GAMMA GT

(γ-Glutamyl Transferase)

Diagnostic reagent for determination of Gamma GT activity.

Liquid. Dual Reagents. Store at 2°C - 8°C. For in Vitro Diagnostic Use. Do not freeze

Ref No	Pack	Ref No	Pack	Ref No	Pack	Ref No	Pack
A2173	5 X 100 mL	DM2170	960 Tests	BY2170	7670 Tests	K2171	4000 Tests
A2170	5 x 50 mL	R2170	2885 Tests	BY2171	5114 Tests	M2170	2512 Tests
A2172	5 x 25 mL	R2171	962 Tests	N2170	800 Tests	M2171	1675 Tests
T2170	4000 Tests	S2170	3077 Tests	N2171	400 Tests	L2170	3750 Tests
T2171	2121 Tests	S2171	1477 Tests	K2170	6000 Tests	L2171	2000 Tests

INTENDED USE

The test is applied for the quantitative determination of Gamma-GT in serum and plasma EDTA

TEST PRINCIPLE

The enzyme γ-GT (EC 2.3.2.2, γ-glutamyl-peptide:amino acid γ-glutamyltransferase; GGT) hydrolizes the GLUPA-C to release p-nitroaniline. The p-nitroaniline formed is detected spectrophotometrically at 405 nm to give a measurement of GGT activity in the sample.

TEST PARAMETERS

Method	: Colorimetric, Kinetic, Increasing Reaction, IFCC
Wavelength	: 405 nm
Temperature	: 37°C
Sample	: Serum, EDTA-Plasma
Linearity	: 4 U/L - 800 U/L (Sample start)

REAGENT COMPOSITION

Tris buffer pH 8.25,	≤ 100 mM
Glycilglycine	≤ 100 mM,
L-Glutamyl-3-carboxy-4-nitroanilide	≤ 5 mM.

REAGENT PREPARATION

Working Reagents:
Mix 4 parts of Reagent 1 (Buffer) with 1 part of Reagent 2
For example: 4 ml Reagent 1 and 1 ml Reagent 2.

Working reagents are stable for minimum 60 days at 2-8ºC in case of closed vials and avoiding from light sources and contamination after preparation.

For manual working procedures; if working reagent will be used; shake the Reagent 2 vial gently before pouring its contents into the Reagent 1 bottle. It is advisable to wash the Reagent 2 vial with a small volume of the prepared mixture in order to completely rinse the vial and avoid any losses.

REAGENT STABILITY AND STORAGE

Once opened vials (reagent 1) are stable minimum 30 days at 2-8°C at optimum conditions. On board stability is strongly related to auto analyzers cooling specification and carry-over values.

SAMPLE

Serum and plasma EDTA are collected by standard procedures. Avoid hemolysis.

GGT is stable for 7 days at 20 - 25°C, 7 days at 2-8ºC and minimum 1 year at -20°C.

TEST PROCEDURE

Sample Start
There have many ready application procedures dedicated to different kind of photometers and ready manual working process can be supplied on request.

There have many ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied on request.

Substrate Start
There have many ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied on request.

CALCULATION

Perform calculation in units per litre, multiplying the ΔA/min by the factor as it is indicated.
Calculation in U/L: ΔA/min x 1280 (sample starter)
Calculation in U/L: ΔA/min x 1571 (reagent starter)
Activity in µkat/L: U/l x 0.0167 = µkat/L

REFERENCE INTERVAL (NORMAL VALUES) (Based on CLSI C28-P Document)*

Men : < 50 U/L (< 0.83 µkat/L)
Women: < 30 U/L (< 0.50 µkat/L)

*It is recommended that each laboratory establish its own reference range.

QUALITY CONTROL AND CALIBRATION

All control sera with Gamma GT values determined by this method can be used. We recommend:

"ARCON N", Assayed Control Serum Normal
Cat.No. A3910

"ARCON P", Assayed Control Serum Abnormal
Cat.No. A3920

The use of a Gamma - GT Calibrator (for automated Systems) is optional. We recommend
A39050ARCAL AUTO

*Calibration Stability: It is strongly depend of application to auto analyzers and auto analyzers specification. Calibration stability is about 25 days.

*Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

Quality control is recommended every morning. Calibration is not recommended if QC control values are acceptable. Reagent should be calibrated after lot changes.

PERFORMANCE CHARACTERISTICS

Low linearity: 4 U/L.

High Linearity: The method is linear up to 800 U/L.

If a ΔA/min of 0.400 is exceeded, it is suggested to dilute sample 1+9 with saline and to repeat the test, multiplying the result by 10.

Linearity may considerably vary depending on the instrument used.

Precision Studies (Based on CLSI EP5 Doc.):

Repeatibility (within run) (Intra-assay)

Mean conc.	SD	CV	n
44.96 U/L	0.41	0.90%	10
187.72 U/L	1.15	0.60%	10

Reproducibility (run to run) (Inter-assay)

Mean conc.	SD	CV	n
44.37 U/L	0.51	1.10%	20
186.70 U/L	1.07	0.60%	20

Sensitivity (LOD) (Based on CLSI EP17 document): The limit of detection is 1 U/L.

Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagents. Details of the comparison experiments are available on request.

Interferences: There is no interference was observed by the presence of:

Hemoglobin	≤ 200 mg/dL
Bilirubin	≤ 25 mg/dL
Lipids	≤ 500 mg/dL

Methods comparison: A comparison between Archem and a commercially available product gave the following results:
GGT Archem = x
GGT competitor = y
n = 112
$y = 1.10x - 1.11$ U/l $r^2 = 0.997$

These performance characteristics have been obtained using an analyzer. Results may vary if a different instrument or a manual procedure is used.

NOTES

1. For in vitro diagnostic use only. Do not pipette by mouth. Avoid contact with skin and mucous membranes.
2. All the calibrators, controls and some reagents must be considered as human & animal sample, so potentially infectious; all the protection actions must be applied to avoid any potential biological risk.
3. Material safety data sheet will be supplied on request.
4. Exercise the normal precautions required for handling laboratory reagents.
5. After measurements are taken, reagent bottles should cap and kept at 2-8°C. Caps of the reagents bottles cannot be used between two different kind of reagent and between R1&R2.
6. Reagents with different lot numbers should not be interchanged or mixed.
7. The linearity limit depends on the sample to reagent ratio.

PRECAUTIONS AND WASTE DISPOSAL

This product is made to be used in professional laboratories and by professional operators. Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.
R36/38 : Irritating to eyes and skin.
S20/21 : When using, do not eat, drink or smoke.
S26 : In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S28 : After contact with skin wash immediately with plenty of water.
S36/37/39: Wear suitable protective clothing, gloves and eye/face protection.
S45 : In case of accident or if you feel unwell, seek medical advice immediately.
S56 : Dispose of this material and its container at hazardous or special waste collection point.

S57 : Use appropriate container to avoid environmental contamination.
S61 : Avoid release in environment. Refer to special instructions/safety data sheets.
Please consult local regulations for a correct waste disposal.

ABBREVIATIONS

CLSI : Clinical and Laboratory Standards Institute
CV% : Coefficient of Variation Percentage
EP : Evaluation Protocols
GGT : Gamma GT
GLP : Good Laboratory Practice
IU : International Unit
mA : miliabsorbance
mL : mililiter
NCCLS : National Committee for Clinical Laboratory Standards
QC : Quality Control

REFERENCES

1. Young DS, Effects of Drugs on Clinical Laboratory Tests, AACC Press, Third Edition, Washington (1990).
2. Tietz Textbook of Clinical Chemistry, Second Edition, Burtis-Ashwood (1994).
3. Szasz G. - Clin. Chem. 22, 2051 (1976)
4. Clinical and Laboratory Standards Institute (formerly NCCLS). Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline - Second Edition. Wayne, PA: Clinical and Laboratory Standards Institute; 2004. NCCLS Document EP05-A2.
5. Shaw LM, Strømme JH, Loudon JL, and Theodosen L. IFCC Methods for the Measurement of Catalytic Concentration of Enzymes. Part 4 IFCC Method for ▪ -Glutamyltransferase. J.Clin Chem. Biochem. 1983;21:633-646.
6. HU Bergmeyer - Method of enzymatic analysis (1987)

SYMBOLS

IVD	Only for invitro diagnostic use
LOT	Lot of manufacturing
R1	Reagent 1
R2	Reagent 2
CONC	Concentration
INGRED	Reagent Ingredients
REF	Reference Number (Catalog No)
SN	Serial Number
	Expiration date
	Storage temperature interval
	Read the directions
	Biological risk

CE

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