


ALAT (GPT) FS* (IFCC mod.)

With/Without Pyridoxal-5-Phosphate FS (P-5-P)

Order Information

Cat. No. 1 2701 99 10 920 **Kit size**  800 (4 x 200)

Pyridoxal-5-Phosphate FS
2 5010 99 10 030 6 x 3 mL

Intended Use

Diagnostic reagent for quantitative in vitro determination of ALAT (GPT) activity in human serum or heparin plasma on automated respons[®]940.

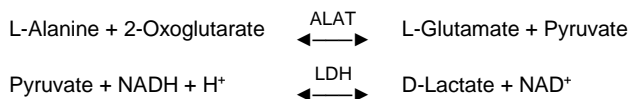
Summary

The enzyme group of aminotransferases catalyzes the reversible conversion of α -keto acids into amino acids by transmitting an amino group [1]. Alanine aminotransferase (ALAT/ALT), formerly called glutamic pyruvic transaminase (GPT) and aspartate aminotransferase (ASAT/AST), formerly called glutamic oxaloacetic transaminase (GOT), are the most important representatives of this group. ALAT is located in the cytosol and is a liver specific enzyme. It serves as a specific parameter of hepatocellular injury and is only significantly elevated in hepatobiliary diseases [1]. Increased ASAT levels, however, can occur in connection with damages of heart or skeletal muscle as well as of liver parenchyma. Parallel measurements of ALAT and ASAT are applied to distinguish between liver and heart or skeletal muscle injuries. The ASAT/ALAT ratio is further a valuable tool for differential diagnosis and severity assessment in liver diseases as well as for the prognostic assessment of myocardial injury in myocardial infarction. While ratios < 1 indicate mild liver damage, ratios > 1 are associated with severe, often chronic liver diseases [1,2].

Method

Optimized UV-test according to IFCC (International Federation of Clinical Chemistry and Laboratory Medicine) [modified] [3]

The reaction between L-alanine and 2-oxoglutarate is catalyzed by ALAT, forming L-glutamate and pyruvate. In the next step, pyruvate reacts with NADH + H⁺, catalyzed by lactate dehydrogenase to D-lactate and NAD⁺. The decrease in absorption is proportional to catalytic ALAT concentration in the sample.



One unit of ALAT is the amount of enzyme that converts 1.0 μmol of L-alanine per minute at the assay specific conditions.

Addition of P-5-P, recommended by IFCC, stabilizes the activity of transaminases and avoids falsely low values in samples containing insufficient endogenous P-5-P, e.g. from patients with myocardial infarction, liver disease and intensive care patients [1].

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
Pyridoxal-5-Phosphate FS			
	Good's buffer	pH 9.6	100 mmol/L
	P-5-P		13 mmol/L

Storage and Stability

Reagents are stable up to the date of expiry indicated on the kit, if stored at 2 – 8°C and contamination is avoided. Do not freeze and protect from light.

The open-vial stability of the reagent with P-5-P is 6 days until expiry date.

The open-vial stability of the reagent without P-5-P is 12 months until expiry date.

Warnings and Precautions

- The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
- The reagents contain material of biological origin. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
- Sulfasalazine and sulfapyridine medication may cause false results in patient samples. Blood collection must be performed prior to drug administration.
- In very rare cases, samples of patients with gammopathy might give falsified results [4].
- In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
- Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.
- Please refer to the safety data sheets (SDS) 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

Refer to local legal requirements for chemical disposal regulations as stated in the relevant SDS to determine the safe disposal.

Warning: Handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Reagent Preparation

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

For determination with P-5-P, add 350 μL of P-5-P to reagent 1 and mix gently.

Stability after mixing:	6 days	at	2 – 8°C
	24 hours	at	15 – 25°C

Materials Required

General laboratory equipment

Specimen

Human serum or heparin plasma

Only use suitable tubes or collection containers for specimen collection and preparation.

When using primary tubes, follow the manufacturer's instructions.

Stability [5]:

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

DiaSys TruCal U is recommended for calibration. Calibrator values have been made traceable to the original IFCC formulation. Use DiaSys TruLab N and P for internal quality control. All target values of the controls are traceable to DiaSys reagent/calibrator system. Quality control must be performed after calibration. Control intervals and limits have to be adapted to the individual requirements of each laboratory. Results must be within the defined ranges. Follow the relevant legal requirements and guidelines. 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

With P-5-P

Measuring range from 6 U/L up to 600 U/L. Linearity < 10 U/L is given with ± 3 U/L, between 10 U/L up to 15 U/L within ± 10%, > 15 U/L within ± 5%.
In case of higher activities re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.

Limit of detection**	6 U/L
Limit of quantitation**	6 U/L
Onboard stability	3 weeks
Calibration stability	3 weeks

Interference by	Interferences ≤ 10% up to	Analyte concentration [U/L]
Ascorbic acid	36 mg/dL	31.5
	36 mg/dL	154
Bilirubin (conjugated)	15 mg/dL	29.5
	70 mg/dL	138
Bilirubin (unconjugated)	70 mg/dL	22.9
	70 mg/dL	140
Hemolysis	300 mg/dL	33.1
	1000 mg/dL	150
Lipemia (triglycerides)	1500 mg/dL	28.4
	1200 mg/dL	153

For further information on interfering substances, refer to the literature [6-8].

Precision			
Repeatability (n=20)	Sample 1	Sample 2	Sample 3
Mean [U/L]	23.3	46.4	122
CV [%]	1.93	1.53	0.742
Within-laboratory (n=80)	Sample 1	Sample 2	Sample 3
Mean [U/L]	20.6	45.0	117
CV [%]	3.45	2.24	2.01
Reproducibility (n=75, no. of instruments=3)	Sample 1	Sample 2	Sample 3
Mean [U/L]	13.9	39.6	544
CV [%]	7.52	3.79	1.39

Method comparison (n=89)	
Test x	Competitor ALAT (GPT) (cobas c 501)
Test y	DiaSys ALAT (GPT) FS (IFCC mod.) (respons [®] 940)
Slope	1.12
Intercept	-2.33 U/L
Coefficient of correlation	0.999

Without P-5-P

Measuring range from 4 U/L up to 600 U/L. Linearity < 10 U/L is given with ± 3 U/L, between 10 U/L up to 15 U/L within ± 10%, linearity > 15 U/L within ± 5%.

In case of higher activities re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.

Limit of detection**	4 U/L
Limit of quantitation**	4 U/L
Onboard stability	16 weeks
Calibration stability	16 weeks

Interference by	Interferences ≤ 10% up to	Analyte concentration [U/L]
Ascorbic acid	36 mg/dL	26.4
	36 mg/dL	144
Bilirubin (conjugated)	10 mg/dL	32.0
	74 mg/dL	138
Bilirubin (unconjugated)	72 mg/dL	19.9
	72 mg/dL	127
Hemolysis	300 mg/dL	29.2
	1000 mg/dL	147
Lipemia (triglycerides)	1400 mg/dL	34.4
	1400 mg/dL	154
Sulfapyridine	32 mg/dL	30.4
Sulfasalazine	9 mg/dL	31.8

For further information on interfering substances, refer to the literature [6-8].

Precision			
Repeatability (n=20)	Sample 1	Sample 2	Sample 3
Mean [U/L]	20.1	41.5	124
CV [%]	1.99	1.44	0.766
Within-laboratory (n=80)	Sample 1	Sample 2	Sample 3
Mean [U/L]	21.9	41.5	115
CV [%]	3.85	2.86	2.37
Reproducibility (n=75, no. of instruments=3)	Sample 1	Sample 2	Sample 3
Mean [U/L]	12.0	35.1	493
CV [%]	17.1	7.29	2.89

Method comparison (n=104)	
Test x	Competitor ALAT (GPT) (cobas c 501)
Test y	DiaSys ALAT (GPT) FS (IFCC mod.) (respons [®] 940)
Slope	1.08
Intercept	-1.33 U/L
Coefficient of correlation	0.999

** according to CLSI document EP17-A2, Vol. 32, No. 8

Conversion Factor

ALAT [U/L] x 0.0167 = ALAT [µkat/L]

Reference Range [1]

With P-5-P

	U/L	µkat/L
Adults		
Female	< 35	< 0.60
Male	< 50	< 0.85
Children		
0 – 1 year	4 – 49	0.07 – 0.82
1 – 3 years	7 – 29	0.11 – 0.49
4 – 6 years	5 – 39	0.08 – 0.65
7 – 12 years	7 – 44	0.12 – 0.73
13 – 17 years	8 – 45	0.13 – 0.75

Without P-5-P

	U/L	µkat/L
Adults		
Female	< 34	< 0.56
Male	< 45	< 0.74
Children		
0 – 1 year	5 – 41	0.09 – 0.68
1 – 3 years	8 – 28	0.14 – 0.47
4 – 6 years	6 – 29	0.10 – 0.49
7 – 12 years	8 – 36	0.13 – 0.60
13 – 17 years	7 – 37	0.12 – 0.62

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. Clinical Laboratory Diagnostics [Internet]. Prof. Lothar Thomas; 2024 [cited 2024 July 10]. Available from: <https://www.clinical-laboratory-diagnostics.com/>
2. Panteghini M, Bais R, van Solinge WW. Enzymes. In: Burtis CA, Ashwood ER, Bruns DE, editors, Tietz Textbook of Clinical Chemistry and Molecular Diagnosis. 4th ed. St. Louis: Elsevier Saunders; 2006. p. 604-6.
3. Bergmeyer HU, Horder M, Rej R. Approved Recommendation (1985) on IFCC Methods for the Measurement of Catalytic Concentration of Enzymes. J Clin Chem Clin Biochem 1986;24:481-495.
4. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. Clin Chem Lab Med. 2007;45:1240–243.
5. Guder WG, da Fonseca-Wollheim F, Heil W, Schmitt Y, Töpfer G, Wisser H, Zawta B. Quality of Diagnostic Samples. 3rd edition; 2010. p. 32-3.
6. 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.
7. Young DS. Effects on Clinical Laboratory Tests - Drugs Disease, Herbs & Natural Products [Internet]. AACC Press and John Wiley and Sons, Inc; 2021 [cited 2021 Sept]. Available from: <https://clinfx.wiley.com/aaccweb/aacc/>
8. Sonntag O, Scholer A. Drug interference in clinical chemistry: recommendation of drugs and their concentrations to be used in drug interference studies. Ann Clin Biochem. 2001 Jul;38:376-85.

Additions and/or changes in the document are highlighted in grey. Deletions are communicated via customer info by stating the edition no. of the package insert/instruction for use.



DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim
Germany
www.diasys-diagnostics.com

* Fluid Stable

ALAT (GPT) FS (IFCC mod.)

Application for serum and plasma

Test Details	Test Volumes	Reference Ranges
Test : ALT		Auto Rerun <input type="checkbox"/>
Report Name : ALAT (GPT)		Online Calibration <input type="checkbox"/>
Unit : U/L	Decimal Places : 1	Cuvette Wash <input type="checkbox"/>
Wavelength-Primary : 340	Secondary : 415	Special Diluent <input type="checkbox"/>
Assay Type : RATE-A	Curve Type : Linear	Warn after : 20
M1 Start : 0	M1 End : 0	Reagents Used : 2
M2 Start : 33	M2 End : 49	Reagent R1 : ALT R1
Sample Replicates : 1	Standard Replicates : 2	Reagent R2 : ALT R2
Control Replicates : 1	Control Interval : 0	Consumables/Calibrators:
Reaction Direction : Decreasing	React. Abs. Limit : 0.5500	Blank /Level 0 : 0
Prozone Limit % : 0	Prozone Check : Upper	Calibrator 1 : *
Linearity Limit % : 0	Delta Abs./Min. : 0.0000	Calibrator 2 :
Technical Minimum : 4.0000	Technical Maximum : 600.0000	Calibrator 3 :
Y = aX + b a= : 1.0000	b= : 0.0000	Calibrator 4 :
Reagent Abs Min : 0.0000	Reagent Abs Max : 0.0000	Calibrator 5 :

Test Details	Test Volumes	Reference Ranges																											
Test : ALT																													
Sample Type : Serum																													
<table border="1"> <thead> <tr> <th colspan="4">Sample Volumes</th> </tr> </thead> <tbody> <tr> <td>Normal</td> <td>: 12.00 μL</td> <td>Dilution Ratio</td> <td>: 1 X</td> </tr> <tr> <td>Increase</td> <td>: 20.00 μL</td> <td>Dilution Ratio</td> <td>: 1 X</td> </tr> <tr> <td>Decrease</td> <td>: 5.00 μL</td> <td>Dilution Ratio</td> <td>: 1 X</td> </tr> <tr> <td>Standard Volume</td> <td>: 12.00 μL</td> <td></td> <td></td> </tr> </tbody> </table>		Sample Volumes				Normal	: 12.00 μ L	Dilution Ratio	: 1 X	Increase	: 20.00 μ L	Dilution Ratio	: 1 X	Decrease	: 5.00 μ L	Dilution Ratio	: 1 X	Standard Volume	: 12.00 μ L			<table border="1"> <thead> <tr> <th>Sample Types</th> </tr> </thead> <tbody> <tr> <td><input checked="" type="checkbox"/> Serum</td> </tr> <tr> <td><input type="checkbox"/> Urine</td> </tr> <tr> <td><input type="checkbox"/> CSF</td> </tr> <tr> <td><input checked="" type="checkbox"/> Plasma</td> </tr> <tr> <td><input type="checkbox"/> Whole Blood</td> </tr> <tr> <td><input type="checkbox"/> Other</td> </tr> </tbody> </table>	Sample Types	<input checked="" type="checkbox"/> Serum	<input type="checkbox"/> Urine	<input type="checkbox"/> CSF	<input checked="" type="checkbox"/> Plasma	<input type="checkbox"/> Whole Blood	<input type="checkbox"/> Other
Sample Volumes																													
Normal	: 12.00 μ L	Dilution Ratio	: 1 X																										
Increase	: 20.00 μ L	Dilution Ratio	: 1 X																										
Decrease	: 5.00 μ L	Dilution Ratio	: 1 X																										
Standard Volume	: 12.00 μ L																												
Sample Types																													
<input checked="" type="checkbox"/> Serum																													
<input type="checkbox"/> Urine																													
<input type="checkbox"/> CSF																													
<input checked="" type="checkbox"/> Plasma																													
<input type="checkbox"/> Whole Blood																													
<input type="checkbox"/> Other																													
<table border="1"> <thead> <tr> <th colspan="4">Reagent Volumes and Stirrer Speed</th> </tr> </thead> <tbody> <tr> <td>RGT-1 Volume</td> <td>: 160.00 μL</td> <td>R1 Stirrer Speed</td> <td>: Medium</td> </tr> <tr> <td>RGT-2 Volume</td> <td>: 40.00 μL</td> <td>R2 Stirrer Speed</td> <td>: High</td> </tr> </tbody> </table>		Reagent Volumes and Stirrer Speed				RGT-1 Volume	: 160.00 μ L	R1 Stirrer Speed	: Medium	RGT-2 Volume	: 40.00 μ L	R2 Stirrer Speed	: High																
Reagent Volumes and Stirrer Speed																													
RGT-1 Volume	: 160.00 μ L	R1 Stirrer Speed	: Medium																										
RGT-2 Volume	: 40.00 μ L	R2 Stirrer Speed	: High																										

Test Details	Test Volumes	Reference Ranges																											
Test : ALT																													
Sample Type : Serum																													
Reference Range : DEFAULT																													
Category : Male																													
<table border="1"> <thead> <tr> <th colspan="4">Reference Range</th> </tr> <tr> <td></td> <td>Lower Limit</td> <td>Upper Limit</td> <td></td> </tr> <tr> <td></td> <td>(U/L)</td> <td>(U/L)</td> <td></td> </tr> </thead> <tbody> <tr> <td>Normal</td> <td>: #</td> <td>: #</td> <td></td> </tr> <tr> <td>Panic</td> <td>: #</td> <td>: #</td> <td></td> </tr> </tbody> </table>		Reference Range					Lower Limit	Upper Limit			(U/L)	(U/L)		Normal	: #	: #		Panic	: #	: #		<table border="1"> <thead> <tr> <th>Sample Types</th> </tr> </thead> <tbody> <tr> <td><input checked="" type="checkbox"/> Serum</td> </tr> <tr> <td><input type="checkbox"/> Urine</td> </tr> <tr> <td><input type="checkbox"/> CSF</td> </tr> <tr> <td><input checked="" type="checkbox"/> Plasma</td> </tr> <tr> <td><input type="checkbox"/> Whole Blood</td> </tr> <tr> <td><input type="checkbox"/> Other</td> </tr> </tbody> </table>	Sample Types	<input checked="" type="checkbox"/> Serum	<input type="checkbox"/> Urine	<input type="checkbox"/> CSF	<input checked="" type="checkbox"/> Plasma	<input type="checkbox"/> Whole Blood	<input type="checkbox"/> Other
Reference Range																													
	Lower Limit	Upper Limit																											
	(U/L)	(U/L)																											
Normal	: #	: #																											
Panic	: #	: #																											
Sample Types																													
<input checked="" type="checkbox"/> Serum																													
<input type="checkbox"/> Urine																													
<input type="checkbox"/> CSF																													
<input checked="" type="checkbox"/> Plasma																													
<input type="checkbox"/> Whole Blood																													
<input type="checkbox"/> Other																													

* Enter calibrator value
Editable by user

ALAT (GPT) FS (IFCC mod.)

Application for serum and plasma with Pyridoxal-5-Phosphate FS

Test Details		Test Volumes		Reference Ranges	
Test	: ALT + PYP			Auto Rerun	<input type="checkbox"/>
Report Name	: ALAT (GPT) with pyridoxal-5-phosphate			Online Calibration	<input type="checkbox"/>
Unit	: U/L	Decimal Places	: 1	Cuvette Wash	<input type="checkbox"/>
Wavelength-Primary	: 340	Secondary	: 450	Special Diluent	<input type="checkbox"/>
Assay Type	: RATE-A	Curve Type	: Linear	Warn after	: 20
M1 Start	: 0	M1 End	: 0	Reagents Used	: 2
M2 Start	: 33	M2 End	: 49	Reagent R1	: ALT + PYP R1
Sample Replicates	: 1	Standard Replicates	: 2	Reagent R2	: ALT + PYP R2
Control Replicates	: 1	Control Interval	: 0	Consumables/Calibrators:	
Reaction Direction	: Decreasing	React. Abs. Limit	: 0.5300	Blank /Level 0	: 0
Prozone Limit %	: 0	Prozone Check	: Upper	Calibrator 1	: *
Linearity Limit %	: 0	Delta Abs./Min.	: 0.0000	Calibrator 2	
Technical Minimum	: 6.0000	Technical Maximum	: 700.0000	Calibrator 3	
Y = aX + b a=	: 1.0000	b=	: 0.0000	Calibrator 4	
Reagent Abs Min	: 0.0000	Reagent Abs Max	: 0.0000	Calibrator 5	

Test Details		Test Volumes		Reference Ranges	
Test	: ALT + PYP				
Sample Type	: Serum				
Sample Volumes				Sample Types	
Normal	: 12.00 <input type="text"/> μ L	Dilution Ratio	: 1 X	<input checked="" type="checkbox"/> Serum	
Increase	: 20.00 <input type="text"/> μ L	Dilution Ratio	: 1 X	<input type="checkbox"/> Urine	
Decrease	: 5.00 <input type="text"/> μ L	Dilution Ratio	: 1 X	<input type="checkbox"/> CSF	
Standard Volume	: 12.00 <input type="text"/> μ L			<input checked="" type="checkbox"/> Plasma	
Reagent Volumes and Stirrer Speed				<input type="checkbox"/> Whole Blood	
RGT-1 Volume	: 160.00 <input type="text"/> μ L	R1 Stirrer Speed	: Medium	<input type="checkbox"/> Other	
RGT-2 Volume	: 40.00 <input type="text"/> μ L	R2 Stirrer Speed	: High		

Test Details		Test Volumes		Reference Ranges	
Test	: ALT + PYP				
Sample Type	: Serum				
Reference Range	: DEFAULT				
Category	: Male				
Reference Range				Sample Types	
	Lower Limit		Upper Limit	<input checked="" type="checkbox"/> Serum	
	(U/L)		(U/L)	<input type="checkbox"/> Urine	
Normal	: <input type="text"/> #		: <input type="text"/> #	<input type="checkbox"/> CSF	
Panic	: <input type="text"/> #		: <input type="text"/> #	<input checked="" type="checkbox"/> Plasma	
				<input type="checkbox"/> Whole Blood	
				<input type="checkbox"/> Other	

* Enter calibrator value
Editable by user