# ALAT (GPT) FS (IFCC mod.)

## ALT/SGPT Reagent Test Kit

**Intended use**
Diagnostic reagent for in vitro quantitative determination of ALAT/SGPT in human serum or plasma on photometric analyzers.

**Reagent Kits**

| Item Code | Pack Size |
|---|---|
| 127019934840 | 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**
L-Alanine + 2-Oxoglutarate <ALAT> L-Glutamate + Pyruvate
Pyruvate + NADH + $H^+$ <LDH> D-Lactate + $NAD^+$

**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!

**Reagent Preparation**
The reagents are ready to use.

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

**Reagents**
**Components and Concentrations**

| | | |
|---|---|---|
| **R1:** | NAD | 0.2 g/L |
| | Tris Buffer | 12.1 g/L |
| | Alanine | 57 g/L |
| | LDH | >1200 U/L |
| **R2:** | 2 Keto Glutaric Acid | 8.5 g/L |
| | NADH | 1.1 g/L |
| Preservatives & Stabilizers | | q.s. |

**Waste Management**
Please refer to local legal requirements.

**Specimen**
Serum, heparin plasma or EDTA 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!

**Assay Procedure**

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

| | |
|---|---|
| **Sample or 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:

**ΔA/min x factor = ALAT activity [U/L]**

| | |
|---|---|
| 340 nm | 1745 |

**With calibrator**

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

**Conversion factor**
ALAT [U/L] x 0.0167 = ALAT [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.

**Reference Range**

| | | |
|---|---|---|
| Women | < 31 U/L | < 0.52 µkat/L |
| Men | < 41 U/L | < 0.68 µkat/L |

**Performance Characteristics**

**Measuring range**
On automated systems the test is suitable for the determination of ALAT activities up to 500 U/L.
In case of a manual procedure, the test is suitable for ALAT activities which correspond to a maximum of ΔA/min of 0.16 at 340.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, hemoglobin up to 400 mg/dL and lipemia up to 2000 mg/dL triglycerides. 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** | 22.33 | 0.44 | 1.95 |
| **Sample 2** | 86.47 | 0.67 | 0.78 |
| **Sample 3** | 112 | 0.89 | 0.79 |

| Inter-assay precision n = 20 | Mean [U/L] | SD [U/L] | CV [%] |
|---|---|---|---|
| **Sample 1** | 28.6 | 0.61 | 2.14 |
| **Sample 2** | 53.4 | 0.51 | 0.96 |
| **Sample 3** | 106 | 1.02 | 0.96 |

**Method Comparison**

A comparison of DiaSys ALAT (GPT) FS without P-5-P (y) with a commercially available test (x) using 51 samples gave following results:
y = 0.971 x + 0.047 U/L; r =1.000

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

**Limitations**

Eventual GPT(ALAT), 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.

**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. Sulfasalazine and sulfapyridine medication may lead to false results in patient samples. Blood collection must be done before drug administration.
5. 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.
6. For professional use only!

**Clinical Interpretation**

SGPT exists predominantly in the liver and leaks into the bloodstream when produced in excess. The SGPT normal range is about 2 to 41 units per liter of blood serum. Thus, very high level of SGPT in the blood can be an indication of damage or problems related to the liver.

**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: 481-495.
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. 14 -5.
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. 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 4: Reference procedure for the measurement of catalytic concentration of alanine aminotransferase. Clin Chem Lab Med 2002;40: 718-24.
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.
9. Zawta B, Klein G, Bablok W. Temperature Conversion in Clinical Enzymology? Klin. Lab. 1994; 40: 3342.


## *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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