AutoPure Gamma - GT
IFCC

Introduction

1. AutoPure Gamma-GT is a reagent kit for direct quantitative determination of gamma-glutamyltransferase (GGT) in human serum and plasma on automated clinical chemistry analyzers.
2. AutoPure Gamma-GT is a ready-to-use, two liquid reagent system.
3. With AutoPure Gamma-GT, the assay is linear upto 1200 IU/l (20.04 µkat/l).

Principle

Gamma-glutamyltransferase (GGT) transfers the γ-glutamyl group of L-γ-glutamyl-3-carboxy-4-nitroanilide to glycylglycine.

L-γ-glutamyl-3-carboxy-4-nitroanilide + glycylglycine
↓ GGT
L-γ-glutamyl-glycylglycine + 5-amino-2-nitrobenzoate

The amount of 5-amino-2-nitrobenzoate liberated is proportional to the GGT activity in the specimen and is measured kinetically.

Reagent Storage, Stability & Handling

AutoPure Gamma-GT is a ready-to-use, two liquid reagent system.

Shelf - Life

Stable till the expiry date indicated on the label, when stored at 2^0 - 8^0C.

On - Board Reagent Stability

R1 : 21 days$^\Delta$ at 2^0 - 8^0C after opening. Protect the reagent from light and contamination.

R2 : 21 days$^\Delta$ at 2^0 - 8^0C after opening. Protect the reagent from light and contamination.

Do not freeze the reagent.

Note: Over a period of time, the reagent R2 may develop a yellow colour. This is expected and does not impair the performance of the assay.

$^\Delta$Minimum stability. Laboratories can increase the stability period upto 30 days by avoiding contamination & ensuring proper reagent storage.

Components & Concentration of Working Solution

Component	Concentration
R1	
• Glycylglycine; pH 8.5	200 mmol/l
• Stabilizers, excipients & surface active agents	
R2	
• MES buffer; pH 5.5	20 mmol/l
• L-γ-glutamyl-3-carboxy-4-nitroanilide	≥ 25 mmol/l
• Stabilizers, excipients & surface active agents	

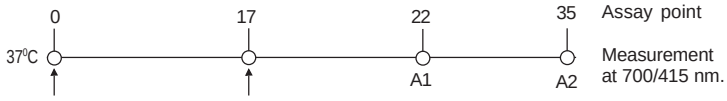
Specimen Collection & Preservation

Collect sample using standard sampling tube. Although serum is preferred, heparinized plasma or EDTA plasma can also be used.

GGT in serum / plasma is stable for 7 days at 2^0 - 8^0C, and for 180 days at -20^0C. Centrifuge samples containing precipitate before performing assay.

Procedure

AutoPure Gamma-GT can be used on various automated analyzers. The procedure described below is for a Hitachi▲▲ 902 auto-analyzer.



Sample : 7 µl R3 : 50 µl
R1 : 250 µl

R2 : NA

▲▲Hitachi is a registered trademark of Roche Diagnostic, Indianapolis, IN

Calculations

Fully automated systems automatically calculate the GGT activity of each sample.

Results in mkat/l = Results in IU/l x 0.0167

Application Sheets

Application sheets for the popular fully automated analyzers are provided along with the kit. For additional system applications, contact our local Accurex representative.

Calibration

Determine the factor using a calibrator. For calibration, it is recommended to use C.f.a.s.* or any other suitable calibrator material.

Calibration frequency :

Re-calibration is recommended

- Whenever the reagent lot is changed
- As per the requirements of quality control procedures

*C.f.a.s. is the brand name of Roche Diagnostics, Germany

Quality Control

Each batch of AutoPure Gamma-GT is assayed with at least six quality control sera — Precinorm**, Precipath**, Biorad I***, Biorad II***, Sero Low**** and Sero High**** prior to release▲.

To ensure adequate quality control, it is recommended that the laboratory should use normal and an abnormal commercial reference control serum. It should be realized that the use of quality control material checks both reagent and instrument functions together. The value of these controls should fall within the specified limits. If control values fall outside specified limits, each of the below criteria should be cross-checked and corrected :

- Proper instrument function - wavelength setting, light source and temperature control
- Cleanliness of probes & cuvettes
- Bacterial contamination of wash water used by the instrument
- Expiry date of the reagent kit

**brand name of Roche Diagnostics, Germany; ***brand name of Biorad, USA
****brand name of Sero, Norway; ▲subject to availability of control serum

Expected Values

Serum/Plasma

		37°C
IU/l	Men	8 - 61
	Women	5 - 36
µkat/l	Men	0.13 - 1.02
	Women	0.08 - 0.60

Note :

Expected range varies from population to population. It is therefore recommended that each laboratory should establish its own normal range. For diagnostic purposes, the GGT results should always be assessed in conjunction with the patient's medical history, clinical examinations and other findings.

Performance Characteristics

Linearity

With AutoPure Gamma-GT, the assay is linear upto 1200 IU/l (20.04 µkat/l). Determine samples with higher concentrations via the rerun function. On instruments without rerun function, manually dilute samples with higher concentrations using 0.9% NaCl or distilled / deionized water (e.g. 1 + 4). Multiply the result by the appropriate dilution factor (e.g. 5).

Interference

There is no significant interference in samples containing upto 30 mg/dl of bilirubin, 90 mg/dl of haemoglobin and 10 mg/dl of ascorbic acid.

Precision

Reproducibility was determined using quality control sera as shown below :

n = 15

	Within run			Between run		
Quality Control Material	Mean IU/l	SD IU/l	%CV	Mean IU/l	SD IU/l	%CV
Low Control Serum	35	1.36	3.9	37	1.30	3.5
High Control Serum	200	3.41	1.7	201	3.20	1.6

Co-Relation Studies

A comparison of the GGT determination using AutoPure Gamma-GT assay (y) and reference GGT kit of Daiichi, Japan (x) gave the following co-relation (IU/l) :

Linear Regression

y = -0.636 + 0.998x

r = 0.9835

Sy.x = 9.62

No. of samples measured : 85

The sample concentrations measured were between 10 and 200 IU/l.

References

1. Persijn, J.P., Van der Slik, W. A new method for the determination of γ-glutamyltransferase. ***J. Clin. Chem. Clin. Biochemk.*** 1976;4:421.
2. Shaw, L.M., Stromme, J.H., London, J.L., et. al. ***Clin. Chem. Acta*** 1983; 135 : 315 - 338.
3. Shaw, L.M. Keeping pace with a popular enzyme GGT. ***Diagnostic Medicine*** 1982; May/June: 1-8.
4. Tietz, N.W. ***Clinical Guide to Laboratory Tests,*** 3rd ed. Philadelphia, Pa : WB Saunders Company, 1995 : 286.
5. In-house test data. ***Accurex Biomedical Pvt. Ltd.,*** 2002.

IVD	*In Vitro* Diagnostic Use		Date of Manufacturing
	Consult Instructions for use		Use by (YYYY-MM-DD)
REF	Catalogue Number		Temperature Limitation
LOT	Batch Code		Manufacturer

CE European Conformity

AR. No.: I 47 AGT-2009-05-00I

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