SGPT/ALT

(IFCC/Kinetic Method)

Liquid Reagent

INTENDED USE:

This reagent kit is used for *in-vitro* quantitative determination of SGPT/ALT human serum.

TEST PRINCIPLE:

NADH is oxidized to NAD^+, the resulting decrease absorbance at 340 nm is directly proportional to the activity GPT in the sample.

REACTION :

$$\text{L-Alanine} + \alpha\text{-Ketoglutarate} \xrightarrow{\text{GPT}} \text{Pyruvate} + \text{L-Glutamate}$$

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

KIT CONTENTS:

Reagent 1: Enzyme Reagent

Reagent 2: Substrate Reagent

Product Insert : 01 No.

PREPARATION OF THE WORKING REAGENT:

Mix 4 parts of reagent 1 with 1 part of reagent 2

REAGENT STABILITY AND STORAGE:

All the reagents must be stored at 2-8°C and are stable till expiry date mentioned on the labels.

WORKING REAGENT :

Working Reagent is stable for 15 days at 2-8°C & 4 days at 21-25°C

Minimum allowable absorbance of the working reagent measured at 340 nm against water as reference is 1.0.

SPECIMEN COLLECTION AND STORAGE:

Unhemolysed serum or heparinised plasma from fasting patients is recommended.

Serum is stable for 4 days at 2-8°C & 2 days at 21-25°C & at least 3 months at -20°C

Discard contaminated specimens.

PRECAUTIONS:

1. Storage conditions as mentioned on the kit to be adhered.
2. Do not freeze or expose the reagents to higher temperature as it may affect the performance of the kit.
3. Before the assy bring all the reagents to room temperature.
5. Avoid contamination of the reagent during assay process.
6. Use clean glassware free from dust or debris.
6. Reagent ratio as mentioned here above must be strictly observed as may change into it will adversly effect the factor..

PROCEDURE (Automated):

Refer to specific instrument application instructions.

TEST PROCEDURE (Manual):

Wevelength: 340 nm & Temperature: 37°C

Note : Bring reagents and samples to room temperature (21-25°C).

Pipette into Test Tube	Test
Working Reagent	1000 µl
Sample	100 µl
Mix and after one minute incubation, measure the change in absorbance (ΔOD/min) for 2 minutes. Determine the mean absorbance change per minute (ΔOD/min) and use this for calculation.	

CALCULATION:

GPT/ALT activity (IU/l) = ΔOD/min x Factor (1746).

NORMAL VALUES*:

Serum < 40 IU/L

*It is recommended that each laboratory establish its own normal range.

PERFORMANCE:

1. **Linearity:** 300 IU/l
2. **Comparison:** r = 0.99

   y = 0.97 x +2.2
3. **Precision:**

	Within Run			Run to Run		
	Mean	**S.D.**	**C.V.%**	**Mean**	**S.D.**	**C.V.%**
Low	19.0	0.9	1.8	20.0	0.9	1.8
High	295.0	2.8	0.9	298.0	1.8	0.9

4. Specificity:

The procedure is specific for SGPT/ALT Liquid Reagent. It is relatively free of interference from commonly occurring circumstances in serum or plasma.

CLINICAL SIGNIFICANCE:

GPT activity is predominantly associated with liver tissues followed by comparatively low levels in the heart, muscles and kidneys. Quantitation of GPT is a useful parameter in evaluating the liver function. Elevated levels of this enzyme are found in cases of hepatitis, obstructive jaundice, metastatic carcinoma, hepatic congestion and in kidney diseases.

AUTOMATED APPLICATIONS:

SGPT/ALT Liquid Reagents can be used with Hitachi 700 series, RA 50, 1000 XT, Express 550, Syncron CX4, LISA 200, BTR 810/820/830, Erbachem-5, Ranlab etc. Application sheets for use on specific semiautomatic / batch analyzers are available on request.

Input parameters for semi- auto / auto analyzers are given below:

INPUT PARAMETERS	VALUES
Type of reaction	Kinetic
Slope of reaction	Decreasing
Wavelength	340 nm
Factor	1746
Incubation time	60 sec.
Interval time	60 sec.
Interval No.	2
Flowcell temperature	37°C
Units	IU/l
Upper Normal value	< 40 IU/l
Lower Normal value	0 IU/l
Linearity	300 IU/l
Working Reagent	1000 µl
Sample volume	100 µl

QUALITY CONTROL:

For accuracy, it is necessary to run known serum controls with each assay.

REFERENCES:

1. Clin. Chem. Acta 105 (1980) S. 147-172.
2. Synopsis der Leberkrankheiten:

   H. Wallhofer, E. Schmidt u. F. W. Schmidt, G. Thieme Verlag, Stuttgart 1974.
3. Thefeld W. et al, Dt. Med. Wschr. 99 (1974), 343.

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