TRUEchemie SGPT (ALT) Test Kit (IFCC)

for the quantitative determination of Serum Glutamate Pyruvate Transaminase (SGPT) in human serum or plasma

INTENDED USE

The TRUEchemie SGPT (ALT) Test Kit (IFCC) Liquid Reagent (kinetic method) Test Kit is used for the quantitative determination of Serum Glutamate Pyruvate Transaminase (SGPT) or Alanine Aminotransferase (ALT) in human serum or plasma.

INTRODUCTION

The enzyme SGPT is widely reported in a variety of tissue sources. The major source of SGPT is of hepatic origin and has led to the application of SGPT determinations to the study of hepatic diseases. Elevated serum levels are found in hepatitis, cirrhosis, and obstructive jaundice. Levels of SGPT are only slightly elevated in patients following a myocardial infarction. UV methods for SGPT determination were first developed by Wroblewski and LaDue in 1956. The method was based on the oxidation of NADH by lactate dehydrogenase (LDH). In 1980, the International Federation of Clinical Chemistry (IFCC) recommended a reference procedure for the measurements of SGPT based on the Wroblewski and LaDue procedure. The SGPT reagent conforms to the formulation recommended by the IFCC.

PRINCIPLE

$$\text{L-Alanine} + \text{2-oxoglutarate} \xrightarrow{\text{SGPT (ALT)}} \text{Pyruvate} + \text{L-Glutamate}$$

$$\text{Pyruvate} + \text{NADH} + \text{H}^+ \xrightarrow{\text{LDH}} \text{Lactate} + \text{NAD}^+ + \text{H}_2\text{O}$$

The pyruvate formed in the first reaction is reduced to lactate in the presence of lactate dehydrogenase and NADH. The activity of SGPT is determined by measuring the rate of oxidation of NADH at 340 nm. Endogenous sample pyruvate is converted to lactate by LDH during the lag phase prior to measurement.

PACK SIZE

Kit size	1 x 50 ml	2 x 50 ml
Cat. no.	ADX215	ADX216
Kit contents		
1) SGPT Reagent (R1)	1 x 40 ml	2 x 40 ml
2) SGPT Reagent (R2)	1 x 10 ml	2 x 10 ml

REAGENTS COMPOSITION

SGPT Reagents (R1) and (R2) provided in separate containers, and both reagents are clear, colorless liquid in ready to use format. After combining SGPT Reagent (R1) and SGPT Reagent (R2), the working reagent composition is

L-Alanine	: 500	mmol/L
LDH	: >1200	U/L
Tris buffer, pH 7.5	: 100	mmol/L
2 - Oxoglutarate	: 15	mmol/L
NADH (Disodium salt)	: 0.18	mmol/L
Stabilizers and Preservatives		

REAGENT PREPARATION

Ready to use reagents.

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use.
2. Specimens should be considered infectious and handled appropriately.
3. Avoid ingestion. DO NOT PIPETTE BY MOUTH.
4. The disposal of the residues has to be done as per local legal regulations.

REAGENT STORAGE & STABILITY

The components of the kit, stored at 2 - 8°C, will remain stable until the expiry date stated on the label.

SPECIMEN COLLECTION AND STORAGE

Non-hemolysis serum or plasma.
Store serum or plasma in stoppered tubes. Sample stored at 2 - 8°C loses 10% of activity in 3 days.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Pipettes to accurately measure required volumes.
2. Test tubes/rack
3. Timer
4. 37°C heating block or water bath
5. Photometer capable of accurately measuring absorbance at 340 nm.

TEST PROCEDURE

Wavelength	:	340 nm
Temperature	:	37°C

Prewarm the reagent to reaction temperature.

	Blank (µL)	Test (µL)
Distilled water	1000	--
SGPT Reagent (R1)	--	800
SGPT Reagent (R2)	--	200
Sample	--	100

Reading & Calculations
Blank the Photometer with D.I Water.
Mix, read the absorbance after 1 min. and start the stopwatch. Read again the absorbance after 1, 2 and 3 minutes

Calculations:
ΔE = Initial absorbance - Absorbance after 1st / 2nd / 3rd min.
Calculations determine the ΔE/min. for every reading and find the mean value.

(Avg ΔE/min.) x 1768 = U/L of SGPT

QUALITY CONTROL

Quality Controls are recommended to monitor the performance of automated assay procedures. Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

EXPECTED VALUE

Normal range: 3 - 35 U/L (37°C).
It is strongly recommended that each laboratory establish its own normal range

PERFORMANCE CHARACTERISTICS

Sensitivity: 1.8 U/L.
Linearity: Up to 500 U/L under the described assay conditions. If the concentration is greater than linearity (500 U/L), dilute the sample with normal saline and repeat the assay. Multiply the result with dilution factor.The linearity limit depends on the sample / reagent ratio, as well as the analyzers used.

PRECISION:

Intra-assay precision within run (n=10)	Mean (U/L)	SD (U/L)	CV (%)
Control Level - 1	30.7	0.4	1.4
Control Level - 2	98.9	0.6	0.6

Inter-assay precision run to run (n=12)	Mean (U/L)	SD (U/L)	CV (%)
Control Level - 1	32.1	0.5	1.6
Control Level - 2	94.9	0.5	0.6

The reagent was tested for 12 days, using two different SGPT(ALT) concentrations. The coefficient of variation was <5%.

AUTOMATED PROCEDURE

Appropriate program sheet is available for different analyzers upon request.

METHOD COMPARISON

Results obtained using TRUEchemie SGPT(ALT) reagent (y) did not show systematic differences when compared with another commercial reagent (x) with similar characteristics. The results obtained is below: The correlation coefficient (r^2) was 0.989 and the regression equation is y=1.002x+1.411. The results of the performance characteristics depend on the analyzer used.

INTERFERENCES

1. Hemolysis must be avoided as the concentration of SGPT (ALT) in red cells is roughly 5 times that of serum.
2. Bilirubin levels up to 40 mg/dl does not interfere.
3. Triglyceride levels up to 2000 mg/dl does not interfere.
4. Certain drugs and other substances also known to affect ALT values.

WASTE MANAGEMENT

Please refer to local regulation requirements.

SYSTEM PARAMETERS

Mode	:	Kinetic
Factor	:	1768
Wave length	:	340 nm
Units	:	U/L
Flow cell temp	:	37°C
Blank	:	Distilled water
Reagent volume	:	800 µL (R1) + 200 µL (R2)
Sample volume	:	100 µL
Lag / Delay time	:	60 sec. (1 min.)
Read time	:	180 sec. (3 min.)
Low normal	:	3
High normal	:	35
Sensitivity	:	1.8
Linearity	:	Up to 500
Reaction slope	:	Decreasing

REFERENCES

1. Henry, J.B.: Clinical Diagnosis and Management by Laboratory Methods, W.B. Saunders and Co., Philadelphia, PA, p-332-335 (1974).
2. Wroblewski, F. and LaDue, J.S. Proc. Soc. Exper. Biol. and Med. 91:569 (1956).
3. International Federation of Clinical Chemistry, J. Clin. Chem. Clin. Bio. 18: 5231(1980).
4. Bergmeyer, H.U. Principles of Enzymatic Analysis. Verlag Chemic, 1978.
5. Young D.S. Effects of drugs on clinical laboratory tests. AACC Press, Washington D.C., 1990.
6. Henry JB. Clinical Diagnosis and Management by Laboratory Methods, 17th ed. WB Saunders Co., 1984, p 1437.
7. ISO 15223-1:2021 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements

Index of Symbols

Consult instructions for use	REF Catalogue number	Caution
IVD *In vitro* diagnostic medical device	LOT Batch code	Non-sterile
2°C 8°C Temperature limit 2-8 °C	Do not re-use	Use-by date
Manufacturer	Date of manufacture	Keep dry
Do not use if package is damaged	Keep away from sunlight	

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