ASAT (GOT) FS (IFCC mod.)

AST/SGOT Reagent Test Kit

Intended Use
Diagnostic reagent for in vitro quantitative determination of ASAT/SGOT in human serum or plasma on photometric analyzers.

Item Code	Pack Size
126019934840	R1: 4 x 60 mL; R2: 4 x 15 mL

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.

Method
Optimized UV-test according to IFCC (International Federation of Clinical Chemistry and Laboratory Medicine) [modified]

Principle

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

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

Reagents
Reagent composition

R 1:	TRIS Buffer	12.1 gm/L
	Asparate	39g/L
	LDH	>1200U/L
R 2:	2-Keto glutaric acid	8.5 gm/L
	NADH	1.1 gm/L
Preservatives & Stabilizers		q.s.

Storage Instructions and Reagent Stability
The reagents are stable up to the end of the indicated month of expiry, if stored at 2 – 8°C, protected from light and contamination is avoided. Do not freeze the reagents!

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 material. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practices.
3. In very rare cases, samples of patients with gammopathy might give falsified results [4].
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.
5. For professional use only!

Traceability
The method has been standardized against the original IFCC formulation.

Waste Management
Please refer to local legal requirements.

Reagent Preparation
The reagents are ready to use.

Specimen
Serum or heparin plasma
Stability [5]:

4 days	at	20 – 25°C
7 days	at	4 – 8°C
3	at	–20°C

Discard contaminated specimens. Only freeze once!

Assay Procedure

Wavelength	340 nm
Optical path	1 cm
Temperature	37°C
Measurement	Against air

Sample/Calibrator	100 µL
Reagent 1	800 µL
Mix, incubate for 5 min., then add:	
Reagent 2	200 µL
Mix, read absorbance after 1 min. and start stopwatch. Read absorbance again 1, 2 and 3 min thereafter.	

Calculation with factor
From absorbance readings calculate A/min and multiply by the corresponding factor from table below:

A/min x factor = ASAT activity [U/L]

340 nm 1745

With calibrator

$$\text{ASAT [U/L]} = \frac{\text{A/min Sample}}{\text{A/min Calibrator}} \times \text{Conc. Calibrator [U/L]}$$

Conversion factor
ASAT [U/L] x 0.0167 = ASAT [µkat/L]

Calibrators and Controls
For the calibration of automated photometric systems, DiaSys TruCal U calibrator is recommended. This method has been standardized against the original IFCC formulation. For internal quality control, DiaSys TruLab N and P controls should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

Performance Characteristics

Measuring range
On automated systems the test is suitable for the determination of ASAT activities up to 500 U/L.
In case of a manual procedure, the test is suitable for ASAT activities which correspond to a maximum of ΔA/min of 0.16 at 340 nm.If such values are exceeded the samples should be diluted 1 + 9 with NaCl solution (9 g/L) and results multiplied by 10.

Specificity/Interferences
No interference was observed by ascorbic acid up to 30 mg/dL, bilirubin up to 40 mg/dL and lipemia up to 2000 mg/dL triglycerides. The presence of hemoglobin in serum indicates destruction of erythrocytes with release of ASAT, thus producing high interference. For further information on interfering substances refer to Young DS [6].

Sensitivity/Limit of Detection
The lower limit of detection is 2 U/L.

Precision

Intra-assay precision n = 20	Mean [U/L]	SD [U/L]	CV [%]
Sample 1	35.15	0.55	1.57
Sample 2	41.81	0.52	1.24
Sample 3	179.43	1.46	0.81

Inter-assay precision n = 20	Mean [U/L]	SD [U/L]	CV [%]
Sample 1	39	0.21	0.53
Sample 2	157	0.95	0.61
Sample 3	193	0.94	0.49

Method Comparison
A comparison of DiaSys ASAT (GOT) Reagent without P-5-P (y) and a commercially available test (x) using 51 samples gave following results:
y = 0.997 x + 0.621 U/L; r = 1.000

Reference Range

Women	< 31 U/L	< 0.52 µkat/L
Men	< 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.

Limitations
Eventual GOT(AST), mod. IFCC carry-over to reagents Carbon Dioxide (CO2) PEP-C and Protein Total in Urine/CSF (Pyrogallol red). The actual carry-over depends on the analyzer.

Clinical Interpretation
The normal range of an SGOT test is generally between 8 and 35 units per liter of serum. In general, men may naturally have higher amounts of AST in the blood. A result above 35 for men and 31 for women is high and may indicate damage.

Literature

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Notes on Symbols and Marks

	Consult instruction for use
	Use-by date
LOT	Batch code
REF	Catalogue number
	Caution
	Manufacturer
IVD	In vitro diagnostic medical device
	Temperature limit
	Do not reuse
CONT.	The pack contains
	Recycle
	Date of manufacture

ISO 9001, ISO 13485 and ICMED 13485 Certified Company

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Revision No. :01
Mar. 2022

IN/0014 v01