SGPT (ALT) IFCC
Kinetic UV Test

Quantitative determination of SGPT (ALT) in serum / plasma
Only for *In Vitro* Diagnostic use

ORDER INFORMATION

REF	Pack Size
GPT 25	2 X 25 mL
GPT 50	2 X 50 mL
GPT 100	4 X 100 mL
GPT 125	5 X 25 mL

CLINICAL SIGNIFICANCE
The 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 traumatisms, 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 the 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
Optimized UV-test according to IFCC (International Federation of Clinical Chemistry and Laboratory Medicine) [modified]

PRINCIPLE
Glutamic-pyruvic Transaminase (GPT - ALT) catalyses the reaction between alpha - ketoglutaric acid and alanine giving L-glutamic acid and pyruvic acid. Pyruvic acid, in the presence of lactate dehydrogenase (LDH) reacts with NADH giving lactic acid and NAD. The rate of NADH consumption is determined photometrically and is directly proportional to the GPT activity in the sample.

REAGENT
Reagent I : Buffer reagent
Reagent ll : Enzyme reagent

MATERIALS REQUIRED BUT NOT PROVIDED
- NaCl solution 9 g/L
- General laboratory equipment

REAGENT PREPARATION
A single working reagent may be prepared by mixing four parts R1 Buffer Reagent with one part R2 Substrate Reagent.

REAGENT STORAGE AND STABILITY
Prior to use:
When stored between 2-8°C the reagent is stable until the expiration date stated on the bottle and kit box label.

Reconstituted Reagent:
When stored capped at 2-8°C, the reagent is stable for at least 30 days.

WARNING AND PRECAUTIONS
- For in vitro diagnostic use.
- Do not use components beyond the expiration date.
- Do not mix materials from different kit lot numbers.
- Exercise the normal precautions required for handling all laboratory reagents.
- The reagent contains preservative. Do not swallow. Avoid contact with skin and mucous membranes.
- For detailed information refer Material Safety Data Sheet.

WASTE MANAGEMENT
Please refer to local legal requirements.

MATERIALS REQUIRED BUT NOT PROVIDED
- NaCl solution 9 g/L
- General laboratory equipment

SAMPLE COLLECTION AND PRESERVATION
Serum or heparin plasma
Stability:
7 days at 4 – 8°C
1 month at –20°C
Discard contaminated specimens. Only freeze once!

ASSAY PROCEDURE
Operating Instructions
- Check reagent inventories at least daily to ensure that quantities are sufficient for the planned work load.
- Bring all reagents, standard and samples to room temperature 18 - 28ºC, prior to analysis.

Automated Parameters	
Wavelength	340 nm
Cuvette	1 cm light path
Reaction Temperature	37°C
Measurement	Against distilled w
Reaction Type	Kinetic test
Reaction Direction	Decreasing
Sample Volume	100 µl
Reagent Volume	1000 µl
Delay/Lag/time	60 Secs
Interval time	30 Secs
No. of Readings	04
Blank Absorbance limit	> 0.8
Factor	1746
Low Normal at 37°C	0 U/l
High Normal at 37°C	40 U/l
Linearity at 37°C	400 U/l

MANUAL ASSAY PROCEDURE
Pipette into Test Tubes

Working Reagent	1000 µl
Sample	100 µl

Mix well and after 1 min 37°C at 340 nm read absorbance values and start timer simultaneously. Measure absorbance Decrease every 30 sec. during 2 minutes & calculate ΔA /min (ΔA/30 sec X 2)

SAMPLE DILUTIONS
- The method is linear to a concentration of 400 U/l.
- If the concentration exceeds this value, the sample should be diluted 1:1 with 0.9% saline solution and reassayed. Multiply the result by 2.

CALCULATION
ALT (SGPT) (U/L) = Δ A/min. X 1746

CLIBRATORS AND CONTROLS
For the calibration of automated photometric systems the commercially available suitable multi-calibrator is recommended.
This method has been standardized against the original IFCC formulation.
It is recommended to run a normal and a pathological control serum which is commercially available to verify the performance of the measured procedure. The value of controls should fall within the established limit.

PERFORMANCE CHARACTERISTICS

WITHIN RUN

Sample	Mean Concentration	SD	CV %
BIORAD 1	27.74	0.49	1.75%
BIORAD 2	102.90	0.23	0.22%

RUN TO RUN

Sample	Mean Concentration	SD	CV %
BIORAD 1	28.05	0.59	2.09%
BIORAD 2	102.97	0.35	0.34%

LINEARITY

The method is linear to a concentration of 400 U/L.
If the concentration exceeds this value, the sample should be diluted 1:1 with 0.9% saline solution and reassayed. Multiply the result by 2.

Limit of detection: The limit of detection for SGPT (ALT) is 5U/L.

METHOD COMPARISON

A comparison of Paramcare SGPT (ALT) with a commercially available assay (x) using 20 samples gave following results: $R^2 = 0.9900$

REFERENCE VALUES

Serum / Plasma	0 - 40 U/l

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

LIMITATION OF THE PROCEDURE

- For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

INTERFERENCE

- Bilirubin: No interference found upto Bilirubin 45mg/dl.
- Hemoglobin: No interference found upto Hemoglobin 250mg/dl.
- Lipemia: No interference found upto 500mg/dl.
- These characteristics have been obtained using an automatic analyzer. Results may vary if a different instrument or a manual procedure is used.

BIBLIOGRAPHY

1. Expert Panel on enzyme of the IFCC, Clin. Chem. Acta, 70, PM, (1976), Teitz.,N.W.

GLOSSARY OF SYMBOL

	Consult Instruction for Use
	Catalog Number
	Store between
	Manufacturer
	Keep away from sunlight



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