LIQUIZYME

SGPT

(IFCC Method)

BEACON

Code	Product Name	Pack Size
LS026A	Liquizyme SGPT	50 ml
LS026B	Liquizyme SGPT	100 ml
LS026C	Liquizyme SGPT	300 ml
LS026G	Liquizyme SGPT	500 ml
LS026H	Liquizyme SGPT	1000 ml

Intended Use

Diagnostic reagent for quantitative *in vitro* determination of ALT/SGPT (Alanine Aminotransferase) in human serum.

Clinical Significance

ALT/SGPT is present in high concentration in liver and to a lesser extent in kidney, heart, skeletal muscle, pancreas, spleen and lung. Increased levels of ALT/SGPT however is generally a result of liver disease associated with some degree of hepatic necrosis such as cirrhosis, viral or toxic hepatitis and obstructive jaundi-ce. Characteristically ALT/SGPT is generally higher than AST/SGOT in acute viral or toxic hepatitis, whereas for most patients with chronic hepatic disease, ALT/SGPT levels are generally lower than AST/SGOT levels. Elevated ALT/SGPT levels have also been found in extensive trauma and muscle disease, circulatory failure with shock, hypoxia, myocardial infarction and haemolytic disease.

Principle

This ALT/SGPT reagent is based on the recommendations of the IFCC without pyridoxal phosphate. The series of reactions involved in the assay system is as follows:

L-Alanine + 2-oxoglutarate $\xrightarrow{\text{ALT / SGPT}}$ Pyruvate + L-Glutamate

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

Sample pyuvate + NADH $\xrightarrow{\text{LDH}}$ L-Lactate + NAD

1. The amino group is enzymatically transfered by SGPT / ALT present in the sample from alanine to the carbon atom of 2-oxoglutarate yielding pyruvate and L- glutamate.
2. Pyruvate is reduced to lactate by LDH present in the reagent with the simultaneous oxidation of NADH to NAD. The reaction is monitored by measuring the rate of decrease in absorbance at 340 nm due the oxidation of NADH.
3. Endogenous sample pyruvate is rapidly and completely reduced by LDH during initial incubation period to avoid interference during the assay.

Reagent Composition

Reagent 1 : SGPT Enzyme Reagent

Tris Buffer	:	>100 mmol/L
Alanine	:	>500 mmol/L
LDH	:	>1500 U/L
2-Oxoglutarate	:	>10 mmol/L

Reagent 2 : SGPT Substrate Reagent

NADH	:	>1.05 mmol/L

Stability And Storage

The unopened reagents are stable till the expiry date stated on the bottle and kit label when stored at 2–8°C.

Material Required But Not Provided

- Clean & Dry container.
- Laboratory Glass Pippetes or Micropippetes & Tips.
- Colorimeter or Bio-Chemistry Analyzer.

Working Reagent Preparation

Mix 4 portion of reaagent R1 with 1 portion of reagent R2.

Stability :

4 days (in the dark)	:	at 20 – 25°C
15 days (in the dark)	:	at 2 – 8°C

Specimen Collection And Handling

Use unheamolytic serum. It is recommended to follow NCCLS procedures (or similar standardized conditions).

Stability

at least 3 months : at -20°C

Discard contaminated specimens.

Quality Control

It's recommended to run normal and abnormal control sera to validate reagent performance.

Unit Conversion

U/l x 0.017 = µkat/l

Expected Values

At 37°C

Serum < 40 U/L

It is recommended that each laboratory verify this range or derives reference interval for the population it serves.

Performance Data

Data contained within this section is representative of performance on Beacon system. Data obtained in your laboratory may differ from these values.

Limit of quantification : 4.4 U/L
Linearity : 400 U/L
Higher Linear Procedure Linearity : 1000 U/L
Measuring range : 4.4 – 400 U/L (Normal Procedure)

Precision

Intra-assay precision Within run (n=20)	Mean (U/L)	SD (U/L)	CV (%)
Sample 1	125	2.96	2.37
Sample 2	95	2.30	2.42

Inter-assay precision Run to run (n=20)	Mean (U/L)	SD (U/L)	CV (%)
Sample 1	38.7	1.175	3.04

Comparison
A comparison between Beacon SGPT (y) and a commercially available test (x) using 20 samples gave following results :
y = 0.942 x + 0.181 U/L
r = 0.992

Interferences
Following substances do not interfere :
haemoglobin up to 2.5 g/l, bilirubin up to 30 mg/dl, triglycerides up to 2000 mg/dl.

Warning And Precautions
For *in vitro* diagnostic use. To be handles by entitled and professionally educated person.
Reagents of the kit are not classified like dangerous but contains less than 0.1% sodium azide - classified as very toxic and dangerous substance for the environment.

Waste Management
Please refer to local legal requirements.

Assay Procedure
Wavelength : 340 nm
Cuvette : 1 cm

Addition Sequence	Normal Procedure	High Linear Procedure
Working Reagent	1000 µl	1000 µl
Sample	100 µl	20 µl

Mix and read the initial absorbance after 1 minute at 37°C and repeat the reading after every 1 and 2 minutes. Calculate the mean absobance change per minute. (ΔA/min).

Calculation
Normal Procedure Factor:
SGPT activity (U/L) = ΔA/min x 1746

High Linear Procedure Factor:
SGPT activity (U/L) = ΔA/min x 8199

Applications for automatic analysers are available on request.

Assay Parameters For Photometers

	Normal Procedure	High Linear Procedure
Mode	Kinetic	Kinetic
Wavelength 1 (nm)	340	340
Sample Volume (µl)	100	20
Working Reagent Volume (µl)	1000	1000
Lag time (sec.)	60	60
Kinetic Interval (sec.).	60	60
No. of Interval	2	2
Kinetic Factor	1746	8199
Reaction temp. (°C)	37	37
Reaction Direction	Decreasing	Decreasing
Normal Low (U/L)	-	-
Normal High (U/L)	40	40
Linearity Low (U/L)	4.4	-
Linearity High (U/L)	400	1000
Blank with	Water	Water
Unit	U/L	U/L

Procedure For Fully Auto Analyzer
Reagent 1 Volume : 120 µl
Reagent 2 Volume : 30 µl
Sample Volume : 6 µl
This reagent is linear up to 850 U/L.
* Refer individual instrument operation manual for programming guidelines.

References
1. Tietz Textbook of Clinical Chemistry. Burtis CA and Ashwood ER, Fifth Edition, 2012.

Symbols Used On Labels

REF	Catalogue Number		Manufacturer
	See Instruction for Use	LOT	Lot Number
CONT	Content		Storage Temperature
	Expiry Date	IVD	In Vitro Diagnostics

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