LiquiCHEK™

AGAPPE

GAMMA GT (S.L)

2 x 10 mL, 2 x 30 mL
11416001, 11416005

Intended Use

This reagent is intended for in vitro Quantitative determination of Gamma GT in serum.

- Szasz methodology
- Linear upto 232 U/L
- Working reagent can be prepared as per requirements

Clinical Significance

GGT activity is elevated in all forms of liver diseases. It is highest in cases of intrahepatic or post hepatic biliary obstruction. (It may be 5 to 30 times higher than normal). It is more sensitive than alkaline phosphatase NTP leucine amino peptidase and transaminases in detection of obstructive jaundice, cholangitis, cholecystis neoplasm, it rises earlier than other enzyme and persists longer.

Moderate increase is observed in infectious hepatitis (2 to 5 times). Increases may also be observed in cases of drug intoxication, acute and chronic pancreatitis.

Principle

Kinetic determination of Gamma GT according to the following reaction.

GLUPA-C+Glycylglycine $\xrightarrow{\text{Gamma GT}}$ L-Gamma-Glutamyl-GlycyLglycine + 5-Amino-2-nitrobenzoic acid.

GLUPA-C: L-Gamma -Glutamyl-3 Carboxy-p-nitroanilide

Kit Components

Reagent/Component	Product Code: 11416001	Product Code: 11416005	Description
Gamma GT R1	2x8 mL	2x24 mL	Tris buffer pH (8.25) -133 mmol/L Glycylglycine -138 mmol/L
Gamma GT R2	2x2 mL	2x6 mL	GLUPA-C - 23 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 21 days at 2-8^{0}C.

Note: Discard the working reagent if the blank absorbance exceeds 1.0 at 405 nm.

Reagent Storage and Stability

The sealed reagents are stable up to the expiry date stated on the label, when stored at 2- 8^{0}C and protected from light.

Open Vial Stability

Once opened, the reagent is stable up to 4 weeks at 2-8^{0}C. if contamination is avoided.

On-board 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 Qualichek Norm & Path control may also be an indication of reagent instability and associated results are invalid. Sample should be retested using 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

Fresh Serum (free of haemolysis).

Interferences

No interference for

Bilirubin up to	20 mg/dL
Ascorbic acid up to	10 mg/dL
Triglycerides up to	700 mg/dL

Materials Provided

GGT Reagent R1& R2.

Materials required but not provided

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

Test Parameter

Mode of Reaction	Kinetic
Slope of reaction	Increasing
Wavelength	405 nm
Temperature	37^{0}C
Factor	1158
Linearity	232 U/L
Blank	DI Water
Delay	60 sec
No of readings	3
Interval	60 sec
Sample volume	100 µL
Reagent volume	1000 µL
Cuvette	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	µ Kat/L	x 0.017

Calibration

Agappe multi calibrator is recommended for calibration of this assay on fully auto analyzers.

Use provided factor (1158) for estimation of Gamma GT on semi auto analyzers.

Procedure notes

Laboratory procedure for Semi Auto Analyzer	
Working reagent	1000 µL
Sample	100 µL
Mix and incubate for 1 minute at 37^{0}C. Read the change in absorbance per minute (△ OD/min) during 3 minutes.	

Calculation

Gamma GT activity (U/L) = (△ OD/min) x 1158

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 should establish its own reference values.

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

AGAPPE DIAGNOSTICS LTD.
'Agappe Hills', Dist. Ernakulam, Kerala, India-683 562.
Tel. +91 484 2867 000 | Customer Support No.: 1800 425 7151(Toll Free)
customersupport@agappe.in | www.agappe.com

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

CE ISO 9001 : 2015
EN ISO 13485: 2016

The following value may be used as guide line.

Female : 5 - 32 U/L

Male : 10 - 45 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 232 U/L.

   If the concentration is greater than linearity (232 U/L) 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= 0.9936 and a regression equation of y = 1.0128x .

3. **Precision**

Intra Run

	Control Level 1	Control Level 2
n	20	20
Mean (U/L)	51.7	129.7
SD	0.50	1.57
CV(%)	0.97	1.21

Inter Run

	Control Level 1	Control Level 2
n	20	20
Mean (U/L)	51.25	128.62
SD	1.25	2.73
CV(%)	2.43	2.13

Accuracy (U/L)

Control	Expected Value	Measured Value
Control Level 1	44.8 ± 8.2	47
Control Level 2	135 ± 29	140
Qualichek Norm	45.20 ± 7.10	43
Qualichek Path	220 ± 40	219.4

4.Sensitivity

Lower detection Limit is 1.5 U/L.

Bibliography

1. Szasz, G.; Clin.Chem., 22, (1976),2051.
2. Scand. J.Clin. Lab.Invest 36:711 (1976)
3. Tietz, N.W.; Text book of Clin.Chem. 678-686 : (1986)

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