

## 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

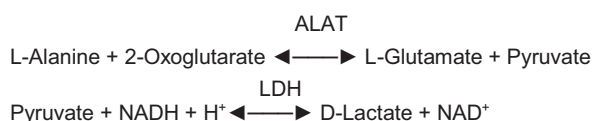
Diagnostic reagent for quantitative in vitro determination of ALAT (GPT) in human serum or heparin plasma on automated DiaSys respons<sup>®</sup>920.

### Summary

Alanine Aminotransferase (ALAT/ALT), formerly called Glutamic Pyruvic Transaminase (GPT) and Aspartate Aminotransferase (ASAT/AST), formerly called Glutamic Oxalacetic Transaminase (GOT) are the most important representatives of a group of enzymes, the aminotransferases or transaminases, which catalyze the conversion of  $\alpha$ -keto acids into amino acids by transfer of amino groups. As a liver specific enzyme, ALAT is only significantly elevated in hepatobiliary diseases. Increased ASAT levels, however, can occur in connection with damages of heart or skeletal muscle as well as of liver parenchyma. Parallel measurement of ALAT and ASAT is, therefore, applied to distinguish liver from heart or skeletal muscle damages. The ASAT/ALAT ratio is used for differential diagnosis in liver diseases. 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]



Addition of pyridoxal-5-phosphate (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 [1,3].

### Reagents

#### Components and Concentrations

<b>R1:</b>	TRIS	pH 7.15	140 mmol/L
	L-Alanine		700 mmol/L
	LDH (lactate dehydrogenase)		≥ 2300 U/L
<b>R2:</b>	2-Oxoglutarate		85 mmol/L
	NADH		1 mmol/L
<b>Pyridoxal-5-Phosphate FS</b>			
	Good's buffer	pH 9.6	100 mmol/L
	Pyridoxal-5-phosphate		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.

### 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 and biological material. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
- Reagent 2 contains biological material. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
- To avoid carryover interference, please take care of efficient washing especially after use of interfering reagents. Please refer to the DiaSys respons<sup>®</sup>920 Carryover Pair Table. Carryover pairs and automated washing steps with the

recommended cleaning solution can be specified in the system software. Please refer to the user manual.

- 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].
- 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

Refer to local legal requirements.

### 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  $\mu$ L 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

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 calibrator is recommended for calibration. This method has been standardized against the original IFCC formulation. Use DiaSys TruLab N and P for internal quality control. 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

Exemplary data mentioned below may slightly differ in case of deviating measurement conditions.

#### with P-5-P

Measuring range up to 600 U/L. 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
Onboard stability	6 days
Calibration stability	6 days

Interfering substance	Interferences $\leq$ 10% up to
Ascorbic acid	30 mg/dL
Bilirubin (conjugated and unconjugated)	60 mg/dL
Hemoglobin	200 mg/dL
Lipemia (triglycerides)	2000 mg/dL

For further information on interfering substances refer to Young DS [6,7].

Precision			
Within run (n=20)	Sample 1	Sample 2	Sample 3
Mean [U/L]	31.6	85.3	107
CV [%]	2.30	0.87	0.78
Between day (n=20)	Sample 1	Sample 2	Sample 3
Mean [U/L]	29.7	52.8	102
CV [%]	3.66	3.85	0.91

Method comparison (n=109)	
Test x	DiaSys ALAT (GPT) FS (Hitachi 917)
Test y	DiaSys ALAT (GPT) FS (respons <sup>®</sup> 920)
Slope	1.01
Intercept	0.136 U/L
Coefficient of correlation	0.997

### without P-5-P

Measuring range up to 600 U/L. In case of higher activities re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.	
Limit of detection**	2 U/L
Onboard stability	4 weeks
Calibration stability	4 weeks

Interfering substance	Interferences ≤ 10% up to
Ascorbic acid	30 mg/dL
Bilirubin (conjugated and unconjugated)	60 mg/dL
Hemoglobin	200 mg/dL
Lipemia (triglycerides)	2000 mg/dL
For further information on interfering substances refer to Young DS [6,7].	

Precision			
Within run (n=20)	Sample 1	Sample 2	Sample 3
Mean [U/L]	34.0	73.0	108
CV [%]	1.20	0.83	0.90
Between day (n=20)	Sample 1	Sample 2	Sample 3
Mean [U/L]	31.3	70.2	104
CV [%]	4.26	3.29	1.09

Method comparison (n=96)	
Test x	DiaSys ALAT (GPT) FS (Hitachi 917)
Test y	DiaSys ALAT (GPT) FS (respons <sup>®</sup> 920)
Slope	0.995
Intercept	0.00 U/L
Coefficient of correlation	0.997

\*\* 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

With P-5-P			
Women [8]		< 34 U/L	< 0.57 µkat/L
Men [8]		< 45 U/L	< 0.75 µkat/L
Children [1]	1 – 30 Day(s)	< 25 U/L	< 0.42 µkat/L
	2 – 12 Months	< 35 U/L	< 0.58 µkat/L
	1 – 3 Year(s)	< 30 U/L	< 0.50 µkat/L
	4 – 6 Years	< 25 U/L	< 0.42 µkat/L
	7 – 9 Years	< 25 U/L	< 0.42 µkat/L
	10 – 18 Years	< 30 U/L	< 0.50 µkat/L

Without P-5-P		
Women [9,10]	< 31 U/L	< 0.52 µkat/L
Men [9,10]	< 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

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\* 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	: ALT(GPT)			Online Calibration	<input type="checkbox"/>
Unit	: U/L	Decimal Places	: 1	Cuvette Wash	<input type="checkbox"/>
Wavelength-Primary	: 340	Secondary	: 405	Total Reagents	: 2
Assay Type	: RATE - A	Curve Type	: Linear	Reagent R1	: ALT R1
M1 Start	: 0	M1 End	: 0	Reagent R2	: ALT R2
M2 Start	: 20	M2 End	: 31		
Sample Replicates	: 1	Standard Replicates	: 3	<b>Consumables/Calibrators:</b>	
Control Replicates	: 1	Control Interval	: 0	Blank /Level 0	: 0
Reaction Direction	: Decreasing	React. Abs. Limit	: 0.51(0.30)**	Calibrator 1	: *
Prozone Limit %	: 0	Prozone Check	: Upper		
Linearity Limit %	: 0	Delta Abs. / Min.	: 0.0000		
Technical Minimum	: 3.0	Technical Maximum	: 600.0		
Y = aX + b	a = 1.0000	b = 0.0000			

\* Enter calibrator value. ( )\*\* With pyridoxal-5-phosphate

Test Details		Test Volumes		Reference Ranges	
Test	: ALT				
Sample Type	: Serum				
<b>Sample Volumes</b>				<b>Sample Types</b>	
Normal	: 12.00 $\mu$ L	Dilution Ratio	: 1 X	<input checked="" type="checkbox"/> Serum	
Increase	: 20.00 $\mu$ L	Dilution Ratio	: 1 X	<input type="checkbox"/> Urine	
Decrease	: 5.00 $\mu$ L	Dilution Ratio	: 1 X	<input type="checkbox"/> CSF	
				<input checked="" type="checkbox"/> Plasma	
				<input type="checkbox"/> Whole Blood	
				<input type="checkbox"/> Other	
Standard Volume	: 12.00 $\mu$ L				
<b>Reagent Volumes and Stirrer Speed</b>					
RGT-1 Volume	: 160 $\mu$ L	R1 Stirrer Speed	: Medium		
RGT-2 Volume	: 40 $\mu$ L	R2 Stirrer Speed	: High		

Test Details		Test Volumes		Reference Ranges	
Test	: ALT				
Sample Type	: Serum				
Reference Range	: DEFAULT				
Category	: Male				
<b>Reference Range</b>				<b>Sample Types</b>	
	Lower Limit	Upper Limit		<input checked="" type="checkbox"/> Serum	
	(U/L)	(U/L)		<input type="checkbox"/> Urine	
Normal	: 0.00	: 45.00		<input type="checkbox"/> CSF	
Panic	: 0.00	: 0.00		<input checked="" type="checkbox"/> Plasma	
				<input type="checkbox"/> Whole Blood	
				<input type="checkbox"/> Other	