respons®910

ALAT (GPT) FS* (IFCC mod.)

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

Order Information

Cat. No.	Kit size
1 2701 99 10 920	Σ 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®910.

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]

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

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

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 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

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 ≤ 10% up to	Analyte concentration [U/L]
Ascorbic acid	30 mg/dL	121
Bilirubin (conjugated)	50 mg/dL	49.8
	55 mg/dL	93.8
Bilirubin (unconjugated)	45 mg/dL	46.1
	45 mg/dL	85.7
Hemoglobin	500 mg/dL	50.9
	850 mg/dL	107
Lipemia (triglycerides)	1000 mg/dL	35.5
	1000 mg/dL	114
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]	21.2	47.4	132
CV [%]	2.88	1.41	0.95
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	19.5	51.2	126
CV [%]	4.02	2.03	1.63

Method comparison (n=107)	
Test x	DiaSys ALAT (GPT) FS (Hitachi 911)
Test y	DiaSys ALAT (GPT) FS (respons®910)
Slope	1.02
Intercept	–1.09 U/L
Coefficient of correlation	0.999

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**	3 U/L
Onboard stability	4 weeks
Calibration stability	4 weeks

Interfering substance	Interferences ≤ 10% up to	Analyte concentration [U/L]
Ascorbic acid	30 mg/dL	81.1
Bilirubin (conjugated)	50 mg/dL	46.7
	55 mg/dL	70.3
Bilirubin (unconjugated)	45 mg/dL	33.5
	45 mg/dL	63.5
Hemoglobin	500 mg/dL	36.0
	850 mg/dL	78.1
Lipemia (triglycerides)	1000 mg/dL	40.3
	1000 mg/dL	131
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]	20.8	36.4	125
CV [%]	2.12	2.04	1.02
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	20.3	40.0	122
CV [%]	4.24	2.28	1.67

Method comparison (n=90)	
Test x	DiaSys ALAT (GPT) FS (Hitachi 911)
Test y	DiaSys ALAT (GPT) FS (respons®910)
Slope	1.00
Intercept	–0.161 U/L
Coefficient of correlation	0.999

** according to CLSI document EP17-A, Vol. 24, No. 34

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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IVD CE

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* Fluid Stable

respons®910

ALAT (GPT) FS (IFCC mod.)

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.

Identification	
This method is usable for analysis:	Yes
Twin reaction:	No
Name:	ALT
Shortcut:	
Reagent barcode reference:	010
Host reference:	

Technic	
Type:	Linear kinetic
First reagent:[µL]	160
Blank reagent	Yes
Sensitive to light	
Second reagent:[µL]	40
Blank reagent	Yes
Sensitive to light	
Main wavelength:[nm]	340
Secondary wavelength:[nm]	405
Polychromatic factor:	1.000
1 st reading time [min:sec]	5:48
Last reading time [min:sec]	9:36
Reaction way:	Decreasing
Linear Kinetics Substrate depletion: Absorbance li	0.3000
Linearity: Maximum deviation [%]	100
Fixed Time Kinetics Substrate depletion: Absorbance limit	
Endpoint Stability: Largest remaining slope	
Prozone Limit [%]	

Reagents	
Decimals	
Units	

Sample	
Diluent	DIL A (NaCl)
Hemolysis:	
Agent [µL]	0 (no hemolysis)
Cleaner	
Sample [µL]	0
Technical limits	
Concentration technical limits-Lower	3
Concentration technical limits-Upper	600
SERUM	
Normal volume [µL]	12
Normal dilution (factor)	1
Below normal volume [µL]	20
Below normal dilution (factor)	1
Above normal volume [µL]	2
Above normal dilution (factor)	1
URIN	
Normal volume [µL]	12
Normal dilution (factor)	1
Below normal volume [µL]	20
Below normal dilution (factor)	1
Above normal volume [µL]	2
Above normal dilution (factor)	1
PLASMA	
Normal volume [µL]	12
Normal dilution (factor)	1
Below normal volume [µL]	20
Below normal dilution (factor)	1
Above normal volume [µL]	2
Above normal dilution (factor)	1
CSF	
Normal volume [µL]	12
Normal dilution (factor)	1
Below normal volume[µL]	20
Below normal dilution (factor)	1
Above normal volume [µL]	2
Above normal dilution (factor)	1
Whole blood	
Normal volume [µL]	12
Normal dilution (factor)	1
Below normal volume[µL]	20
Below normal dilution (factor)	1
Above normal volume [µL]	2
Above normal dilution (factor)	1

Results	
Decimals	1
Units	U/L
Correlation factor-Offset	0.000
Correlation factor-Slope	1.000

Range	
Gender	Male
Age	
SERUM	>= <=41.0
URINE	
PLASMA	>= <=41.0
CSF	
Whole blood	
Gender	Female
Age	
SERUM	>= <=31.0
URINE	
PLASMA	>= <=31.0
CSF	
Whole blood	

Contaminants
Please refer to r910 Carryover Pair Table

Calibrators details	
Calibrator list	**Concentration**
Cal. 1/Blank	0
Cal. 2	*
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
	Max delta abs.
Cal. 1	0.002
Cal. 2	0.005
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
Drift limit [%]	0.8

Calculations	
Model	X
Degree	1

* Enter calibrator value

respons®910

ALAT (GPT) FS (IFCC mod.) with P-5-P activation

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.

Identification	
This method is usable for analysis:	Yes
Twin reaction:	No
Name:	ALT
Shortcut:	
Reagent barcode reference:	63
Host reference:	

Technic	
Type:	Linear kinetic
First reagent:[µL]	160
Blank reagent	Yes
Sensitive to light	
Second reagent:[µL]	40
Blank reagent	Yes
Sensitive to light	
Main wavelength:[nm]	340
Secondary wavelength:[nm]	405
Polychromatic factor:	1.000
1 st reading time [min:sec]	5:48
Last reading time [min:sec]	9:36
Reaction way:	Decreasing
Linear Kinetics Substrate depletion: Absorbance li	0.3900
Linearity: Maximum deviation [%]	100
Fixed Time Kinetics Substrate depletion: Absorbance limit	
Endpoint Stability: Largest remaining slope	
Prozone Limit [%]	

Reagents	
Decimals	
Units	

Sample	
Diluent	DIL A (NaCl)
Hemolysis:	
Agent [µL]	0 (no hemolysis)
Cleaner	
Sample [µL]	0
Technical limits	
Concentration technical limits-Lower	3
Concentration technical limits-Upper	600
SERUM	
Normal volume [µL]	12
Normal dilution (factor)	1
Below normal volume [µL]	20
Below normal dilution (factor)	1
Above normal volume [µL]	2
Above normal dilution (factor)	1
URIN	
Normal volume [µL]	12
Normal dilution (factor)	1
Below normal volume [µL]	20
Below normal dilution (factor)	1
Above normal volume [µL]	2
Above normal dilution (factor)	1
PLASMA	
Normal volume [µL]	12
Normal dilution (factor)	1
Below normal volume [µL]	20
Below normal dilution (factor)	1
Above normal volume [µL]	2
Above normal dilution (factor)	1
CSF	
Normal volume [µL]	12
Normal dilution (factor)	1
Below normal volume[µL]	20
Below normal dilution (factor)	1
Above normal volume [µL]	2
Above normal dilution (factor)	1
Whole blood	
Normal volume [µL]	12
Normal dilution (factor)	1
Below normal volume[µL]	20
Below normal dilution (factor)	1
Above normal volume [µL]	2
Above normal dilution (factor)	1

Results	
Decimals	1
Units	U/L
Correlation factor-Offset	0.000
Correlation factor-Slope	1.000

Range	
Gender	Male
Age	
SERUM	>= <=45.0
URINE	
PLASMA	>= <=45.0
CSF	
Whole blood	
Gender	Female
Age	
SERUM	>= <=34.0
URINE	
PLASMA	>= <=34.0
CSF	
Whole blood	

Contaminants
Please refer to r910 Carryover Pair Table

Calibrators details	
Calibrator list	**Concentration**
Cal. 1/Blank	0
Cal. 2	*
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
	Max delta abs.
Cal. 1	0.002
Cal. 2	0.005
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
Drift limit [%]	0.8

Calculations	
Model	X
Degree	1

* Enter calibrator value