

Order information:

Catalogue number	Size
9541C	10 x 65 + 10 x 33 ml
9542C	4 x 65 + 4 x 33 ml

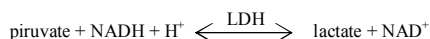
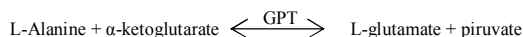
Reagent kit for quantitative in vitro determination of alanine-aminotransferase (GPT) in serum and plasma.

Summary

ALT is found in the cytosol of cells, it is a non-tissue specific soluble enzyme. ALT catalyses the transfer of amino groups during the transformations of aminoacids and alpha-ketoacids. Pyridoxal phosphate activates the process. The enzyme found in the serum is principally derived from the liver and kidney. The serum enzyme activity is increased during various hepatic disease states including hepatitis.

Method

Optimized IFCC method without pyridoxal-5-phosphate



Reagents

Composition and concentrations

Reagent 1

Tris buffer, pH=7.50	110 mmol/l
L-alanine	1200 mmol/l
LDH	4500 U/l
NADH	900 µmol/l

Reagent 2

α-ketoglutarate	60 mmol/l
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Storage and stability

The reagent is stable up to the end of the indicated month of expiry without opening, if stored at 2 – 8°C, protected from light and contamination is avoided. Do not freeze!
Onboard stability after opening and the frequency of calibration is 72 days.
The absorbance at 340 nm should not be lower than 1,1

Warnings and precautions

Do not use reagents after the expiry date stated on each reagent container label.

Chemical safety

This product is not classified as dangerous. Safety data sheet is available upon request. The product contains sodium azide. Sodium azide can react with copper and lead plumbing to form explosive metal azides. If disposal into a drain is in compliance with federal, state, and local requirements, flush reagents with a large amount of water to prevent the buildup of azides.

Preparation

The reagent is ready for use.

Sample

Serum, EDTA plasma
3 days loss of activity in serum
<10% at 2 – 8°C
<17% at 15 – 25°C

Stability in serum: 3 months at -20°C

Expected values and reference range

Serum: <40 U/l

It is recommended that each laboratory should assign its own normal range.

Assay procedure

Wavelength:	340 nm / 410 nm (primary/secondary)
Optical path:	1 cm
Temperature:	37°C
Measurement:	against water blank
Reaction:	kinetic, decreasing

	blank	sample or standard
reagent 1	200 µl	200 µl
dist. water (diluent)	400 µl	400 µl
dist. water (blank)	90 µl	-
sample or standard	-	90 µl
Mix and incubate for 1 minute		
reagent 2	100 µl	100 µl
dist. water (diluent)	200 µl	200 µl
Mix and incubate for 2 minute then continuously read the absorbances for 2 minutes		

Calculation

$\text{GPT}[\text{U/l}] = \Delta A_{\text{sample}} / \Delta A_{\text{standard}} \times \text{standard concentration}[\text{U/l}]$

Conversion factor

$[\text{U/l}] = [\mu\text{kat/l}] \times 60$

Calibration and quality control

S1: Distilled water

S2: Roche C.F.A.S. (Calibrator for automated system) or

Randox Calibration Serum Level I or

Randox Calibration Serum Level II

Calibration is recommended:

- after opening new reagent batch
- after system maintenance or troubleshooting

For internal quality control, two levels controls are recommended (normal and pathological) at least once a day. The measured values must in the range which was given by the control's manufacturer. Each laboratory should establish corrective measures to be taken if values fall outside the limits.

Performance characteristics

Measuring range

The method is linear in the range 5 – 450 U/l

Interferences

No significant interference was observed by bilirubin up to 1000 µmol/l bilirubin, triglycerides up to 11 mmol/l, hemoglobin up to 1 g/l and ascorbate up to 4 g/l. Significant interference: >10%.

Limit of detection

The limit of detection is 2,01 U/l

Precision

Repeatability	mean	SD	CV
n = 20	[U/l]	[U/l]	[%]
normal sample	40,5	1,64	4,05
pathological sample	145,5	1,1	0,76
Reproduceability	mean	SD	CV
n = 10	[U/l]	[U/l]	[%]
normal sample	40,1	1,78	4,45
pathological sample	143	2,61	1,83

Method comparison

Comparison with the non-concentrated reagent.

analyser: Advia 2400

number of samples: 137

range: 1 – 355 U/l










correlation coefficient: 0,9995

regression line equation: $y = 1,02x - 0,763$

(x= normal reagent, y= concentrated reagent)

For in vitro diagnostic use only!

The following symbols can be used on the labels

	In vitro diagnostic device
	Manufacturer
	CE-marking
	Temperature limitations
	Use by (year/month)
	Batch code
	Catalogue number
	This way up
	Biological risk

Literature

Expert Panel on enzyme of the IFCC, Clin. Chim. Acta, 1976. 70:F19
Tietz Clinical Guide To Laboratory Tests, 4th edition, Elsevier, 2006