BioMajesty®

ALAT (GPT) FS* (IFCC mod.)

with/without Pyridoxal-5-Phosphate FS (P-5-P)

Order Information

Cat. No.	Kit size
1 2701 99 10 962	1380 (R1: 6 x 230, R2: 6 x 230)
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 BioMajesty® JCA-BM6010/C.

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 α-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]

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

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

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

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
	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

1. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
2. Reagent 1 contains animal and biological material. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
3. Reagent 2 contains biological material. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
4. Sulfasalazine and sulfapyridine medication may cause false results in patient samples. Blood collection must be performed prior to drug administration.
5. In very rare cases, samples of patients with gammopathy might give falsified results [4].
6. 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.
7. 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 250 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

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

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Performance Characteristics

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

with P-5-P

Measuring range up to 1000 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**	4 U/L
Onboard stability	3 weeks
Calibration stability	3 weeks

Interfering substance	Interferences ≤ 10% up to	Analyte concentration [U/L]
Ascorbic acid	30 mg/dL	36.0
	60 mg/dL	110
Bilirubin (conjugated)	54 mg/dL	36.0
	60 mg/dL	120
Bilirubin (unconjugated)	54 mg/dL	36.0
	60 mg/dL	106
Hemoglobin	500 mg/dL	36.0
	500 mg/dL	118
Lipemia (triglycerides)	400 mg/dL	36.0
	900 mg/dL	99.2

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]	26.0	33.7	191
CV [%]	2.67	1.37	0.801
Total Precision CLSI (n=80)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	23.5	42.6	505
CV [%]	3.82	1.76	0.975

Method comparison (n=154)	
Test x	Competitor ALAT (GPT) (cobas® c 501)
Test y	DiaSys ALAT (GPT) FS (BioMajesty®JCA-BM6010C)
Slope	1.08
Intercept	0.771 U/L
Coefficient of correlation	0.990

without P-5-P

Measuring range up to 1000 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**	6 U/L
Onboard stability	8 weeks
Calibration stability	8 weeks

Interfering substance	Interferences ≤ 10% up to	Analyte concentration [U/L]
Ascorbic acid	30 mg/dL	40.0
	60 mg/dL	84.8
Bilirubin (conjugated)	60 mg/dL	40.0
	60 mg/dL	97.1
Bilirubin (unconjugated)	55 mg/dL	40.0
	60 mg/dL	81.3
Hemoglobin	500 mg/dL	40.0
	1000 mg/dL	98.6
Lipemia (triglycerides)	400 mg/dL	40.0
	1000 mg/dL	76.3

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]	21.4	34.5	191
CV [%]	2.45	1.54	0.853
Total Precision CLSI (n=80)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	19.9	36.1	393
CV [%]	2.76	1.98	0.917

Method comparison (n=154)	
Test x	Competitor ALAT (GPT) (cobas® c 501)
Test y	DiaSys ALAT (GPT) FS (BioMajesty®JCA-BM6010C)
Slope	1.07
Intercept	1.33 U/L
Coefficient of correlation	0.994

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

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.

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Literature

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IVD CE

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* Fluid Stable

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Chemistry code 10 270

Application for serum and plasma samples

This application was set up and evaluated by DiaSys. It is based on the standard equipment at that time and does not apply to any equipment modifications undertaken by unqualified personnel.

Analytical Conditions	
R1 volume	80
R2e volume	0
R2 volume	20
R1 diluent vol	0
R2e diluent vol	0
R2 diluent vol	0
Sample vol (S)	6
Sample vol (U)	6
Reagent 1 mix	weak
Reagent 2e mix	strong
Reagent 2 mix	strong
Reaction time	10

Sub-analy. Conditions	
Name	ALT
Digits	2
M-wave L.	340
S-wave.L	410
Analy.mthd.	RRA
Calc.mthd.	STD
Qualit. judge	No

Analysis Test Condition Setting (M)		
Sample Type	**Serum**	**Urine**
Reac. sample vol.	6	6
Diluent method	No dil	No dil
Undil. sample vol.	0	0
Diluent volume	0	0
Diluent position	0	0

entered by user

Endpoint method	
Re.absorb (u)	9.999
Re. Absorb (d)	-9.999

Calculation Method Setting	
M-DET.P.I	21
M-DET.P.m	25
M-DET.P.n	42
S-DET.P.p	0
S-DET.P.r	0
Check D.P.I.	21
Limit value	0.003
Variance	10
Reac.type	Dec

Reaction Rate Method	
Cycle	2
Factor	2
E2 corre	Do
Blank (u)	9.999
Blank (d)	-9.999
Sample (u)	9.999
Sample (d)	0.7

Standards Setting	
FV	#
BLK H	9.999
BLK L	-9.999
STD H	9.999
STD L	-9.999