

# SGPT / ALT TEST KIT

IFCC Method Without Pyridoxal Phosphate (Kinetic UV)



<b>Product Code:</b> 10047	<b>Reaction Type:</b> Kinetic with Factor
<b>Pack Size:</b> 5 x 10 ml	<b>Matrix Target:</b> Human Serum & Plasma
<b>Storage Temp:</b> 2–8°C	<b>Wavelength:</b> 340 nm (Photometric Light Path: 1 cm)

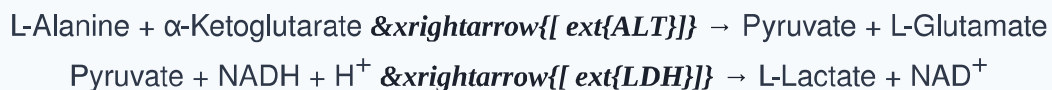
## INTENDED USE & CLINICAL SIGNIFICANCE

**Intended Use:** This liquid diagnostic reagent system is configured for the direct quantitative in vitro kinetic UV determination of SGPT/ALT activity in human serum or plasma specimens.

**Clinical Significance:** Alanine aminotransferase (ALT), formerly known as Glutamate Pyruvate Transaminase (GPT), is present in high concentrations within hepatic tissue, and to a lesser extent in renal, cardiac, and skeletal muscle structures. Damage to hepatocytes causes ALT to leak into the vascular bed, making it a highly specific indicator of parenchymal liver disease, cell necrosis, and acute hepatitis. ALT tracking is valuable when paired with AST to differentiate hepatic lesions from generalized tissue trauma.

## METHOD PRINCIPLE

This kinetic formulation aligns with IFCC recommendations without pyridoxal phosphate. ALT catalyzes the specific transamination of L-alanine and  $\alpha$ -ketoglutarate into pyruvate and L-glutamate. Pyruvate is subsequently reduced to L-lactate by Lactate Dehydrogenase (LDH) while NADH is oxidized to  $\text{NAD}^+$ :



The decrease in optical absorbance at 340 nm, corresponding to the systematic oxidation of NADH, is tracked continuously. The rate of change ( $\Delta A/\text{min}$ ) is directly proportional to the absolute catalytic concentration of ALT.

## STEP 1: REAGENT CONFIGURATION & PIPETTING BASELINE

**Working Reagent Preparation:** Reconstitute the R1 Enzyme Reagent vial with R2 Buffer Reagent as stated on the vial. Bring the required volume to room temperature before testing. Reconstituted working solutions are stable for 30 days at 2–8°C.

Reagent / Component Line	Test Vector Volume
Prepared ALT Working Reagent (Brought to room temperature)	1000 $\mu\text{l}$

Reagent / Component Line	Test Vector Volume
Patient Sample (Hemolysis-free serum or plasma)	100 µl

**Operational Directive:** Mix thoroughly. After an initial 1-minute incubation hold, record the decrease in absorbance per minute ( $\Delta A/min$ ) across a 3-minute reading window.

## STEP 2: CALCULATIONS & DATA TRACKING

$$\text{SGPT / ALT Activity (IU/L)} = \Delta A/min \times 1768 \text{ Factor}$$

## TECHNICAL PARAMETERS & CLINICAL SUPPORT MATRIX

<b>Universal Safeguards</b>	Professional in vitro diagnostic use. Contains less than 0.1% sodium azide. Use single-use glass elements or thoroughly rinsed items to prevent cross-contamination. ALT catalytic activity can falsely decrease in individuals with an underlying Vitamin B6 deficiency. Substrate depletion limits apply to highly active samples.
<b>Expected Range</b>	Normal Clinical Interval: < 40 IU/L. Each laboratory must independently validate its internal reference range.
<b>Analytical Linearity</b>	Linear up to 300 IU/L. Samples with higher activity should be diluted with standard saline and re-assayed.

**Manufactured by: M/s. SAWIN BIOMEDICALS PVT. LTD.**

Plot No: M82/2, Medical Devices Park, Sultanpur, Ameenpur Mandal, Sangareddy Dist-502 319, Hyderabad, Telangana, INDIA.

An ISO 13485 Certified Company | Mfg. Lic. No.: MFG/IVD/2024/000109 | Rev.A