respons®920

ASAT (GOT) FS* (IFCC mod.)

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

Order Information

Cat. No.	Kit size
1 2601 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 ASAT (GOT) in human serum or heparin plasma on automated DiaSys respons®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 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]

$$\text{L-Aspartate} + \text{2-Oxoglutarate} \xleftrightarrow{\text{ASAT}} \text{L-Glutamate} + \text{Oxalacetate}$$

$$\text{Oxalacetate} + \text{NADH} + \text{H}^+ \xleftrightarrow{\text{MDH}} \text{L-Malate} + \text{NAD}^+$$

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 7.65	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 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. To avoid carryover interference, please take care of efficient washing especially after use of interfering reagents. Please refer to the DiaSys respons®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.
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]:

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 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**	3 U/L
Onboard stability	6 days
Calibration stability	6 days

Interfering substance	**Interferences ≤ 10% up to**
Ascorbic acid	30 mg/dL
Bilirubin (conjugated and unconjugated)	60 mg/dL
Hemoglobin interferes at low concentrations; indicates destruction of erythrocytes and therefore release of ASAT	
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]	37.5	115	191
CV [%]	2.28	1.29	0.87
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	36.4	129	187
CV [%]	3.85	2.64	1.73

Method comparison (n=110)	
Test x	DiaSys ASAT (GOT) FS (Hitachi 917)
Test y	DiaSys ASAT (GOT) FS (respons®920)
Slope	0.916
Intercept	1.35 U/L
Coefficient of correlation	0.999

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
Ascorbic acid	30 mg/dL
Bilirubin (conjugated and unconjugated)	60 mg/dL
Hemoglobin interferes at low concentrations; indicates destruction of erythrocytes and therefore release of ASAT.	
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]	34.7	86.5	186
CV [%]	1.21	1.15	0.85
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	18.3	34.2	184
CV [%]	3.39	1.80	1.37

Method comparison (n=97)	
Test x	DiaSys ASAT (GOT) FS (Hitachi 917)
Test y	DiaSys ASAT (GOT) FS (respons®920)
Slope	1.05
Intercept	-0.730 U/L
Coefficient of correlation	0.999

** 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 [8]		< 31 U/L	< 0.52 µkat/L
Men [8]		< 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 [9,10]	< 31 U/L	< 0.52 µkat/L
Men [9,10]	< 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.
3. Bergmeyer HU, Horder M, Rej R. Approved Recommendation (1985) on IFCC Methods for the Measurement of Catalytic Concentration of Enzymes. L.Clin. Chem. Clin. Biochem 1986; 24: 497-510.
4. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240-1243.
5. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 18-9.
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, https://clinfx.wiley.com/aaccweb/aacc/, accessed in September 2021. Published by AACC Press and John Wiley and Sons, Inc.
8. Schumann G, Bonora R, Ceriotti F, Férard G et al. IFCC primary reference procedure for the measurement of catalytic activity concentrations of enzymes at 37°C. Part 5: Reference procedure for the measurement of catalytic concentration of aspartate aminotransferase. Clin Chem Lab Med 2002;40:725-33.
9. 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.
10. Zawta B, Klein G, Bablok W. Temperature Conversion in Clinical Enzymology? Klin. Lab. 1994; 40: 33-42.

IVD CE

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

* Fluid Stable

respons®920

ASAT (GOT) FS (IFCC mod.)

Application for serum and plasma

Test Details			Test Volumes			Reference Ranges		
Test	:	AST				Auto Rerun	☐	
Report Name	:	AST (GOT)				Online Calibration	☐	
Unit	:	U/L	Decimal Places	:	1	Cuvette Wash	☐	
Wavelength-Primary	:	340	Secondary	:	405	Total Reagents	:	2
Assay Type	:	RATE - A	Curve Type	:	Linear	Reagent R1	:	AST R1
M1 Start	:	0	M1 End	:	0	Reagent R2	:	AST R2
M2 Start	:	19	M2 End	:	30			
Sample Replicates	:	1	Standard Replicates	:	3	**Consumables/Calibrators:**		
Control Replicates	:	1	Control Interval	:	0	Blank /Level 0		0
Reaction Direction	:	Decreasing	React. Abs. Limit	:	0.45 (0.20)**	Calibrator 1		*
Prozone Limit %	:	0	Prozone Check	:	Upper			
Linearity Limit %	:	0	Delta Abs. / Min.	:	0.0000			
Technical Minimum	:	3.0	Technical Maximum	:	700.0			
Y = aX + b a=	:	1.0000	b=	:	0.0000			

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

Test Details			Test Volumes			Reference Ranges
Test	:	AST				
Sample Type	:	Serum				

Sample Volumes

Normal	:	12.00	µL	Dilution Ratio	:	1	X
Increase	:	20.00	µL	Dilution Ratio	:	1	X
Decrease	:	6.00	µL	Dilution Ratio	:	1	X
Standard Volume	:	12.00	µL				

Reagent Volumes and Stirrer Speed

RGT-1 Volume	:	160	µL	R1 Stirrer Speed	:	Medium
RGT-2 Volume	:	40	µL	R2 Stirrer Speed	:	High

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other

Test Details			Test Volumes	Reference Ranges
Test	:	AST		
Sample Type	:	Serum		
Reference Range	:	DEFAULT		
Category	:	Male		

Reference Range

		Lower Limit (U/L)	Upper Limit (U/L)
Normal	:	0.00	35.00
Panic	:	0.00	0.00

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other