

Gamma-GT FS* Szasz mod./IFCC stand.

Diagnostic reagent for quantitative in vitro determination of gamma-glutamyltransferase (gamma-GT) in serum or plasma on Sysmex BX-Series

Order information

Cat. No.	Kit size	Number of tests
1 2801 99 10 972	R1 3 x 13.0 mL	BX-3010 3 x 100 tests BX-4000 3 x 69 tests
	R2 3 x 5.5 mL	BX-3010 3 x 100 tests BX-4000 3 x 69 tests

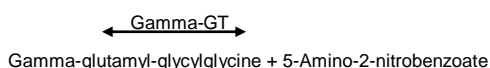
Method

Kinetic photometric test according to Szasz/Persijn [1]. The test has also been standardized to the method according to IFCC (International Federation of Clinical Chemistry) [2]. Results according to IFCC are obtained using the calibrator value given for the IFCC method.

Principle

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

L-Gamma-glutamyl-3-carboxy-4-nitranilide + Glycylglycine



Reagents

Components and Concentrations

R1:	TRIS	pH 8.28	135 mmol/L
	Glycylglycine		135 mmol/L
R2:	L-Gamma-glutamyl-3-carboxy-4-nitroanilide	pH 6.00	22 mmol/L

Storage Instructions and Reagent Stability

The reagents are stable up to the end of the indicated month of expiry, if stored at 2 – 8°C, protected from light and contamination is avoided. Do not freeze the reagents!

Warnings and Precautions

- The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
- In very rare cases, samples of patients with gammopathy might give falsified results [8].
- Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patients' medical history, clinical examinations and other findings.
- For professional use only!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

The reagents are ready to use. The bottles are placed directly into the reagent trays.

Specimen

Serum or heparin plasma

Stability [3]:

at least 1 week between –20°C and +25°C

Only freeze once. Discard contaminated specimens.

Calibrators and Controls

For calibration DiaSys TruCal U calibrator is recommended. In case TruCal U is used as a calibrator, use the according calibrator value for the Szasz method respectively for the IFCC method. For calculation according to IFCC, standardization was performed against the original IFCC formulation. For internal quality control DiaSys TruLab N and P controls should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruCal U	5 9100 99 10 063	20 x 3 mL
	5 9100 99 10 064	6 x 3 mL
TruLab N	5 9000 99 10 062	20 x 5 mL
	5 9000 99 10 061	6 x 5 mL
TruLab P	5 9050 99 10 062	20 x 5 mL
	5 9050 99 10 061	6 x 5 mL

Performance Characteristics

Measuring range up to 1200 U/L (20.0 µkat/L) GGT (in case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function).	
Limit of detection**	0.3 U/L (0.005 µkat/L)
On-board stability	6 weeks
Calibration stability	6 weeks

** lowest measurable concentration which can be distinguished from zero mean + 3 SD (n=20) of an analyte free specimen

Interfering substance	Interferences < 10%	Analyte concentration
Ascorbate	up to 30 mg/dL	33.6 U/L (0.561 µkat/L)
Hemoglobin	up to 60 mg/dL	50.6 U/L (0.845 µkat/L)
Bilirubin, conjugated	up to 45 mg/dL	47.4 U/L (0.791 µkat/L)
Bilirubin, unconjugated	up to 50 mg/dL	47.9 U/L (0.801 µkat/L)
Lipemia (triglycerides)	up to 2000 mg/dL	46.4 U/L (0.775 µkat/L)

For further information on interfering substances refer to Young DS [1].

Precision BX-4000			
Within run (n=20)	Sample 1	Sample 2	Sample 3
Mean [U/L]	30.6	89.6	228
Mean [µkat/L]	0.511	1.50	3.79
Coefficient of variation [%]	1.09	0.441	0.402
Between run (n=20)	Sample 1	Sample 2	Sample 3
Mean [U/L]	30.3	88.3	219
Mean [µkat/L]	0.506	1.47	3.64
Coefficient of variation [%]	1.14	0.737	0.892

Method comparison (n=107)	
Test x	Gamma-GT FS (BioMajesty 6010C)
Test y	Gamma-GT FS (BX-3010)
Slope	0.997
Intercept	-1.77 U/L (-0.030 µkat/L)
Coefficient of correlation	0.9999

Conversion factor

Gamma-GT [U/L] x 0.0167 = Gamma-GT [µkat/L]

Reference Range

According to Szasz [4]

Women	< 32 U/L	< 0.53 µkat/L
Men	< 49 U/L	< 0.82 µkat/L

According to IFCC

	Female U/L	Male U/L
Adults [2]	< 38	< 55
Children/adolescents [5]		
1 day – 6 months	15 – 132	12 – 122
6 months – 1 year	1 – 39	1 – 39
1 – 2 year(s)	4 – 22	3 – 22
13 – 18 years	4 – 24	2 – 42

	Female µkat/L	Male µkat/L
Adults [2]	< 0.63	< 0.92
Children/adolescents [5]		
1 day – 6 months	0.250 – 2.20	0.200 – 2.03
6 months – 1 year	0.017 – 0.651	0.017 – 0.651
1 – 12 year(s)	0.067 – 0.367	0.050 – 0.367
13 – 18 years	0.067 – 0.401	0.033 – 0.701

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Literature

1. Persijn JP, van der Silk W. A new method for the determination of gamma-glutamyltransferase in serum. *J Clin Chem Clin Biochem* 1976; 14: 421-7.
2. Schumann G, Bonora R, Ceriotti F, Féraud G et al. IFCC primary reference procedure for the measurement of catalytic activity concentrations of enzymes at 37 °C. Part 5: Reference procedure for the measurement of catalytic concentration of γ-glutamyltransferase. *Clin Chem Lab Med* 2002; 40: 734-8.
3. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 30-1.
4. Fischbach F, Zawta B. Age-dependent reference limits of several enzymes in plasma at different measuring temperatures. *Klin Lab* 1992; 38: 555-61.
5. Thomas L. *Clinical Laboratory Diagnostics*. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 80-6.
6. Szasz G. Gamma-Glutamyltranspeptidase. In: Bergmeyer HU. *Methoden der enzymatischen Analyse*. Weinheim: Verlag Chemie, 1974. p. 757.
7. Young DS. *Effects of Drugs on Clinical Laboratory Tests*. 15th ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press 2000.
8. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. *ClinChemLabMed* 2007;45(9):1240-1243.

Manufacturer



DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany

Alte Strasse 9 65558 Holzheim Germany			Sysmex BX-3010 Chemistry Analyzer		
Chemistry Parameters 1			Analytical Parameters		
Method No.	* <input type="text"/>	Method Name	<input type="text" value="GGT"/>	Reagent Name	Reagent (µL)
Print Name	<input type="text" value="GGT"/>	MethodColor		R1	<input type="text" value="GGT"/> <input type="text" value="100"/>
Sample Type	<input type="text" value="Serum"/>			R2	<input type="text" value="GGT"/> <input type="text" value="25"/>
Unit	<input type="text" value="U/L"/>			Diluent	<input type="text" value="Disable"/>
Assay Type	<input type="text" value="Rate"/>			Sample Ppt. Wash	<input type="text" value="Disable"/>
Measuring points		Start	End	Stirring Speed R1	R2
		1	<input type="text" value="30"/> - <input type="text" value="45"/>	<input type="text" value="Middle"/>	<input type="text" value="Middle"/>
		2	<input type="text" value="Disable"/> - <input type="text"/>		
Wave Length	Prim. <input type="text" value="415"/>	Sec. <input type="text" value="700"/>			
Normal Range					
	No.	Normal Range Name	Min	Max	
	1	Male-G1	*	*	
	2	Male-G2	*	*	
	3	Male-G3	*	*	
	4	Female-G1	*	*	
Normal	Sample Volume (µL)	Diluted Sample (µL)	Diluent (µL)	Technical Range	
	Low Normal High			(Conc)	<input type="text" value="0.3"/> - <input type="text" value="1200"/>
<input type="checkbox"/> Diluent	<input type="text" value="0.0"/> < <input type="text" value="3.8"/> < <input type="text" value="0.0"/>	<input type="text"/>	<input type="text"/>	(mAbs/10)	* - *
<input type="checkbox"/> Rerun (High/Prozone)				Previous Result Comparison (%)	* - * %
<input type="checkbox"/> Diluent	<input type="text" value="0.0"/> < <input type="text" value="3.8"/> < <input type="text" value="0.0"/>	<input type="text"/>	<input type="text"/>	Abnormal Range	(Conc) * - *
<input type="checkbox"/> Rerun (Low)				Panic Range	(Conc) * - *
<input type="checkbox"/> Diluent	<input type="text" value="0.0"/> < <input type="text" value="3.8"/> < <input type="text" value="0.0"/>	<input type="text"/>	<input type="text"/>	Decimal Point	<input type="text" value="0"/>
				Profile SI	<input type="text" value="Disable"/>

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Chemistry Parameters 2			Sysmex BX-3010 Chemistry Analyzer		
			Analytical Parameters		
Method No.	* <input type="text"/>	Method Name	<input type="text" value="GGT"/>	Sample	<input type="text" value="Serum"/>
Limit Checks					
<input checked="" type="checkbox"/> Duplicate Limit	<input type="text" value="20"/>	mAbs/10			
<input checked="" type="checkbox"/> Sensitivity Limit	<input type="text" value="150"/>	mAbs/10			
<input checked="" type="checkbox"/> Linearity Limit	<input type="text" value="10"/>	%			
	<input type="text" value="240"/>	(mAbs/10)/min			
<input type="checkbox"/> Prozone Limit	<input type="text" value="Higher"/>	%			
	<input type="text"/>				
	SL1-S <input type="text"/>	-	SL1-F <input type="text"/>		
	SL2-S <input type="text"/>	-	SL2-F <input type="text"/>		
	Sensitivity <input type="text"/>	mAbs/10			
<input checked="" type="checkbox"/> Absorbance Limit					
	Abs. in reaction	<input type="text" value="Increase"/>			
	Limit	<input type="text" value="17000"/> mAbs/10			
Blank measurement					
Blank measurement:					
<input type="text" value="Disable reagent blank and C1 blank"/>					
Measurement of Reagent Blank during Run:					
<input type="text" value="None"/>					
Reagent blank measurement at calibration:					
<input type="text" value="Reagent blank (No sample)"/>					
The number of measurement:					
<input type="text" value="Duplicate"/>					
Reagent blank limit checks:					
<input checked="" type="checkbox"/> Duplicate Limit	<input type="text" value="20"/>	mAbs/10			
Instrument Factor					
	a	<input type="text" value="1.00"/>	b	<input type="text" value="0.00"/>	

Calibration Registration

Sysmex BX-3010 Chemistry Analyzer
Analytical Parameters

Method No.

Method Name

Sample Type

Replication

Check Interval

Test without calibration

Calibration Type

Reagent Lot

Calibrator Name

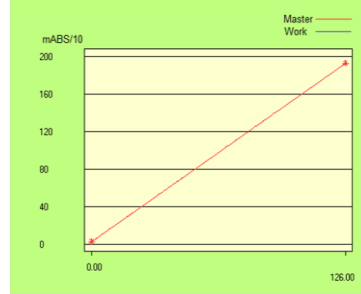
	Conc.	WORK	MASTER	Calibr. Lot No.	<input type="checkbox"/> All
C1	0	Automatic entry	Automatic entry	*	
C2	*	Automatic entry	Automatic entry	*	
C3	*				
C4	*				
C5	*				
C6	*				
C7	*				

K C1 Blank
 Reagent Blank for C1

Reagent Lot No.

(R1)
(R2)

Last



The calibration curve is lot dependent

Reagent blank mAbs/10 Last

Blank mAbs/10 Last

Calibration Curve Conc.

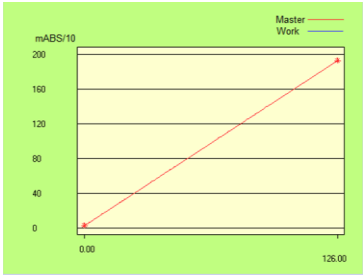
Absorbance mAbs/10

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Chemistry Parameters		Sysmex BX-4000 Chemistry Analyzer Analytical Parameters																							
Method	* <input type="text"/>	Name	<input type="text" value="GGT"/>																						
Print Name	<input type="text" value="GGT"/>	R1	<input type="text" value="GGT"/>	<input type="text" value="150"/>	<input type="text"/>																				
Sample	<input type="text" value="Serum"/>	R2	<input checked="" type="checkbox"/> Enable	<input type="text" value="GGT"/>	<input type="text" value="38"/>																				
Unit	<input type="text" value="U/L"/>																								
Assay Type	<input type="text" value="Rate"/>	Diluent	<input type="checkbox"/> Enable	<input type="text"/>	<input type="text"/>																				
Measuring points		Start	End	Decimal Points	<input type="text" value="0"/>																				
		1	<input type="text" value="43"/>	-	<input type="text" value="66"/>																				
<input type="checkbox"/> Enable		2	<input type="text"/>	-	<input type="text"/>																				
Wave Length	Prim. <input type="text" value="415"/>	Sec	<input type="checkbox"/> Disable	<input type="text" value="700"/>																					
<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th>No.</th> <th>Normal Range Name</th> <th>Min</th> <th>Max</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Male-G1</td> <td>*</td> <td>*</td> </tr> <tr> <td>2</td> <td>Male-G2</td> <td>*</td> <td>*</td> </tr> <tr> <td>3</td> <td>Male-G3</td> <td>*</td> <td>*</td> </tr> <tr> <td>4</td> <td>Female-G1</td> <td>*</td> <td>*</td> </tr> </tbody> </table>						No.	Normal Range Name	Min	Max	1	Male-G1	*	*	2	Male-G2	*	*	3	Male-G3	*	*	4	Female-G1	*	*
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2	Male-G2	*	*																						
3	Male-G3	*	*																						
4	Female-G1	*	*																						
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<input type="checkbox"/> Rerun (High/Prozone)	<input type="text"/>	Diluent (µL)	<input type="text"/>	Technical Range	(Conc) <input type="text" value="0.3"/> - <input type="text" value="1200"/>																				
<input type="checkbox"/> Dilution	<input type="text" value="5.6"/>				(mAbs/10) <input type="text"/>																				
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		Stirring Speed	R1	<input type="text" value="Middle"/>	R2 <input type="text" value="Middle"/>																				

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Chemistry Parameters		Sysmex BX-4000 Chemistry Analyzer Analytical Parameters																																																																																													
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Registration Calibration			Sysmex BX-4000 Chemistry Analyzer Analytical Parameters																																										
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<table border="1" style="width: 100%; border-collapse: collapse; font-size: x-small;"> <thead> <tr> <th style="width: 5%;"></th> <th style="width: 15%;">Conc.</th> <th style="width: 20%;">WORK</th> <th style="width: 20%;">MASTER</th> <th style="width: 40%;">Lot No. (S) <input type="checkbox"/> All</th> </tr> </thead> <tbody> <tr><td>S1</td><td><input style="width: 80%;" type="text" value="0"/></td><td>Automatic entry</td><td>Automatic entry</td><td></td></tr> <tr><td>S2</td><td><input style="width: 80%;" type="text" value="*"/></td><td>Automatic entry</td><td>Automatic entry</td><td></td></tr> <tr><td>S3</td><td><input style="width: 80%;" type="text" value="*"/></td><td></td><td></td><td></td></tr> <tr><td>S4</td><td><input style="width: 80%;" type="text" value="*"/></td><td></td><td></td><td></td></tr> <tr><td>S5</td><td><input style="width: 80%;" type="text" value="*"/></td><td></td><td></td><td></td></tr> <tr><td>S6</td><td><input style="width: 80%;" type="text" value="*"/></td><td></td><td></td><td></td></tr> <tr><td>S7</td><td><input style="width: 80%;" type="text" value="*"/></td><td></td><td></td><td></td></tr> </tbody> </table>			Conc.	WORK	MASTER	Lot No. (S) <input type="checkbox"/> All	S1	<input style="width: 80%;" type="text" value="0"/>	Automatic entry	Automatic entry		S2	<input style="width: 80%;" type="text" value="*"/>	Automatic entry	Automatic entry		S3	<input style="width: 80%;" type="text" value="*"/>				S4	<input style="width: 80%;" type="text" value="*"/>				S5	<input style="width: 80%;" type="text" value="*"/>				S6	<input style="width: 80%;" type="text" value="*"/>				S7	<input style="width: 80%;" type="text" value="*"/>				Blank <input style="width: 80%;" type="text" value="Automatic entry"/> mAbs/10 Last <input style="width: 80%;" type="text"/>			
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S4	<input style="width: 80%;" type="text" value="*"/>																																												
S5	<input style="width: 80%;" type="text" value="*"/>																																												
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S7	<input style="width: 80%;" type="text" value="*"/>																																												
<input style="width: 80%;" type="text"/> <input type="checkbox"/> S1 Blank <input type="checkbox"/> Reagent Blank for S1		Type <input style="width: 80%;" type="text"/> Conc. <input style="width: 80%;" type="text"/>																																											
*Entered by user		Absorbance <input style="width: 80%;" type="text"/> mAbs/10 <input type="button" value="Recalculation"/>																																											