GPT / ALT Test Kit

REF	Pack Size	Reagent 1	Reagent 2
GPTLMS01	2×25 ml	2×20 ml	2×5 ml
GPTLMS02	4×25 ml	4×20 ml	4×5 ml
GPTLMS03	1x25 ml	1x20 ml	1x5 ml
GPTLMS04	4x50 ml	4x40 ml	4x10 ml

INTENDED USE
GPT/ALT reagent is used for the quantitative determination of GPT/ALT activity in human serum.

CLINICAL SIGNIFICANCE
ALT is a cellular enzyme found in highest concentration in liver and kidney. High levels are observed in hepatic disease like hepatitis, diseases of muscles and traumatism. Its better application is in the diagnosis of the diseases of the liver.
When they are used in conjunction with AST Aid in the diagnosis of infarcts in the myocardium, since the value of ALT stays within the normal limits in the presence of elevated levels of AST. Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.
METHOD: UV Kinetic Method

TEST PRINCIPLE
Oxoglutarate + L – Alanine $\xrightleftharpoons{GPT}$ L- Glutamate +

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

KIT CONTENTS/COMPONENTS
Reagent 1 : Buffer Enzymes
Reagent 2 : Standard Substrate

MATERIAL REQUIRED BUT NOT PROVIDED
Laboratory instrumentation, spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi-automated, calibrated micropipettes, glass or high-quality polystyrene cuvettes, test tubes/rack, heating bath, controls, saline.

SAFETY PREQUATIONS AND WARNINGS
1.For in-vitro diagnostics use only.
2.Do not pipette by mouth. Avoid contact with skin and eyes. If spilt thoroughly wash affected area with water.
3.Do not use the reagent after the expiration date printed on the kit.

REAGENT PREPARATION, STORAGE AND STABILITY
Reagent 1 & 2 are ready to use & are stable up to expiry date when stored at 2 – 8°C.
Step 1: For working reagent formation, Mix well four part of Reagent 1 and one part of Reagent 2. i.e. (800 µl R1 + 200 µl R2). The mixture is stable for 4 weeks at 2 – 8°C.

REAGENT DETERIORATION
Discard the reagent if absorbance less than 1.0 at 340 nm against distilled water.

SPECIEMEN
Use serum, GPT- ALT is stable for 7 days at 2 – 8°C. or 7 days at -20°C.

PROGRAM AND PROCEDURE

Reaction Mode	Kinetic
Wavelength	340 nm
Light Path	10 mm
Reagent Volume	1000 µl
Sample Volume	100 µl
Delay Time	30 sec.
Interval Time	60 sec.
Factor	1746
Linearity	5000U/L

PROCEDURE

Addition Sequence	Test
Working Reagent	1000 µl
Sample	100 µl

Mix & incubate for 30 sec. at assay temperature, read the first reading at 30 second and subsequently two more readings with 60 seconds interval at 340 nm.

CALCULATION
Calculate the average change in absorbance per minute.
GPT activity (U/L) = ΔA/min. x 1746

NORMAL VALUES
Men: Up to 40 U/L
Women: Up to 31 U/L

LIMITATIONS
If the value exceeds 500U/L, dilute the sample with 0.9% saline solution rerun and result multiplied by dilution factor.

QUALITY CONTROL AND CALIBRATION
It is suggested to perform internal quality control with assayed normal and assayed abnormal, to confirm the validity of the test and assure the accuracy of patient result. Using the recommended calibrator or the Standard included, calibrate the assay.
1.When using a new reagent or lot
2.When QC values are out of range

WASTE DISPOSAL
This Product is made to be used in professional laboratories.

HIGHLIGHTS
1.Storage condition mentioned on the kit is to be used.
2.Do not freeze or expose the reagents to higher temperature as it may affect the performance of the kit.
3.Before testing bring the reagents to the RT.
4.Avoid reagents contamination.
5.Every time use new pipette-tips for pipetting out the reagents.
6.These Reagent kits meant for laboratory/professional use only, not for Drug use.

REFERENCE
Tietz N.W., ed. Clinical Guide to laboratory Tests, 3rd ed. Philadelphia, Pa: W.B. Saunders,1995:20-21.
Lords Data File.

REF	Catalog No.	Σ	Contain Sufficient for test
LOT	Batch No.		Instruction for use
	Manufacturing Date	IVD	*In-vitro* Diagnostics
	Expiry Date		Storage temperature
	Manufacturer		

IFU/GPT/01 Rev.: 03; Rev Dated.: 22/07/2024

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