

ALAT (GPT) FS* (IFCC mod.)

Diagnostic reagent for quantitative in vitro determination of ALAT (GPT) in serum or plasma on Sysmex BX-Series

Order information

Cat. No.	Kit size	Number of tests
1 2701 99 10 972	R1 3 x 17.0 mL	BX-3010 3 x 100 tests BX-4000 3 x 72 tests
	R2 3 x 6.5 mL	BX-3010 3 x 100 tests BX-4000 3 x 72 tests

Method

Optimized UV-test according to IFCC (International Federation of Clinical Chemistry and Laboratory Medicine) [modified]

Principle

L-Alanine + 2-Oxoglutarate $\xrightarrow{\text{ALAT}}$ L-Glutamate + Pyruvate

Pyruvate + NADH + H⁺ $\xrightarrow{\text{LDH}}$ D-Lactate + NAD⁺

Reagents

Components and Concentrations

R1: TRIS	pH 7.15	140 mmol/L
L-Alanine		700 mmol/L
LDH (lactate dehydrogenase)		≥ 2300 U/L
R2: 2-Oxoglutarate		85 mmol/L
NADH		1 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.
- Reagent 1 contains animal material. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practices.
- In very rare cases, samples of patients with gammopathy might give falsified results [2].
- Sulfasalazine and sulfapyridine medication may lead to false results in patient samples. Blood collection must be done before drug administration.
- 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 patient's 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, heparin plasma or EDTA plasma

Stability [3]:

3 days at 20 – 25°C

7 days at 4 – 8°C

7 days at –20°C

Only freeze once. Discard contaminated specimens.

Calibrators and Controls

For calibration the DiaSys TruCal U calibrator is recommended. This method has been standardized 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 600 U/L (10 µkat/L) ALAT (in case of higher activities re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function).	
Limit of detection**	< 3 U/L (0.05 µkat/L) ALAT
On-board stability	6 weeks
Calibration stability	6 weeks

Interfering substance	Interferences < 10%	Analyte concentration
Ascorbate	up to 30 mg/dL	43.7 U/L (0.728 µkat/L)
Hemoglobin	up to 500 mg/dL	27.3 U/L (0.455 µkat/L)
Bilirubin, conjugated	up to 60 mg/dL	27.2 (0.453 µkat/L)
Bilirubin, unconjugated	up to 30 mg/dL	27.4 (0.456 µkat/L)
Lipemia (triglycerides)	up to 450 mg/dL	29.7 (0.496 µkat/L)

For further information on interfering substances refer to Young DS [4].

Precision (BX-4000)			
Within run (n=20)	Sample 1	Sample 2	Sample 3
Mean [U/L]	28.5	38.8	110
Mean [µkat/L]	0.475	0.647	1.83
Coefficient of variation [%]	1.85	1.55	0.604
Between run (n=20)	Sample 1	Sample 2	Sample 3
Mean [U/L]	33.2	40.9	115
Mean [µkat/L]	0.553	0.682	1.92
Coefficient of variation [%]	1.43	1.31	0.724

Method comparison (n=115)	
Test x	ALAT FS (Biomajesty 6010C)
Test y	ALAT FS (BX-4000)
Slope	0.991
Intercept	0.841 U/L (0.014 µkat/L)
Coefficient of correlation	0.9995

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

Conversion factor

ALAT [U/L] x 0.0167 = ALAT [µkat/L]

Reference Range

Women [6,7] < 31 U/L < 0.52 µkat/L

Men [6,7] < 41 U/L < 0.68 µkat/L

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

Literature

1. Thomas L. Alanine aminotransferase (ALT), Aspartate aminotransferase (AST). In: Thomas L, editor. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 55–65.
2. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240–1243.
3. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 14-5.
4. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press 2000.
5. Schumann G, Bonora R, Ceriotti F, Férard G et al. IFCC primary reference procedure for the measurement of catalytic activity concentrations of enzymes at 37°C. Part 4: Reference procedure for the measurement of catalytic concentration of alanine aminotransferase. Clin Chem Lab Med 2002; 40: 718-24.
6. Lorentz K, Röhle G, Siekmann L. Einführung der neuen Standardmethoden 1994 zur Bestimmung der katalytischen Enzymkonzentrationen bei 37 °C. DG Klinische Chemie Mitteilungen 26; 1995; Heft 4.
7. Zawta B, Klein G, Bablok W. Temperature Conversion in Clinical Enzymology? Klin. Lab. 1994; 40: 33-42.
8. Moss DW, Henderson AR. Clinical enzymology. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999. p. 617–721.

Manufacturer



DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany

Chemistry Parameters 1				Sysmex BX-3010 Chemistry Analyzer Analytical Parameters		
Method No.	*	Method Name	ALAT	Reagent Name	Reagent (µL)	Water (µL)
Print Name	ALT	MethodColor		R1	ALAT	140
Sample Type	Serum			R2	ALAT	35
Unit	U/L			Diluent	Disable	
Assay Type	Rate			Sample Ppt. Wash	Disable	
Measuring points		Start	End	Stirring Speed R1	Middle	R2 Fast
		1	30 - 46			
		2	Disable -			
Wave Length	Prim. 340	Sec. 415		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 0.0	Normal 10.5	High 0.0	(Conc)	3	600
<input type="checkbox"/> Diluent	0.0 <	10.5 <	0.0	(mAbs/10)	*	*
	Rerun (High/Prozone)			Previous Result Comparison (%)	*	* %
<input type="checkbox"/> Diluent	0.0 <	10.5 <	0.0	Abnormal Range	*	*
	Rerun (Low)			Panic Range	*	*
<input type="checkbox"/> Diluent	0.0 <	10.5 <	0.0	Decimal Point	0	Profile SI Disable

*Entered by user

Chemistry Parameters 2				Sysmex BX-3010 Chemistry Analyzer Analytical Parameters		
Method No.	*	Method Name	ALAT	Sample	Serum	
Limit Checks				Blank measurement		
<input checked="" type="checkbox"/> Duplicate Limit	50	mAbs/10		Blank measurement:	Disable reagent blank and C1 blank	
<input checked="" type="checkbox"/> Sensitivity Limit	250	mAbs/10		Measurement of Reagent Blank during Run:	None	
<input checked="" type="checkbox"/> Linearity Limit	10	%		Reagent blank measurement at calibration:	Reagent blank (No sample)	
	220	(mAbs/10)/min		The number of measurement:	Duplicate	
<input type="checkbox"/> Prozone Limit	Higher	%		Reagent blank limit checks:		
				<input checked="" type="checkbox"/> Duplicate Limit	20	mAbs/10
SL1-S		-	SL1-F	Instrument Factor		
SL2-S		-	SL2-F	a	1.00	b 0.00
Sensitivity		mAbs/10				
<input checked="" type="checkbox"/> Absorbance Limit						
	Abs. in reaction	Decrease				
	Limit	4500	mAbs/10			

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

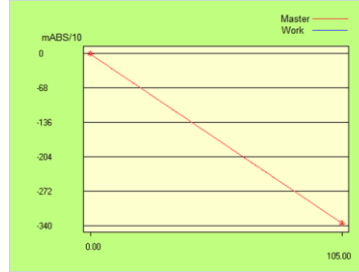
	Conc.	WORK	MASTER	Calibr. Lot No.	<input type="checkbox"/> All
C1	0	Automatic entry	Automatic entry	*	
C2	*	Automatic entry	Automatic entry	*	
C3	*				
C4	*				
C5	*				
C6	*				
C7	*				

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

*Entered by user

Chemistry Parameters		Sysmex BX-4000 Chemistry Analyzer Analytical Parameters																							
Method	* <input type="text"/>	Name	<input type="text" value="ALAT"/>																						
Print Name	<input type="text" value="ALT"/>	R1	<input type="text" value="ALAT"/>	<input type="text" value="200"/>	<input type="text"/>																				
Sample	<input type="text" value="Serum"/>	R2	<input checked="" type="checkbox"/> Enable	<input type="text" value="ALAT"/>	<input type="text" value="50"/>																				
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="44"/>	-	<input type="text" value="68"/>																				
<input type="checkbox"/> Enable		2	<input type="text"/>	-	<input type="text"/>																				
Wave Length		Normal Range																							
Prim.	<input type="text" value="340"/>	Sec	<input type="checkbox"/> Disable	<input type="text" value="415"/>																					
		<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	*	*
No.	Normal Range Name	Min	Max																						
1	Male-G1	*	*																						
2	Male-G2	*	*																						
3	Male-G3	*	*																						
4	Female-G1	*	*																						
Normal	Sampling	Sample (μL)	Diluent (μL)	Technical Range																					
<input type="checkbox"/> Dilution	<input type="text" value="15.0"/>	<input type="text"/>	<input type="text"/>	(Conc)	<input type="text" value="3"/> - <input type="text" value="600"/>																				
	Rerun (High/Prozone)			(mAbs/10)	<input type="text"/>																				
<input type="checkbox"/> Dilution	<input type="text" value="15.0"/>	<input type="text"/>	<input type="text"/>																						
	Rerun (Low)																								
<input type="checkbox"/> Dilution	<input type="text" value="15.0"/>	<input type="text"/>	<input type="text"/>																						
		SPT Wash	<input type="checkbox"/> Enable	Reagent Name	<input type="text"/>																				
		Stirring Speed	R1	<input type="text" value="Middle"/>	R2 <input type="text" value="High"/>																				
*Entered by user																									

Chemistry Parameters		Sysmex BX-4000 Chemistry Analyzer Analytical Parameters			
Method No.	* <input type="text"/>	Name	<input type="text" value="ALAT"/>	Sample	<input type="text" value="Serum"/>
Limit Checks		Blank measurement			
<input checked="" type="checkbox"/> Duplicate Limit	<input type="text" value="50"/>	Blank measurement:			
	mAbs/10	<input type="text" value="Disable reagent blank and S1 blank"/>			
<input checked="" type="checkbox"/> Sensitivity Limit	<input type="text" value="250"/>	Measurement of Reagent Blank during Run:			
	mAbs/10	<input type="text" value="None"/>			
<input checked="" type="checkbox"/> Linearity Limit	<input type="text" value="10"/>	Reagent blank measurement at calibration:			
	%	<input type="text" value="Reagent blank (No sample)"/>			
<input type="checkbox"/> Prozone Limit	<input type="text"/>	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			
SL1-S	<input type="text"/>	-	SL1-F	<input type="text"/>	
SL2-S	<input type="text"/>	-	SL2-F	<input type="text"/>	
Sensitivity	<input type="text"/>	Instrument Factor			
<input checked="" type="checkbox"/> Absorbance Limit	<input type="text"/>	a <input type="text" value="1.00"/>			
	mAbs/10	b <input type="text" value="0.00"/>			
Reaction	<input type="text" value="Decrease"/>				
Limit	<input type="text" value="4500"/>				
	mAbs/10				

Registration Calibration

Sysmex BX-4000 Chemistry Analyzer
Analytical Parameters

Method Name

Sample

Sampling

Check Interval days

Auto

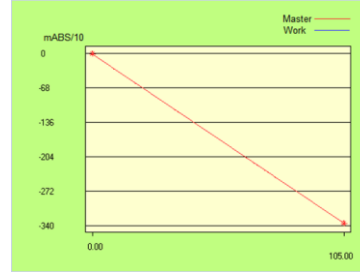
Auto Interval hours

Type Lot

Material Name

R Lot No. R1
R2

Last



The calibration curve is lot dependent

Reagent blank mAbs/10 Last

Blank mAbs/10 Last

Type Conc.

Absorbance mAbs/10

	Conc.	WORK	MASTER	Lot No. (S) <input type="checkbox"/> All
S1	<input type="text" value="0"/>	Automatic entry	Automatic entry	
S2	<input type="text" value="*"/>	Automatic entry	Automatic entry	
S3	<input type="text" value="*"/>			
S4	<input type="text" value="*"/>			
S5	<input type="text" value="*"/>			
S6	<input type="text" value="*"/>			
S7	<input type="text" value="*"/>			

K S1 Blank Reagent Blank for S1

*Entered by user