

# Gamma GT Reagent

Catalog #: 43713

for use with the

## SDI CA480 Clinical Chemistry System

### INTENDED USE

This reagent is intended for the *in vitro* quantitative kinetic determination of gamma glutamyltransferase (Gamma-GT) in human serum.

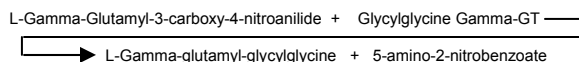
### SUMMARY AND EXPLANATION<sup>1,2</sup>

Gamma-glutamyltransferase (Gamma-GT) is an enzyme present in liver and bile duct which is the most sensitive indicator of hepatobiliary diseases. Due to a high negative predictive value for these diseases the measurement of Gamma GT is widely used to rule out an hepatic or biliary origin. Together with other enzymes Gamma-GT is a valuable tool for the differential diagnosis in liver diseases.

### METHODOLOGY

Methods for determining Gamma-GT are based on the use of glutamyl derivatives of aromatic amines as substrate material.<sup>3</sup> Orlovski and Meiser introduced Gamma-Glutamyl-p-nitroanilide as a substrate in 1963<sup>4</sup> with Kulhanek and Dimov (1966) adding glycylglycine and significantly increasing the speed of the reaction.<sup>5</sup> In 1969, Szasz published a kinetic procedure for Gamma-GT<sup>6</sup> on whose principle the present procedure is based. Szasz and Persijn<sup>7</sup> later reported that the 3-carboxyl derivative, L-Gamma-glutamyl-3-carboxy-4-nitroanilide could be substituted for the L-γ-glutamyl-p-nitroanilide, producing a more water soluble and stable reagent. SDI Gamma-GT reagent uses this soluble 3-carboxyl derivative. This method is based on the kinetic photometric test, according to the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC).<sup>8</sup>

### Principle



Gamma-GT in the sample catalyzes the transfer of the glutamyl group from L-Gamma-glutamyl-3-carboxy-4-nitroanilide to glycylglycine according to the above reaction. The amount of 5-amino-2-nitrobenzoate formed is proportional to Gamma-GT activity and may be measured kinetically at 405 nm by the increasing intensity of the yellow color formed.

### REAGENT COMPOSITION

#### Active Ingredients Concentrations

**Reagent 1**  
Glycylglycine 150 mM

**Reagent 2**  
L-Gamma-glutamyl-3-carboxy-4-nitroanilide 6.0 mM  
Concentrations are those in the working reagent.

### Precautions and Warnings:

- For *in vitro* diagnostic use only.
- DO NOT pipette by mouth. Avoid contact with skin and eyes. If spilt, thoroughly wash affected area with water. For further information, consult the SDI Gamma-GT Reagent Material Safety Data Sheet.
- Reagent contains Sodium Azide as a preservative. In a dry state may react with copper or lead plumbing to form explosive metal azides. Upon disposal, flush with large amounts of water to prevent azide build up.
- Do not use the reagent after the expiration date printed on the kit.

### REAGENT PREPARATION

Reagents are supplied in a two vial, ready to use, liquid form.

### REAGENT STORAGE

- Store the reagents at 2-8°C (refrigerated).
- The reagents are stable until the expiration date when stored at 2-8°C.
- Working reagent is stable for 4 weeks when stored at (2-8°C).
- Do not freeze the reagents.
- Reagent 2 should be protected from light.

### REAGENT DETERIORATION

DO NOT USE THE REAGENT IF:

- The reagent is turbid.
- The reagent has an optical density greater than 1.0 at 405 nm.

### SPECIMEN COLLECTION AND STORAGE

- Use non-hemolyzed serum or EDTA plasma.
- Serum Gamma-GT is stable for seven days at 2-8°C and two months frozen (-20°C) and protected from evaporation.<sup>9</sup>

### INTERFERENCES

Studies to determine the level of interference for hemoglobin, bilirubin, lipemia, and ascorbic acid were carried out, the following results were obtained:

#### Hemoglobin:

No significant interference (± 10%) from hemoglobin up to 500 mg/dL.

#### Bilirubin:

No significant interference (± 10%) from bilirubin up to 40 mg/dL.

#### Lipemia:

No significant interference (± 10%) from lipemia up to 2000 mg/dL measured as triglycerides.

#### Ascorbic acid:

No significant interference (± 10%) from ascorbic acid up to 30.0 mg/dL.

A number of drugs and substances may affect the accuracy of this test. See Young, et al.<sup>10</sup>

### ADDITIONAL EQUIPMENT REQUIRED BUT NOT PROVIDED

- SDI CA480 Clinical Chemistry System.
- Deionized water and related equipment, e.g.: pipettes
- Analyzer specific consumables, e.g.: sample cups
- Control material such as those provided by SDI Biomed.

### ASSAY PROCEDURE

	System Parameters
<b>Gamma-GT (Liquid)</b>	
TEMPERATURE:	37°C
WAVELENGTH:	405 nm
ASSAY TYPE:	Rate/Kinetic
DIRECTION:	Increase
e.g. Sample Vol.	0.050 mL (50 mL)
Reagent 1 Vol.	1.0 mL (1000 mL)
Reagent 2 Vol.	0.250 mL (250 mL)
DELAY/LAG TIME:	1 Min
READ TIME:	3 Min

### Procedure Notes:

- The reagent and sample volumes may be altered proportionally to accommodate various instrument requirements.
- Samples with values above 1000 U/L should be diluted 1:1 with saline, re-assayed and the results multiplied by two.

### Calculation

One Unit (U/L) is defined as the amount of enzyme that catalyzes the transformation of one micromole of substrate per minute under specified conditions. For example:

$$\text{U/L} = \frac{\text{AAbs}/\text{min} \times 1000 \times 1.270}{9.5 \times 1 \times 0.050} = \text{AAbs}/\text{min} \times 5333$$

Where:	AAbs / min.	= Absorbance change
	1000	= Conversion of U/ml to U/L
	1.270	= Total reaction volume (mL)
	9.5	= Millimolar absorptivity of 5-amino-2-nitrobenzoate.
	1	= Light path in cm
	0.020	= Sample volume (mL)

Example: If your DAbs / min. = 0.06  
then 0.06 x 5333 = 320 U/L.

### NOTE:

If test parameters are altered the factor has to be recalculated using the above formula. To convert to SI units (nkat/L) multiply U/L by .01667.

### CALIBRATION

The procedure is calibrated by means of the millimolar absorptivity of 5-amino-2-nitrobenzoate taken as 9.5 at 405nm under the specified conditions. Results are based on the change in absorbance per minute. All parameters must be known and controlled.

### QUALITY CONTROL

The integrity of the reaction should be monitored by use of a two level control with known Gamma-GT values.

### EXPECTED VALUES (37°C)<sup>7,8</sup>

Adults:	Female	9 - 36 U/L
	Male	12 - 64 U/L
Children / Adolescents:	Female	15 - 132 U/L
	Male	12 - 122 U/L
6 months - 1 year	Female	1 - 39 U/L
	Male	1 - 39 U/L
1 - 12 year(s)	Female	4 - 22 U/L
	Male	3 - 22 U/L
13 - 18 years	Female	4 - 24 U/L
	Male	2 - 42 U/L

It is strongly recommended that each laboratory determine its own reference range.

### PERFORMANCE

#### Linearity:

When run as recommended the assay is linear from 2 to 1000 U/L.

#### Method Comparison:

Studies performed between this procedure and a similar procedure yielded the following results:

Number of samples pairs:	68
Correlation Coefficient:	1.00
Slope:	1.01
Intercept:	0.56 (U/L)

#### Precision:

Within Run	Level 1	Level 2	Level 3
n=20			
Mean (U/L)	43.3	79.3	217.0
S.D. (U/L)	0.64	0.65	1.12
C.V. (%)	1.47	0.81	0.51

#### Total

n=20			
Mean (U/L)	45.2	78.2	216.0
S.D. (U/L)	0.61	0.62	0.78
C.V. (%)	1.34	0.79	0.36

### REFERENCES

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