INTRODUCTION

1. AutoZyme Gamma-GT is a reagent set for determination of gamma-glutamyltransferase (GGT) in serum and plasma based on **IFCC method.**
2. AutoZyme Gamma-GT is a **ready-to-use,** two liquid reagent system, using single step reconstitution.
3. AutoZyme Gamma-GT estimates GGT activity in just **3 minutes.**
4. AutoZyme Gamma-GT is **linear** upto 1000 IU/l.
5. AutoZyme Gamma-GT can be used on any **Spectrophotometer, Discrete semiautomated and Automated analyzers.** Programme can be designed for any specific analyzer upon request.
6. AutoZyme Gamma-GT is **stable till expiry** at 2- 8°C.

PRINCIPLE

Gamma-glutamyltransferase (GGT) transfers the γ-glutamyl group of L-γ-glutamyl-3-carboxy-4-nitroanilide to glycylglycine. The amount of 5-amino-2-nitrobenzoate liberated at 405 nm. is proportional to the activity of GGT in serum/plasma and is measured kinetically.

L-γ-glutamyl-3-carboxy-4-nitroanilide + glycylglycine

↓ GGT

L-γ-glutamyl-glycylglycine + 5-amino-2-nitrobenzoate

PREPARATION OF WORKING SOLUTION

R1 : Buffer reagent is ready-to-use.

R2 : Transfer contents of diluent bottle R_2(b) into substrate bottle R_2(a) as per the instructions indicated on the label. Mix gently by inversion. Prepare working solution by mixing **Reagent R_1 and Reagent R_2** in the ratio 4 : 1 as per requirement.

Note : Over a period of time, the reagent R_2 after reconstitution may develop a yellow colour. This is expected and does not affect the performance of the assay.

REAGENT STORAGE & STABILITY

The reagent kit should be stored at 2 - 8° C and is stable till the expiry date indicated on the label.

R_1 & R_2 reagents are stable till expiry at 2 - 8° C.

The working solution (4 R_1 + 1 R_2) is stable for 21 days at 2 - 8° C.

COMPONENTS & CONCENTRATION OF WORKING SOLUTION

R_1 Buffer Reagent

- Glycylglycine, pH 8.5 — 170 mmol/l

R_2(a) Substrate

- L-γ-glutamyl-3-carboxy-4-nitroanilide — 3 mmol/l

R_2(b) Diluent for Substrate

- MES buffer, pH 5.5 — 4 mmol/l

SPECIMEN COLLECTION & PRESERVATION

Blood should be collected in a clean dry container. Although serum is preferred, plasma with heparin or EDTA can be used. GGT in serum/plasma is stable for 7 days at 2 - 8° C and 6 months at -20° C. Centrifuge samples containing precipitate before performing the assay. The samples should be brought to room temperature prior to use.

PROCEDURE

- **Reaction type** ..... **Kinetic**
- **Reaction direction** ..... **Increasing**
- **Wavelength** ..... **405 nm.**
- **Flowcell temperature** ..... **37°C**
- **Zero setting with** ..... **Working solution**
- **Delay time** ..... **60 seconds**
- **No. of readings** **3**
- **Interval** ..... **60 seconds**
- **Sample volume** ..... **0.05 ml (50 µl)**
- **Working solution volume (4 R_1 : 1 R_2)** ..... **1.0 ml (1000 µl)**
- **Factor** **2201**
- **Linearity** ..... **1000 IU/l**

Manual assay procedure

Prewarm at 37°C the required amount of working solution before use.

Perform the assay as given below:

1.0 ml procedure

Serum / Plasma ..... **0.05 ml**
Working solution ..... **1.0 ml (800 µl R_1 + 200 µl R_2)**

Mix thoroughly and transfer the assay mixture immediately to the thermostated cuvette and start the stop watch simultaneously. Record the first reading at 60th second and subsequently two more readings with 60 seconds interval at 405 nm.

Calculation :

Calculate the change in absorbance per minute.

Activity of GGT in IU/l = Δ Abs./min. x 2201

100-0-0002-IFCC

EXPECTED VALUES

Serum/Plasma

Temperature	at 37°C
Men	8 - 61 IU/l
Women	5 - 36 IU/l

Expected range varies from population to population. It is therefore recommended that each laboratory should establish its own normal range

PROCEDURE LIMITATIONS

1. If the GGT activity exceeds 1000 IU/l, dilute the specimen with normal saline and repeat the assay. In such cases the results obtained should be multiplied with the dilution factor to obtain correct GGT activity.
2. The working solution is considered unsatisfactory and should not be used if the absorbance exceeds 1.000 at 405 nm. against distilled water.

QUALITY CONTROL

To ensure adequate quality control, it is recommended that each batch should include normal and an abnormal commercial reference control the serum. It should be realized that the use of quality control material checks both instrument and reagent functions together. Factors which might affect the performance of this test include proper instrument function, temperature control, cleanliness of glassware and accuracy of pipetting.

REFERENCES

1. Pefsijn, J.P., van der Slik W. A new method for the determination of -γ-glutamyltransferase. ***J. Clin. Chem. Clin. Biochem.*** 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. ***Cinical Guide to Laboratory Tests,*** 3rd ed. Philadelphia, Pa : WB Saunders Company, 1995 : 286.
5. In-house test data. ***Accurex Biomedical Pvt. Ltd.,*** 2003.

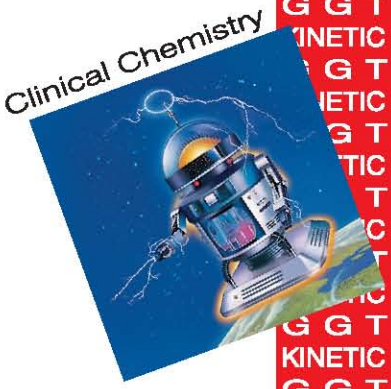
Liquid dispensing facility

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 59 *GT-2009-06-00I*

ACCUREX BIOMEDICAL PVT. LTD.
Head Office - Mumbai. Tel.: 91(022) 67446744; Fax: 91(022) 67446755
E-mail: accurex@vsnl.com; Website: www.accurex.org
Plant : G-54, MIDC Tarapur, Boisar, Thane - 401 506. INDIA.



AutoZyme

GAMMA-GT

IFCC

GGT • GGT • GG
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