Liquid Reagents – ready to use

GAMMA GT

(γ-Glutamyl Transferase)

SZASZ, standardized to IFCC

2 Reagents

Diagnostic reagent for quantitative in vitro determination of gamma-glutamyltransferase (gamma-GT) in human serum or plasma on photometric systems

REF Cont.

D95604	**5 x 50 ml**	4 x 50 ml	Reagent 1
		1 x 50 ml	Reagent 2

Additionally offered:

D98485	5 x 3 ml	Calibrator	Diacal Auto
D98481	12 x 5 ml	Control normal	Diacon N
D98482	12 x 5 ml	Control abnormal	Diacon P

TEST PARAMETERS

Method:	Colorimetric, Kinetic, Increasing Reaction SZASZ, standardized to IFCC
Wavelength:	405 nm (400 – 420 nm)
Temperature:	37°C
Sample:	Serum, heparin plasma
Linearity:	up to 284 U/L (Szasz, Substrate start)
	up to 232 U/L (Szasz, Sample start)
	Up to 321 U/L (IFCC, Substrate start)
	Up to 262 U/L (IFCC, Sample start)
Sensitivity:	The lower limit of detection is 2 U/L

REAGENT COMPOSITION

COMPONENTS	FINAL CONCENTRATION
Reagent 1:	
Glycylglycine	100 mmol/L
Tris, pH 8.25	100 mmol/L
Reagent 2:	
L-Gamma-Glutamyl-3-Carboxy-4-Nitroanilide	4 mmol/L

REAGENT PREPARATION

Substrate Start:
Reagents are ready for use.

Sample Start:
Mix 4 parts of Reagent 1 with 1 part of Reagent 2.
(= Working Reagent)

REAGENT STABILITY AND STORAGE

Conditions: protect from light
close immediately after use
do not freeze!

Substrate Start:

Storage:	at 2 – 8°C
Stability:	up to the expiration date

Sample Start (Working Reagent):

Storage:	at 2-8°C	at 15-25°C
Stability:	4 weeks	5 days

Maximum allowable absorbance of the Working Reagent measured at 405 nm against water as reference is 1.3.

SAMPLE STABILITY AND STORAGE

Stability:	at -20 - +25°C	at least 1 week

INTERFERING SUBSTANCES

no interference up to:	
ascorbic acid	30 mg/dl
bilirubin	40 mg/dl
triglycerides	2000 mg/dl
hemoglobin	400 mg/dl

MANUAL TEST PROCEDURE

Bring reagents and samples to room temperature.

Substrate start 37°C

Pipette into test tubes:	Blank	Sample
Reagent 1	1000 µl	1000 µl
Distilled water	100 µl	
Sample		100 µl
Mix. Incubate for approximately 1 minute. Then add:		
Reagent 2	250 µl	250 µl
Mix. Read initial absorbance after 1 minute and start a timer. Read absorbance again after exactly 1, 2 and 3 minutes. Determine ΔA/min. during the linear part of the assay.		

Sample start 37°C

Pipette into test tubes	Blank	Sample
Working reagent	1000 µl	1000 µl
Distilled water	100 µl	
Sample		100 µl
Mix. Read initial absorbance after 1 minute and start a timer. Read absorbance again after exactly 1, 2 and 3 minutes. Determine ΔA/min. during the linear part of the assay.		

CALCULATION (light path 1 cm)

ΔA/min = [ΔA/min sample] – [ΔA/min blank]
Gamma-GT (U/L) = ΔA/min x Factor

Factors (25/30/37°C):

	Szasz	IFCC
For Substrate Start:	1421	1606
For Sample start:	1158	1309

UNIT CONVERSION

U/L x 0.01667 = µkatal/L

REFERENCE RANGE *(U/L)

According to Szasz:

Women	< 32
Men	< 49

According to IFCC:

	Female	**Male**
Adults	< 38 U/L	< 55 U/L
1 day – 6 months	15 – 132 U/L	12 – 122 U/L
6 months – 1 year	1 – 39 U/L	1 – 39 U/L
1 – 12 years	4 – 22 U/L	3 – 22 U/L
13 – 18 years	4 – 24 U/L	2 – 42 U/L

* It is recommended that each laboratory establishes its own normal range.

TEST PRINCIPLE

Gamma-GT catalyzes the transfer of glutamic acid to acceptors like glycylglycine. This process releases 5-amino-2-nitrobenzoate, which can be measured at 405 nm. The increase in absorbance at this wavelength is directly related to the activity of gamma-GT.

L-γ-glutamyl-3-carboxy-4-nitroanilide+glycylglycine $\xrightarrow{\gamma\text{-GT}}$
L-γ-glutamyl-glycylglycine + 5-amino-2-nitrobenzoate

PERFORMANCE CHARACTERISTICS

LINEARITY

The assay is linear up to a ΔA/min = 0.20.
That is 284 U/L (Substr. Start) and 232 U/L (Sample start). Above this concentration, dilute the sample 1+5 with NaCl solution (9 g/L sodium chloride in water) and reassay multiplying the result by 6.

PRECISION (at 37°C)

Intra-assay n = 20	Mean [U/L]	SD [U/L]	CV [%]
Sample 1	39.9	0.99	2.48
Sample 2	73.6	0.85	1.16
Sample 3	206	1.32	0.64

Inter-assay n = 20	Mean [U/L]	SD [U/L]	CV [%]
Sample 1	41.5	0.62	1.49
Sample 2	72.3	0.61	0.85
Sample 3	205	0.74	0.36

METHOD COMPARISON

A comparison between Dialab Gamma-GT, standardized to IFCC (y) and the IFCC reference reagent (x) using 51 samples gave following results:
y = 1.005 x – 0.741 U/L; r = 0.999

A comparison between Dialab Gamma-GT, Szasz (y) and a commercially available test (x) using 51 samples gave following results: y = 0.996 x +1.354 U/l; r= 1.000.

QUALITY CONTROL

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

REF	Cont.		
D98481	12 x 5 ml	**DIACON N**	Assayed Control Serum Normal
D98482	12 x 5 ml	**DIACON P**	Assayed Control Serum Abnormal

CALIBRATION

The use of a Gamma GT Calibrator is optional.
We recommend:

REF	Cont.		
D98485	5 x 3 ml	**DIACAL AUTO**	Assayed Multi Calibration Serum

AUTOMATION

Special adaptations for automated analyzers can be made on request.

WARNINGS AND PRECAUTIONS

1. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
2. Take the necessary precautions for the use of laboratory reagents.

WASTE MANAGEMENT

Please refer to local legal requirements.

REFERENCES

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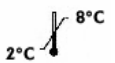
5. Fischbach F, Zawta B. Age-dependent reference limits of several enzymes in plasma at different measuring temperatures. Klin Lab 1992;38:555-61.



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