

Ana-Chek® SGPT (ALT)

METHOD – UV-KINETIC
PRODUCT CODE – LG06

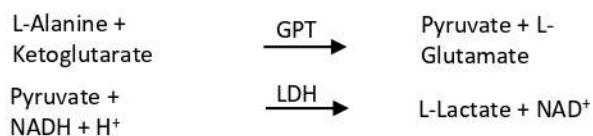


INSTRUCTIONS FOR USE

INTENDED USE: Test for estimation of SGPT activity in serum/plasma using IFCC recommended UV-Kinetic method.

SUMMARY AND PRINCIPLE

Elevated serum SGPT (ALT) levels are found in hepatitis, cirrhosis, and obstructive jaundice. Levels of SGPT (ALT) are only slightly elevated in patients following a myocardial infarction. Characteristically SGPT (ALT) is generally higher than SGOT in acute viral or toxic hepatitis whereas for most patients with chronic hepatic disease SGPT levels are generally lower than SGOT levels. Ana-Chek® SGPT is a reagent set for determination of SGPT (ALT) in human serum / plasma based on UV Kinetic method, recommended by International Federation of Clinical Chemistry (IFCC).



KIT COMPONENTS

Reagent 1 : SGPT Reagent 1
Reagent 2 : SGPT Reagent 2

REAGENT PREPARATION, STORAGE & STABILITY

Reagent R1 and R2 are ready to use liquid reagents. Mix the reagent R1 and R2 in the ratio of 4:1 respectively to prepare the desired volume of working reagent prior to use. Do not shake vigorously. The working reagent is stable for 20 days at 2-8 °C. The reagent kit should be stored at 2-8 °C and is stable till the expiry date indicated on the label.

PRECAUTIONS & HANDLING

The reagents/samples should be handled by qualified personnel only. Discard reagent/sample as per good laboratory practices and local regulatory requirements. Read the instructions given on the labels and instructions for use carefully before using the kit. The kit is intended for in-vitro diagnostic use only. Don't freeze the reagent. Do not shake the reagent vigorously. Discard the reagent if the absorbance of the reagent goes below 0.900 O.D. against D/W at 340 nm. Contamination of the reagent should be avoided.

TEST PARAMETERS

Name	SGPT	Reagent Volume	1000 µl
Reaction Type	Kinetic (↓)	Sample Volume	100 µl
Wavelength Primary	340 nm	Incubation Temp.	37 °C
Flow Cell Temp.	37 °C	Delay Time	60 sec.
Instrument Blank setting	D.W.	Read Time	30 sec.
Reagent Blank Abs Limit	>0.900	Factor	1749
Linearity	1700 IU/L	Standard Conc.	-

MATERIALS REQUIRED BUT NOT PROVIDED

Test tubes, Micropipette with tips, Analyzer, Controls, Incubation chamber.

SPECIMEN COLLECTION & PRESERVATION

Blood should be collected in a clean dry container. Serum is preferred. Heparinized or EDTA - Plasma can be used. Specimen with any visible haemolysis is not acceptable. SGPT in serum / plasma is stable for 7 days at 2-8 °C and for 30 days at -10 °C.

COMPONENTS OF REAGENT

Component	Concentration
Tris Buffer, pH 7.7	80 mmol/l
L-Alanine	200 mmol/l
NADH	0.15 mmol/l
LDH	2000 IU/L
Ketoglutarate	12 mmol/l
Stabilizers, inactive ingredients and surface agents.	

ASSAY PROCEDURE

	Test
Reagent	1000 µl
Serum / Plasma	100 µl
Mix the reagent and sample in the above-mentioned ratio and start the stop watch.	
Aspirate the reaction mixture into the flow cell and record the absorbance at 60 th and 90 th sec.	

CALCULATION

SGPT Activity (IU/L) = Δ Abs. per min x 1749.

REFERENCE VALUES FOR NORMAL PEOPLE

Upto 50 IU/L at 37 °C.

PERFORMANCE CHARACTERISTICS

Measuring Range: The assay is linear between 09 - 1700 IU/L. If the SGPT value exceeds linearity limit (above 1700 IU/L), dilute the specimen suitably with normal saline and repeat the assay. In that case, assay value should be multiplied with the dilution factor to obtain correct SGPT value of the specimen.

Interference: There is no significant interference in samples containing Bilirubin upto 20 mg/dL. Haemolysis interferes due to SGPT activity from erythrocytes.

Precision: Precision studies has been carried out using quality control sera as shown below:

(n=10)	Within Run			Between Run		
Specimen Material	Mean (IU/L)	SD (IU/L)	CV %	Mean (IU/L)	SD (IU/L)	CV %
Low Value Serum	29	0.59	2.0	23.1	0.69	3.0
High Value Serum	97.8	0.68	0.7	90.4	0.87	1.0

Note: We recommend all the laboratories to establish its own accuracy and precision data.

QUALITY CONTROL

Inclusion of a normal value and abnormal value chemistry control serum in each test run ensures optimum quality control. Consistent use of same type and methodology of control serum provides between run precision and accuracy data for SGPT. We recommend to produce such data on daily basis for greater accuracy in assay system which include reagents, instrument, apparatus and operator.

PRECAUTIONS

1. Discard the working reagent if its absorbance is less than 0.900 at 340 nm against distilled water.
2. Haemolysis must be avoided.
3. If the SGPT value exceeds 1700 IU/L then dilute the specimen suitably with normal saline and repeat the assay. In such case multiply the result obtained with the dilution factor to obtain correct SGPT value.

BIBLIOGRAPHY

1. Tietz NW, ed. Clinical Guide to Laboratory Test, 3rd ed. Philadelphia, Pa : W.B. Saunders, 1995 : 76 - 77.
2. Bergmeyer HU, Horder M, Rej R. Approved recommendation (1985) on IFCC methods for the measurement of catalytical concentration of enzymes, Part3. IFCC method for alanine aminotransferase. J Clin. Chem. Clin.Biochem 1986; 24: 481- 489.
3. Fischbach F, Zawta B. Age - dependent Reference Limits of Several Enzymes in plasma at different measuring temperatures. Klin. Lab. 1992; 38:556 - 561.
4. Penttila, I.M., et al., Scand, J.Clin, Lab. Invest 35, 275/ (1975).
5. Hafkenshield, J.C, et al. J.Clin Chem.Clin.Biochem.17, 219 (1979).

Symbol	Explanation	Symbol	Explanation
	Manufactured By		In Vitro Diagnostic Use
	Lot Number		Read Instructions Before Use
	Catalogue Number		Storage Temperature
	Manufacturing Date		Number of Tests / Volume
	Expiry Date		Do Not Reuse
	Protect from Sunlight		Keep Dry

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ISO 9001: 2015
ISO 13485: 2016
GMP
CE