

ASAT (GOT) FS* (IFCC mod.)

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

Order Information

Cat. No. 1 2601 99 10 920 **Kit size**  800 (4 x 200)

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

Intended Use

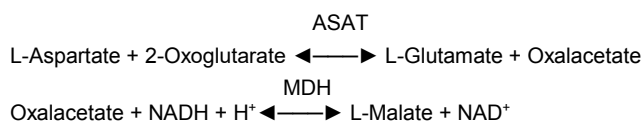
Diagnostic reagent for reagent for quantitative in vitro determination of ASAT (GOT) in serum or plasma on respons[®]910.

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]



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 7.65	110 mmol/L
	L-Aspartate		320 mmol/L
	MDH (malate dehydrogenase)		≥ 800 U/L
	LDH (lactate dehydrogenase)		≥ 1200 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 Reagent Stability

The reagents are stable up to the end of the indicated month of expiry, if stored at 2 – 8°C and contamination is avoided. Do not freeze the reagents and protect them 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 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 [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 reagent is ready to use. The bottles are placed directly into the reagent rotor.

For the determination with P-5-P add 350 μ 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

Serum or heparin plasma

Stability [5]:
4 days at 20 – 25°C
7 days at 4 – 8°C
3 months 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 675 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	6 days
Calibration stability	6 days

Interfering substance	Interferences \leq 10% up to	Analyte concentration [U/L]
Ascorbic acid	30 mg/dL	108
Hemoglobin	20 mg/dL	22.9
	100 mg/dL	166
Bilirubin (conjugated)	55 mg/dL	42.6
	55 mg/dL	165
Bilirubin (unconjugated)	60 mg/dL	44.0
	60 mg/dL	173
Lipemia (triglycerides)	1000 mg/dL	39.2
	500 mg/dL	149

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

Precision			
Within run (n=20)	Sample 1	Sample 2	Sample 3
Mean [U/L]	35.1	44.4	172
CV [%]	1.54	1.85	1.47
Between day (n=20)	Sample 1	Sample 2	Sample 3
Mean [U/L]	27.9	44.7	174
CV [%]	4.07	2.71	1.34

Method comparison (n=115)	
Test x	DiaSys ASAT (GOT) FS (Hitachi 917)
Test y	DiaSys ASAT (GOT) FS (respons [®] 910)
Slope	1.033
Intercept	-2.309 U/L
Coefficient of correlation	0.9996

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

without P-5-P

Measuring range up to 700 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	Analyte concentration [U/L]
Ascorbic acid	30 mg/dL	125
Hemoglobin	50 mg/dL	22.6
Bilirubin (conjugated)	10 mg/dL	19.0
	65 mg/dL	36.7
Bilirubin (unconjugated)	70 mg/dL	18.6
Lipemia (triglycerides)	1000 mg/dL	43.7
	1300 mg/dL	175

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

Precision			
Within run (n=20)	Sample 1	Sample 2	Sample 3
Mean [U/L]	23.5	40.1	199
CV [%]	2.54	1.61	1.07
Between day (n=20)	Sample 1	Sample 2	Sample 3
Mean [U/L]	25.5	49.4	205
CV [%]	3.13	1.55	1.00

Method comparison (n=105)	
Test x	DiaSys ASAT (GOT) FS (Hitachi 917)
Test y	DiaSys ASAT (GOT) FS (respons [®] 910)
Slope	0.996
Intercept	0.079 U/L
Coefficient of correlation	0.9999

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

Conversion Factor

ASAT [U/L] x 0.0167 = ASAT [µkat/L]

Reference Range

With P-5-P			
Women [7]		< 31 U/L	< 0.52 µkat/L
Men [7]		< 35 U/L	< 0.58 µkat/L
Children [1]	1 – 3 Year(s)	< 50 U/L	< 0.83 µkat/L
	4 – 6 Years	< 45 U/L	< 0.75 µkat/L
	7 – 9 Years	< 40 U/L	< 0.67 µkat/L
	10 – 12 Years	< 40 U/L	< 0.67 µkat/L
	13 – 15 Years	< 35 U/L	< 0.58 µkat/L
	16 – 18 Years	< 35 U/L	< 0.58 µkat/L

Without P-5-P		
Women [8,9]	< 31 U/L	< 0.52 µkat/L
Men [8,9]	< 35 U/L	< 0.58 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. 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.
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8. 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.
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* Fluid Stable

ASAT (GOT) 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:	AST
Shortcut:	
Reagent barcode reference:	011
Host reference:	

Technic	
Type:	Linear Kinetic
First reagent:[μ L]	160
Blank reagent	Yes
Sensitive to light	
Second reagent:[μ L]	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]	8:48
Reaction way:	Decreasing
Linear Kinetics	
Substrate depletion: Absorbance li	0.2700
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 [μ L]	0 (no hemolysis)
Cleaner	
Sample [μ L]	0
Technical limits	
Concentration technical limits-Lower	2.00
Concentration technical limits-Upper	700
SERUM	
Normal volume [μ L]	12
Normal dilution (factor)	1
Below normal volume [μ L]	20
Below normal dilution (factor)	1
Above normal volume [μ L]	2
Above normal dilution (factor)	1
URIN	
Normal volume [μ L]	12
Normal dilution (factor)	1
Below normal volume [μ L]	20
Below normal dilution (factor)	1
Above normal volume [μ L]	2
Above normal dilution (factor)	1
PLASMA	
Normal volume [μ L]	12
Normal dilution (factor)	1
Below normal volume [μ L]	20
Below normal dilution (factor)	1
Above normal volume [μ L]	2
Above normal dilution (factor)	1
CSF	
Normal volume [μ L]	12
Normal dilution (factor)	1
Below normal volume [μ L]	20
Below normal dilution (factor)	1
Above normal volume [μ L]	2
Above normal dilution (factor)	1
Whole blood	
Normal volume [μ L]	12
Normal dilution (factor)	1
Below normal volume [μ L]	20
Below normal dilution (factor)	1
Above normal volume [μ L]	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	>= <=35.0
URINE	
PLASMA	>= <=35.0
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

ASAT (GOT) 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:	AST
Shortcut:	
Reagent barcode reference:	64
Host reference:	

Technic	
Type:	Linear Kinetic
First reagent:[μ L]	160
Blank reagent	Yes
Sensitive to light	
Second reagent:[μ L]	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]	8:48
Reaction way:	Decreasing
Linear Kinetics	
Substrate depletion: Absorbance li	0.3500
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 [μ L]	0 (no hemolysis)
Cleaner	
Sample [μ L]	0
Technical limits	
Concentration technical limits-Lower	2.00
Concentration technical limits-Upper	675
SERUM	
Normal volume [μ L]	12
Normal dilution (factor)	1
Below normal volume [μ L]	20
Below normal dilution (factor)	1
Above normal volume [μ L]	2
Above normal dilution (factor)	1
URIN	
Normal volume [μ L]	12
Normal dilution (factor)	1
Below normal volume [μ L]	20
Below normal dilution (factor)	1
Above normal volume [μ L]	2
Above normal dilution (factor)	1
PLASMA	
Normal volume [μ L]	12
Normal dilution (factor)	1
Below normal volume [μ L]	20
Below normal dilution (factor)	1
Above normal volume [μ L]	2
Above normal dilution (factor)	1
CSF	
Normal volume [μ L]	12
Normal dilution (factor)	1
Below normal volume [μ L]	20
Below normal dilution (factor)	1
Above normal volume [μ L]	2
Above normal dilution (factor)	1
Whole blood	
Normal volume [μ L]	12
Normal dilution (factor)	1
Below normal volume [μ L]	20
Below normal dilution (factor)	1
Above normal volume [μ L]	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	>= <=35.0
URINE	
PLASMA	>= <=35.0
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