

LiquiMAX SGPT (ALT) (REITMAN & FRANKEL'S COLORIMETRIC DNPH METHOD)

ORDERING INFORMATION

Ref. No.	Pack Size
AVGPT1 - 30	30 Tests

INTENDED USE:

LiquiMAX SGPT (ALT) is an in-vitro diagnostic kit is use for the quantitative estimation of Serum Glutamate Pyruvate Transaminase (ALT) in human serum.

PRODUCT FEATURES:

1. Three Liquid Reagents.
2. Avoids cumbersome graph preparation. No need to plot any standard curve.
3. No inhibitory intermediate products produced during the assay.
4. Results correlate with UV-Kinetic Method.
5. Calibrator is calibrated against WHOAST (E.C.2.6.1.2) enzyme calibrator.
6. For colorimeters only.
7. Can be used on any colorimeter and photometer.

CLINICAL SIGNIFICANCE:

Serum Glutamate Pyruvate Transaminase (SGPT), also called Alanine Aminotransferase (ALT), belongs to the transferase class of enzymes. It is found to be distributed mainly in the liver and to a lesser extent in the kidney and muscles. In hepatitis of different etiologies, SGPT is an important indicator not only in the diagnosis of the ailment but also in assessing the prognosis and process of the disease. An elevated SGPT level is characteristic in alcoholics.

PRINCIPLE:



SGPT (ALT) catalyses the transfer of amino group from L-Alanine to 2-Oxoglutarate to form pyruvate and L-Glutamate. The Pyruvate thus formed reacts with 2,4 Dinitrophenyl Hydrazine (2,4 DNPH) to form a corresponding Hydrazone, a brownish red colored complex in an alkaline medium. The color intensity is directly proportional to the SGPT concentration in the serum and is measured photometrically at 505 nm (490-546).

STORAGE AND STABILITY

Dilute Reagent-4 (Alkaline Reagent) 1:10 with deionised water (1 part Alkaline Reagent and 9 parts Deionized water). All the other reagents are ready to use. All the reagents are stable at 2-8°C up to the expiry date mentioned on the label when properly stored.

KIT COMPONENTS

1. Substrate Reagent R1
2. Color Reagent R2
3. Calibrator Reagent R3
4. Alkaline Reagent R4

COMPOSITION:

Reagent	Contents	Active Ingredient	Composition
Reagent-1	Substrate Reagent	L-Alanine 2-Oxoglutarate	220 mm/l 12 mmol/l
Reagent-2	Color Reagent	2,4-DNPH	7 mmol/l
Reagent-3	Calibrator	Sodium Pyruvate	Conc: 170 U/L
Reagent-4	Alkaline Reagent	Sodium Hydroxide	4N

REAGENT RECONSTITUTION & STABILITY

Dilute Reagent-4 (Alkaline Reagent) 1:10 with deionised water (1 part Alkaline Reagent and 9 parts Deionized water). All the other reagents are ready to use. All the reagents are stable at 2-8°C up to the expiry date mentioned on the label when properly stored.

MATERIAL REQUIRED BUT NOT PROVIDED

Laboratory Instrumentation, Spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi auto, calibrated micropipettes, glass or high quality polystyrene cuvettes, test tube/rack, heating bath controls, saline.

REAGENT DETERIORATION

Discard any turbid reagent if blank reagent absorbance exceeds 1.1 at 505 nm against distilled water.

WARNING & PRECAUTIONS

- Reagent may contain some non reactive and preservative components. It is recommended to handle carefully, avoiding contact with skin and ingestion.
- Specimen should be considered infectious and handled appropriately.
- Contamination by soap or glycerol will affect this assay.
- Perform the test according to the general " Good Laboratory Practice" GLP

SPECIMEN COLLECTION AND STORAGE

Clear, unhemolysed serum is preferred.

(Serum should be removed from the clot as soon as possible after collection because of the presence of approximately 10 fold greater concentrations of SGPT in erythrocytes than in serum). For similar reason hemolysis of the specimen must be avoided.

Read absorbances of all the tubes against distilled water at 505 nm (490-546).

TEST PROCEDURE:

Pipette into test tubes labeled as Blank, Calibrator, Control, Test and proceed as per given below.

Reagent	Blank	Calibrator	Control	Test
Substrate Reagent	0.25 ml	0.25 ml	0.25 ml	0.25 ml
Deionised Water	50 µL	-	-	-
Serum Sample	-	-	-	50 µL
Calibrator (Conc. 170 U/L)	-	50 µL	-	-

Mix and incubate at 37°C for 30 minutes.

Color Reagent	0.25 ml	0.25 ml	0.25 ml	0.25 ml
Serum Sample (Same Serum Sample Which is used above)	-	-	50 µL	-

Mix and incubate at 37°C for 20 minutes.

Alkaline Reagent (Prediluted)	1.5 ml	1.5 ml	1.5 ml	1.5 ml
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CALCULATION:

$$\text{SGPT (ALT) activity in U/L} = \frac{\text{Abs of Test} - \text{Abs of Control}}{\text{Abs of Calibrator} - \text{Abs of Blank}} \times \text{Conc of Calibrator (Conc:170 U/L)}$$

EXPECTED VALUE

Male : Up to 42 U/L at 37°C
Female : Up to 38 U/L at 37°C

(The expected value should be used as a reference only. It is recommended that each laboratory should establish its own normal range.)

QUALITY CONTROL & CALIBRATION:

To ensure adequate quality control, the use of commercial reference control serum is recommended with each assay batch. Use of quality control material checks both the instrument as well as reagent functions.

PERFORMANCE CHARACTERISTICS

1. Linearity

Linearity : 300 U/l

2. Sensitivity/ Limit of Detection (LOD)

The lower limit of detection is 0.2 mg/dl

3. Interferences

No interference was observed by ascorbic acid up to 32 mg/dl, bilirubin up to 43 mg/dl, hemoglobin up to 500 mg/dl and lipemia up to 2200 mg/dl.

4. Precision:

Intra-assay (N=20)	Mean	SD	CV
Sample	(IU/L)	(IU/L)	(%)
sample 1	30.6	0.59	1.92
sample 2	79.5	1.28	1.61
sample 3	119.0	1.08	0.91

Inter-assay (N=20)	Mean	SD	CV
Sample	(IU/L)	(IU/L)	(%)
sample 1	33.1	0.78	2.37
sample 2	93.3	1.25	1.34
sample 3	137.0	2.20	1.61

5. Method Comparison:

A comparison of the LiquiMAX SGPT (y) with a commercial obtainable assay (x) gave with 20 samples the following result $y = 1.062x + 0.261$; $r = 0.997$

LIMITATIONS

This method is linear upto 300 U/L. For samples above the linearity limit, dilute suitably with saline and re assay. Multiply by the dilution factor to calculate the end result.














WASTE DISPOSAL

Reagents must be disposed off in accordance with local regulations.

REFERENCES:

1. Reitman, S. Frankel, S. Am.J. Clin. Path. 25:56 (1957).
2. Henry, J.B., Clinical Diagnosis and Management by Laboratory Method P. 361 (1974). W.B. Saunders Co.

Symbols Used on Pack

 REF	Catalogue Number		Warning/Caution
 LOT	Batch No.	 IVD	In vitro diagnostic device
	Manufacturing Date		Storage Limit
	Expiry Date		Consult instruction for use
	Manufacturer		Keep away from sunlight
	Keep Dry		Do not use if package is damaged
	Contains sufficient no. of test		



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