

PRODUCT CODE

CZ003

INTENDED USE

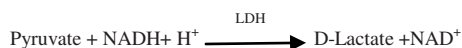
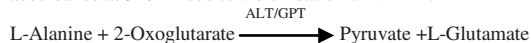
This reagent is intended for *in vitro* quantitative determination of ALT/GPT in serum or plasma.

CLINICAL SIGNIFICANCE

Alanine Aminotransferase (ALT or GPT) is present in high concentrations in the liver and to a lesser extent in kidney, heart and skeletal muscle, pancreas, spleen and lung. Increased levels of ALT however are generally a result of liver disease associated with some degree of hepatic necrosis such as cirrhosis, carcinoma, viral or toxic hepatitis and obstructive jaundice. Characteristically ALT is generally higher than AST in acute viral or toxic hepatitis, whereas for most patients with chronic hepatic disease, ALT levels are generally lower than AST levels. Elevated ALT levels have also been found in extensive trauma and muscle disease, circulatory failure with shock, hypoxia, myocardial infarction and haemolytic disease.

PRINCIPLE

The amino group is enzymatically transferred by ALT present in the sample from alanine to the carbon atom of 2-oxoglutarate yielding pyruvate and L-glutamate. Pyruvate is reduced to lactate by LDH present in the reagent with the simultaneous oxidation of NADH to NAD⁺. The reaction is monitored by measuring the rate of decrease in absorbance at 340nm due to the oxidation of NADH.



REAGENT COMPOSITION

REAGENT 1 (enzyme reagent)

Tris pH 7.5 100 mmol/L
L-Alanine 500 mmol/L
LDH ≥ 1200 u/L

REAGENT 2 (substrate)

2-Oxoglutarate 15 mmol/L
NADH 0.18 mmol/L

REAGENT PREPARATION

SUBSTRATE START

R1 and R2 are ready-to-use and stable upto the expiry date if contamination is avoided and stored at 2-8°C and protect from light.

SAMPLE START

Mix 4 parts of R1 + 1 Part of R2 = Mono reagent

Stability of mono reagent: 4 Weeks at 2-8°C, 4 days at 15-25°C

Protect from light.

Note: Discard the working reagent if the blank absorbance less than 1.0 at 340 nm

SPECIMEN

Serum, heparinized plasma

PRECAUTION

- The reagents contain sodium azide as preservative. Do not swallow and avoid contact with skin and mucous membranes.
- To avoid contamination, use clean laboratory wares. Avoid direct exposure of reagent to light.

ASSAY

Wavelength : 340 nm, Hg 365 nm, Hg 334 nm

Cuvette : 1 cm light path

Temperature : 25°C/30°C/37°C

Adjust the instrument to zero with distilled water or air

PROCEDURE

SUBSTRATE START

Temperature-->	25°C or 30°C	37°C
Reagent 1 Buffer	1000 µL	1000 µL
Sample	200 µL	100 µL
Mix incubates for approx... 1 min, then add,		
Reagent 2 Substrates	250 µL	250 µL

SAMPLE START

Mono reagent (R1+R2)	1000 µL	1000 µL
Sample	200 µL	100 µL

READING FOR BOTH

Mix and read absorbance after 1 min and start stop watch.

Read absorbance again after 1, 2 and 3 min.

CALCULATION

Multiply factor from table below with ΔA/min,

Substrate start	25°C / 30°C	37°C
340 nm	1151	2143
334 nm	1173	2184
365 nm	2132	3971
Sample start	25°C / 30°C	37°C
340 nm	952	1745
334 nm	971	1780
365 nm	1765	3235

LINEARITY

up to 400 U/L, the sample should be diluted 1 + 9 with 0.9 % NaCl solution, if ΔA/min exceeds 0.16 at 340 nm or 334 nm, or 0.08 at 365 nm. Multiply the result by 10.

NORMAL RANGE















	25°C	30°C	37°C
Men up to	22 U/L	30 U/L	42 U/L
Women up to	17 U/L	23 U/L	32 U/L

Each laboratory should establish reference ranges for its own patients' population.

QUALITY CONTROL

All control sera with values determined by this method can be used.

SYMBOL ON LABELS

Symbols	Signify	Symbols	Signify
	Catalogue Number		Pack Size
	Expiry Date		Volume
	Storage Condition		Lot Number
	Instruction for Use		In Vitro Diagnostics
	Manufacturing Date		Manufacturer
	Number of Tests		For Single Use Only
	EC Representative		European conformity

BIBLIOGRAPHY

- Clin. Chem. ACTA 105 (1980) S. 147-172 Synopsis Der Leberkrankheiten : H. Wallhofer, E. Schmidt.
- .Thefeld W. ET. AI. DT . MED. WSCHR. 99 (1974) 343.