OBio...
Supporting Care to Cure
A Division of Orchard Medical

ALT/GPT (IFCC Modified)

without pyridoxal-5-phosphate

Order Information

Cat. No.	Kit Configuration
OMR1026	Reagent 1: 2 x 40 mL Reagent 2: 2 x 10 mL

Summary

Alanine aminotransferase (ALAT) is an enzyme found primarily in the liver and kidney. It was originally referred to as serum glutamic pyruvic transaminase (SGPT). Normally, a low level of ALAT exists in the serum. ALAT is increased with liver damage and is used to screen for and/or monitor liver disease. Alanine aminotransferase (ALAT) is usually measured concurrently with ASAT as part of a liver function panel to determine the source of organ damage.

Method

Optimized UV-test according to International Federation of Clinical Chemistry and Laboratory medicine (IFCC modified) without pyridoxal-5-phosphate.

Principle

$$\text{L-Alanine} + \text{2-Oxoglutarate} \xrightarrow{\text{ALAT}} \text{L-Glutamate} + \text{Pyruvate}$$

$$\text{Pyruvate} + \text{NADH} + \text{H} \xrightarrow{\text{LDH}} \text{L-Lactate} + \text{NAD+}$$

The rate of NADH consumption is measured photometrically and is directly proportional to the ALAT concentration in the sample.

Reagents

Storage Instructions and Reagent Stability
Reagent are stable up to the end of the indicated month of expiry, if stored at 2 – 8°C, protected from light and contamination is avoided. Do not freeze the reagents!
Reagent 1: Enzyme
Solution Reagent 2:
Substrate Solution

Composition

TRIS buffer 12.1 g/L, L – Alanine 24.1 g/L, LDH (lactate dehydrogenase) ≥ 1200 U/L, 2-Keto glutaric acid 7.9 g/L, NADH 1.1 g/L

Warnings and Precautions

Keep out of reach of children. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
Take off immediately all contaminated clothing.
The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow. Avoid contact with skin and mucous membranes.
For professional use only!

Waste Management

Please refer to latest Biological Medical Waste (BMW) guidelines and local legal requirements.

Reagent Preparation

Mix, 4 parts of reagent 1 and 1 part of reagent 2 = working reagent.
The stability of the working
reagent is 5 days at 15°-25°C.
4 weeks at 2°- 8°C.
Protect the reaction solution from light.

Materials required but not provided

NaCl solution 9 g/L
General laboratory equipment

Specimen

Serum, heparin, plasma or EDTA plasma separate at the latest 1h after blood collection from cellular contents.
7days at 2° –8°C
30 days at –20°C
Only freeze once! Discard contaminated specimens.

Assay Procedure

Wavelength	340nm
Optical Path	10mm
Temperature	37°C

Sample Start

Sample	100 µL
Working reagent	1000 µL
Mix incubate for 1 min. and read absorbance after every 1 min. for 3 min.	

Substrate Start

	Sample/ Calibrator
Sample	100 µL
Reagent 1	1000 µL
Mix and Incubate 5 min. then add	
Reagent 2	250 µL
Mix, Incubate for 1 min. and read absorbance after every 1 min. for 3 min.	

Calculation

ΔA/min and multiply by the corresponding factor from table below:
ALAT activity U/L = ΔA/min x factor.

Conversion Factor

ALAT/GPT (U/L) x 16.67 = ALAT/GPT (nkat/L)

Factor

Sample start	340 nm	1745
Substrate start	340 nm	2143

Quality Controls

For internal quality control any normal and abnormal controls should be assayed with each batch of samples. Each laboratory should establish corrective action in case of deviations in control recovery.

Performance Characteristics Measuring Range

The test has been developed determine ALAT/GPT activities within a measuring range from 6 - 800 U/L. If such value is exceeded the sample should be diluted 1 + 9 with NaCl solution (9 g/L) and results multiplied by 10.

Interferences

No interference was observed by, Ascorbic acid up to 30 mg/dL, Bilirubin up to 40 mg/dL and Triglycerides up to 2000 mg/dL.

Sensitivity/Limit of Detection

The lower limit of detection is 6 U/L

Linearity

The Linearity of detection is 800 U/L.

Precision

Intra-assay n = 20	Mean (U/L)	SD (U/L)	CV (%)
Sample 1	5.69	0.03	0.53
Sample 2	8.27	0.08	0.92

Inter-assay n = 20	Mean (U/L)	SD (U/L)	CV (%)
Sample 1	5.28	0.06	1.04
Sample 2	8.88	0.13	1.41

Method Comparison

A comparison of Nucleus Diagnosys ALAT/GPT (y) with a commercially available test (x) using 15 samples gave following results:

$y = 0.977x + 0.765$; $r^2 = 0.998$.

Reference Range

Women	< 31 U/L
Men	< 41 U/L

Each laboratory should check if reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Literature

1. 1st ed. Frankurt: TH-Books Verlagsgesellschaft; 1998.p.55-65.
2. Tietz Textbook of clinical chemistry.3rded.
3. Philadelphia: W.B saunders company; 1999.p.617-721. 4. Clin Chem Lab Med 2002; 40:718-24.
5. Association for Clinical Biochemistry and Laboratory Medicine. Retrieved 7 October 2013.
6. Central Pollution Control Board (CPCB) Guidelines for Management of healthcare waste as per Biomedical Waste Management rules, 2016. https://www.cpcb.nic.in/uploads/hwmd/Guidelines_healthcare June_2018.pdf

MANUFACTURED BY: NUCLEUS DIAGNOSYS LLP, INDIA

Marketed By: ORCHARD MEDICAL,

DIAMOND ARCADE, 68 JESSORE ROAD,

1st FLOOR, UNIT No. 110 & 112, KOLKATA – 700 055

CUSTOMER CARE No: 84200 69980

CUSTOMER CARE E-MAIL: sales.orchardmedical@gmail.com