LiquiCHEK™

AGAPPE

SGPT (S.L)

2 x 30 mL, 3 x 50 mL, 4 x 125 mL
11409005, 11409003, 11409006

Intended Use

This reagent is intended for *in vitro* quantitative determination of SGPT in serum or plasma.

- IFCC recommended methodology
- Linear up to 1000 U/L
- Working reagent can be prepared as per requirements

Clinical Significance

It is present in most of the tissues, but mainly found in the liver. Increased levels are found in hepatitis, cirrhosis, obstructive jaundice & other hepatic disease. SGPT activity is markedly elevated even before clinical signs of jaundice become apparent in disease associated with hepatic necrosis. Slight elevations are also found in myocardial infarction.

Principle

Kinetic determination of Alanine Aminotransferase (ALT) according to the following reaction.

$$\text{L-Alanine + alpha-ketoglutarate} \xrightarrow{\text{ALT}} \text{Pyruvate + L-Glutamate}$$

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

ALT – Alanine aminotransferase

LDH - Lactate dehydrogenase

Kit Components

Reagent/ Component	Product code 11409005	Product code 11409003	Product code 11409006	Description
SGPT (S.L) R1	2 x 24 mL	3 x 40 mL	4 x 100 mL	Tris buffer (pH 7.5) 110 mmol/L L-Alanine 600 mmol/L LDH > 1500 U/L
SGPT (S.L) R2	2 x 6 mL	3 x 10 mL	4 x 25 mL	alpha –ketoglutarate 16 mmol/L NADH 0.24 mmol/L

Risk & safety

Material Safety data sheets (MSDS) will be provided on request

Reagent Preparation

Mix 4 volume of Reagent 1 (R1) with 1 volume of Reagent 2 (R2)

This Working reagent is stable for 30 days at 2-8°C.

Note: Discard the working reagent, if the blank absorbance is less than 1.0 at 340 nm.

Reagent Storage and Stability

The sealed reagents are stable up to the expiry date stated on the label, when stored at 2- 8°C and protected from light.

Open Vial Stability

Once opened, the reagent is stable up to 4 weeks at 2–8°C if contamination is avoided.

Onboard Calibration Stability

On-board Calibration stability is 20 days

Reagent Deterioration

Turbidity or precipitation in any kit component indicates deterioration and the component must be discarded. Values outside the recommended acceptable range for the Agappe Qualicheck Norm & Path control may also be an indication of reagent instability and associated results are invalid. Sample should be retested using a fresh vial of reagent.

Precaution

To avoid contamination, use clean laboratory wares. Use clean, dry disposable pipette tips for dispensing. Close reagent bottles immediately after use.

Avoid direct exposure of reagent to light.Do not blow into the reagent bottles.

This reagent is only for IVD use and follow the normal precautions required for handling all laboratory reagents

Waste Management

Reagents must be disposed off in accordance with local regulations

Sample

Serum /Plasma (free of haemolysis)

Interferences

No interference for

Bilirubin up to : 10 mg/dL

Ascorbic acid up to : 500 mg/dL

Haemoglobin up to : 1000 mg/dL

Materials provided

SGPT Reagent R1& R2

Materials required but not provided

- Pipettes & Tips
- Test Tubes & racks
- Timer
- Incubator
- Analyzer

Test Parameters

	Normal procedure	High Linearity procedure
Mode of Reaction	Kinetic	Kinetic
Slope of reaction	Decreasing	Decreasing
Wavelength	340 nm	340 nm
Temperature	37°C	37°C
Factor	1745	1745
Linearity	350 U/L	1000 U/L
Blank	DI Water	DI Water
Delay	60 sec	60 sec
No of reading	3	3
Interval	60 sec	20 sec
Sample volume	100 µL	100 µL
Reagent volume	1000 µL	1000 µL
Cuvette	1 cm light path	1 cm light path

Application parameters for various instrument are available. Please contact customer support department for specific information.

Unit Conversion

Traditional Unit	SI Unit	Conversion from Traditional to SI
U/L	µKat/L	x 0.017

Calibration

Agappe multicalibrator is recommended for calibration of this assay on fully auto analyzer.

Use provided factor (1745) for estimation of this assay on semi auto analyzer

Procedure notes

Laboratory procedure for Semi Auto Analyzer	
Working reagent	1000 µL
Sample	100 µL
Mix and incubate at 37°C for 1 minute. Measure the change in absorbance per minute (△ OD/min) during 3 minutes.	
High Linearity Procedure	
Mix and incubate for 1 minute at 37°C. Read the change in absorbance per 20 sec during 1 minutes.	

Calculation

SGPT activity (U/L) = (△OD/min) x 1745

SYMBOLS USED ON THE LABELS

IVD IN VITRO DIAGNOSTIC USE | SEE PACKAGE INSERT FOR PROCEDURE | LOT LOT NUMBER | MANUFACTURER'S ADDRESS | MANUFACTURING DATE | EXPIRY DATE | TEMPERATURE LIMIT

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REV. NO.: ADL/IFU/SGPT/LIQ/R02

CE ISO 9001 : 2015
EN ISO 13485: 2016

Quality control

It is recommended to use Agappe Qualicheck Norm & Path (11601001) to verify the performance of the assay. Each laboratory has to establish its own internal quality control scheme and procedure for corrective action, if control do not recover within the acceptable range.

Reference Range

It is recommended that each laboratory has to establish its own reference values.

The following value may be used as guide line.

Serum up to : 49 U/L

Results obtained for patient samples are to be correlated with clinical findings of patient for interpretation and diagnosis.

Performance

1. **Linearity**

This reagent is linear up to 1000 U/L.

If the concentration is greater than 350 U/L, follow the high linearity procedure to get higher linearity of 1000 U/L.

If the concentration is greater than linearity dilute the sample with normal saline and repeat the assay. Multiply the result with dilution factor.

2. **Comparison**

A comparison study has been performed between Agappe reagent and another internationally available reagent yielded a correlation coefficient of r^2= 0.9997 and a regression equation of y = 0.9906x.

3. Precision

Intra Run		
	Control Level 1	**Control Level 2**
n	20	20
Mean (U/L)	38.0	115.9
SD	1.08	3.29
CV(%)	2.86	2.84

Inter Run		
	Control Level 1	**Control Level 2**
n	20.00	20.00
Mean (U/L)	38.7	115.1
SD	1.2	2.7
CV(%)	3.1	2.3

Accuracy (U/L)		
Control	**Expected Value**	**Measured Value**
Control Level 1	28 ± 10.2	31.3
Control Level 2	98.5 ± 25	106.1
Qualichek Norm	48 ± 9.8	52.4
Qualichek Path	125 ± 30	130

4. Sensitivity

Lower detection Limit is 0.5 U/L

Bibliography

1. Clin. Chem, Acta. 105, 147-172 (1780)

2. Thefeld, W., *et al.*; Dtsch. Med Wschr.99, 343 (1994)

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