SWEMED DIAGNOSTICS

SGPT REAGENT KIT

(Mod. IFCC Method)

For photometric determination of SGPT in serum/plasma

For In vitro diagnostics only

Ref no.

SGPT25

SGPT125

Summary

SGPT (ALT) is widely distributed in tissues with the highest concentrations found in the liver and kidneys. Even so, SGPT is considered more liver-specific than SGOT. Elevated levels of SGPT are often only observed in liver diseases such as cirrhosis, hepatitis, or metastatic carcinoma. However, there can be elevated levels of ALT with infectious mononucleosis, muscular dystrophy, and dermatomyositis.

Principle

ALT catalyzes the transfer of the amino group from L-alanine to α ketoglutarate - resulting in the formation of pyruvate and L-glutamate. Lactate dehydrogenase catalyzes the reduction of pyruvate and the simultaneous oxidation of NADH to NAD. The resulting rate of decrease in absorbance is directly proportional to ALT activity.

L-Alanine+ α ketoglutarate $\xrightarrow{SGPT}$ L-Glutamate + Pyruvate

Pyruvate + $NADH+H^+$ $\xrightarrow{LDH}$ L-Lactate + NAD^+ $+H_2O$

Kit Contents

Kit size	25ml	125ml
Ref no.	SGPT25	SGPT125
SGPT–R1	1	2
SGPT– R2	1	1
IFU	1	1

Material required not provided

Test tubes, yellow tips, blue tips

Storage & Stability of the Reagents

1. The reagents are stable till the date of expiry, when stored at 2^0-8^0 C, protect from light &contamination is avoided.
2. Do not freeze the reagents.
3. Ensure the reagents shelf life is valid.
4. Do not use reagent if:
   - The initial absorbance at 340nm is below 0.800.
   - The reagent fails to meet stated parameters of performance.

Reagent preparation

Mix, 4 parts of reagent 1 & 1 part of reagent 2 = working reagent.

The stability of the working reagent is

7 days at 15^0-25^0C &

4 Weeks at 2^0-8^0C.

Alternatively 0.8ml of R1& 0.2ml R2 may also be used instead of 1ml of the working reagent directly during the assay.

The working reagent should have an absorbance above 1.0 against distilled water at 340nm.

Discard the reagent if the absorbance is below 1.0

Reagent composition

Reagent 1	Tris buffer Ph 7.8	5gm/L
	L-Alanine	37.5gm/L
	LDH (lactate dehydrogenase)	4k U/L
Reagent 2	α-ketoglutarate	3.4gm/L
	NADH	1.1 gm/L

Specimen

Serum/plasma

Specimen collection

1. Fresh, clear, non-hemolysed serum from fasting patients is recommended.
2. Blood collection devices lubricate with glycerin (glycerol) should not be used.
3. Pyridoxal phosphate can elevate SGPT values by activating the apoenzyme form of the transaminase pyridoxal phosphate may be found in water contaminated with microbial growth.

Storage & Stability of the Specimen

SGPT in serum is stable for three days at room temperature (15-30°C), seven days refrigerated (2-8°C), and thirty days frozen (-20°C).

Warning & Precautions

1. Keep out of reach children. In case of contact with eyes, rinse immediately with plenty of water &seek medical advice.

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2. Take off immediately all contaminated clothing.
3. Wear suitable gloves and eye /face protection.
4. Always use safety pipettes to pull the reagents into a pipette.
5. Reagents may contain some non-reactive and preservative components. It is suggested to handle carefully, avoid direct contact with skin and do not swallow.
6. Perform the test according to the current "Good Laboratory Practice"(GLP) guidelines.

Assay procedure

Wave length	: 340 nm
Temperature	: 37^0 c
Light path	: 10 mm

Pipette into cuvettes	Macro	Semi-Micro
Reagent (R1+R2)	800μl +200μl	400μl+100μl
Sample	100μl	50μl

Mix well & read the initial absorbance A_0 after 1minute and repeat the absorbance reading after every 1, 2, & 3minutes. Calculate the mean absorbance change per minute (ΔA/min).

Calculation

SGPT (U/L) = ΔA/min × 1746

Performance Characteristics

Measuring range

The test has been developed determine SGPT activities which correspond to a maximal A/min of 0.17 at 340nm. If such value is exceeded the sample should be diluted 1+9 with NaCl solution (9g/l) & result multiplied by 10.

Linearity

The linearity is 300U/L

Interferences

Bilirubin to at least 30 mg/dl, and hemoglobin to at least 400 mg/dl, have been found to have a negligible effect on this procedure.

Reference range

Women	<42 U/L
Men	<32 U/L

"It is recommended that each laboratory establish its own normal range representing its patient population."

Quick References

Parameter	SGPT
Method	Kinetic
Wavelength	340nm
Unit	IU/L
Temperature	37^0C
Factor	1746
Reaction slope	Decreasing
Reagent volume	1000µl
Sample volume	100µl
Reaction time	180sec
Delay time	60sec
Delta time	60sec
Blanking	Water blank
linearity	300 U/L

Literature

1. Henry ,R.J.,et al, Am. J.Clin. Path. 34:381.
2. ClinChem Lab Med 2002; 40:718-24.
3. 1st ed. Fraunkurt: TH –Books Verlagsgesellschaft; 1998.p.55-65.
4. Tietz , N. W .,Fundamentals of clinical chemistry, W.B Saunders Co.

Note on symbols and marks

Instructions for use	Use by	Batch number	Manufacturer
Invitro Diagnostic Medical Device	Date of manufacturer	Temperature limit	Reference number