be stored at 2℃ ~ 8℃ for 4 weeks and under the room temperature for 5 days.
5. The reagent blank absorbance of the working solution should not be less than 1.000.

APPLICABLE INSTRUMENT

This kit is theoretically suitable for all biochemistry analyzers and spectrophotometers covering the wavelength range of 340nm.
It is recommended to use this kit on a biochemistry analyzer for testing according to laboratory conditions.

SAMPLE COLLECTION AND PREPARATION

Serum, heparin lithium anticoagulant plasma.
Samples are stable for a week at 2-8 ℃.

ASSAY PROCEDURE

Test Condition(Hitachi 917)

Main wavelength	340 nm	Sample(S)	10 μl
Secondary wavelength	405 nm	Reagent 1(R)	200μl
Reaction temperature	37℃	Reagent 2(R2)	50μl
Cuvette diameter	1cm	Reaction type	Rate

Operate procedure

Add into cuvette：	
Sample(S)	10μl
Reagent 1(R1)	200μl
Mix well and incubate for 5 minutes at 37℃,	
Reagent 2(R2)	50μl
Mix well and incubate for 60 seconds at 37℃; measure the absorbance continuously in 250 seconds; Calculate(△A/min).	

Note: Parameters above are only introduced with Hitachi 917 as an example. The parameters of different biochemistry analyzers are slightly different. Please read the manual carefully before setting parameters.

CALIBRATION

It is recommended to use Gcell calibration serum, calibration trace to JCCLS CRM-001.
1.According to the requirements of the calibration procedure in the operation manual of biochemistry analyzer, each laboratory establishes its own calibration procedure according to the specific conditions.
2.Treatment of the calibrator: the calibrator is dry powder, the zero-point calibrator is ultrapure water, and the dry powder needs to be reconstituted with ultrapure water.
3.Calibration mode: two-point linear calibration.
4.Requirements for calibration and frequency: It is recommended to calibrate at least once every two weeks. When the following situations occur, it is recommended to re-calibrate: change the reagent batch number, the indoor quality control runs out of control, the biochemistry analyzer carries out major maintenance or replaces the main parts such as light source or cuvette.

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CONTROL

It is recommended to use Gcell control serum. The absorbance of quality control should be within the labeled value range. If the results deviate from the scope, please find out the reason by following steps:

1. Check the parameter setting and light source.
2. Check the cleanliness of the cuvette and sampling needle.
3. Check whether water is contaminated or not. Bacterial growth can lead to incorrect results.
4. Check the reaction temperature.
5. Check the validity of the kit.

CALCULATION RESULT

Setting calibration curve by calibrator concentrations against the corresponding ΔA values. The concentration of AAT in the sample is obtained by ΔA value read from the calibration curve.

NORMAL VALUE

Men:	9-50 U/L
Women:	7-40 U/L

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

INTERFERENCE

The effect of Intralipid≤333 mg/dl, TBIL≤40 mg/dl, Hemoglobin≤500mg/dl, VC≤50mg/dl is less than 10%.

ACCURACY

The kit is tested with JCCLS CRM001 international reference material. The deviation of the results should ≤ ±15%.

SENSITIVITY

When the sample concentration is 130.0U/L, the change of absorbance should ≥ 0.0100.

LINEARITY

In the range of [10.0, 1000.0] U/L, the linearity correlation coefficient r ≥ 0.990. In the range of [10.0, 20.0] U/L, the absolute deviation measured should ≤ ±2.0 U/L, In the range of (20.0, 1000.0] U/L, the relative deviation measured should ≤ ±10%.

PRECISION

Repeatability precision was obtained by testing control or sample for 20 times of repeated measurement. Intermediate precision was obtained by testing human samples or control for 2 batches 5 days, and each batch was measured for 5 times.The results are as follows:

A)Repeatability(N=20)

	Mean(U/L)	CV(%)
Level1	35.325	<2.71
Level 2	124.970	<0.85

B)Intermediate precision(N=25)

	Mean(U/L)	CV(%)
Level1	27.86	<5.7
Level 2	134.91	<3.1

SAFETY PRECAUTIONS AND WARNINGS

1.The reagent contains preservatives. If it enters the eyes, mouth or contact on the skin, please rinse it thoroughly with clean water immediately and go to the hospital if necessary.

2.The reagent contains preservatives, which can react strongly with copper, lead and other metals to form azide metal. Therefore, please dilute the waste liquid and flush the drain pipe to avoid residual when disposal.

3.Do not mix or exchange reagents with different batches in the process of detection.

4.Opened reagents should be sealed and stored according to the specified method. Expired product should not be used.

5. Please dispose of test tubes and other instruments that have been in contact with test specimens in accordance with relevant medical waste disposal regulations. The following treatment methods can be selected:

Use an autoclave to autoclave at 121°C for 15 minutes (but do not use autoclave to treat waste containing hypochlorous acid solution), or soak in hypochlorous acid solution (effective concentration greater than 1000ppm) for one hour the above.

REFERENCES

1. Shang Hong, Wang Yusan, Shen Ziyu. National Clinical Laboratory Procedures. 4th Edition, Beijing: People's Medical Publishing House, 2015:279-281

2. The Health Industry Standard of the People's Republic of China, WS/T 404.1-2012 Reference Interval of Commonly Used Clinical Biochemical Test Items Part 1: Serum Alanine Aminotransferase, Aspartate Aminotransferase, Alkaline Phosphatase and γ-Glut Aminotransferase

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

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