GPT / ALT Test Kit

REF	Pack Size	Reagent 1	Reagent 2
GPTLMB01	1 x 60 + 1x 15	1 x 60 ml	1 x 15 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: IFCC 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
Fully Auto Biochemistry Analyzer: LM1016-400TPH.
Calibrator
Controls.

REAGENT PREPARATION, STORAGE AND STABILITY
Reagent 1 & 2 are ready to use & are stable up to expiry date when stored at 2 – 8°C.

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

APPLICATION For LM1016-400 TPH

Method	Kinetic
Reaction	Decreasing
Primary filter	340
Secondary filter	No
R1 Volume	240
R1 Position	*
Incubation time (Sec)	144
R2 Volume	60
R2 Position	*
Incubation time (Sec)	30
Sample Volume	30
Read Time	180
Calibrator Concentration	As on vial label
Mix speed set	Middle
Unit	U/l
Decimal	2

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CALIBRATION
For calibration, it is recommended to use any multi calibrator.

CALCULATION
Calculations Fully automated systems automatically calculate the GPT concentration of each sample.

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.

SAFETY PRECAUTIONS AND WARNINGS
1. For in-vitro diagnostics use only.
2. Do not use the reagent after the expiration date printed on the kit.
3. Avoid reagents contamination.
4. These Reagent kits meant for laboratory/professional use only, not for Drug use.

QUALITY CONTROL AND CALIBRATION
It is recommended 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 multi calibrator, calibrate the assay.
1. When using a new reagent or lot
2. When QC values are out of range

PRECISION
Reproducibility was determined using quality control sera as shown below

	Intra run		Inter run	
Control	Level 1	Level 2	Level 1	Level 2
n	20	20	20	20
Mean (gm/dl)	24.0	99.0	24.04	99.01
SD	1.27	1.7	1.27	1.72
CV (%)	0.05	0.02	0.05	0.02

WASTE DISPOSAL
Reagents must be disposed off in accordance with local regulations.

REFERENCES
Tietz NW, ed. Clinical Guide to Laboratory Tests, 3rd ed. Philadelphia Pa: WB Saunders, 1995:22-24.
Lords Data File.

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

IFU/GPT/03 Rev.: 00; Rev Date.: 22/07/2024

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