

ALAT (GPT) FS* (IFCC mod.)**Order Information**

| Cat. No. | Kit size | Instrument | Σ |
|------------------|----------------|------------|---------------|
| 1 2701 99 10 972 | R1 3 x 13.8 mL | BX-3010 | 300 (3 x 100) |
| | | BX-4000 | 216 (3 x 72) |
| | R2 3 x 6.1 mL | BX-3010 | 300 (3 x 100) |
| | | BX-4000 | 216 (3 x 72) |

Intended Use

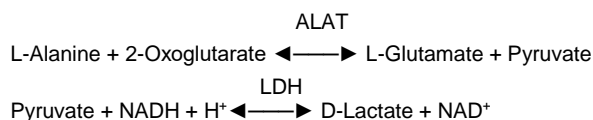
Diagnostic reagent for quantitative in vitro determination of ALAT (GPT) in serum or plasma on Sysmex BX-Series.

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]

**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 |

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

- 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 practice.
- In very rare cases, samples of patients with gammopathy might give falsified results [3].
- Sulfasalazine and sulfapyridine medication may lead to false results in patient samples. Blood collection must be done before drug administration.
- 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.

Materials Required

General laboratory equipment

Specimen

Serum or heparin plasma

Stability [4]:

| | | |
|--------|----|-----------|
| 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.

| | |
|--|----------------------------|
| Measuring range up to 600 U/L (10 μ kat/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 (0.05 μ kat/L) |
| Onboard stability | 6 weeks |
| Calibration stability | 6 weeks |

| Interfering substance | Interferences $\leq 10\%$ up to | Analyte concentration |
|--------------------------|---------------------------------|---------------------------------|
| Ascorbic acid | 30 mg/dL | 43.7 U/L (0.728 μ kat/L) |
| Bilirubin (conjugated) | 60 mg/dL | 27.2 U/L (0.453 μ kat/L) |
| Bilirubin (unconjugated) | 30 mg/dL | 27.4 U/L (0.456 μ kat/L) |
| Hemoglobin | 500 mg/dL | 27.3 U/L (0.455 μ kat/L) |
| Lipemia (triglycerides) | 450 mg/dL | 29.7 U/L (0.496 μ kat/L) |

For further information on interfering substances refer to Young DS. [5,6]

| Precision (BX-4000) | | | |
|---------------------|----------|----------|----------|
| Within run (n=20) | Sample 1 | Sample 2 | Sample 3 |
| Mean [U/L] | 28.5 | 38.8 | 110 |
| Mean [μ kat/L] | 0.475 | 0.647 | 1.83 |
| CV [%] | 1.85 | 1.55 | 0.604 |
| Between run (n=20) | Sample 1 | Sample 2 | Sample 3 |
| Mean [U/L] | 33.2 | 40.9 | 115 |
| Mean [μ kat/L] | 0.553 | 0.682 | 1.92 |
| CV [%] | 1.43 | 1.31 | 0.724 |

| Method comparison (n=115) | |
|----------------------------|-------------------------------|
| Test x | ALAT FS (Biomajesty 6010C) |
| Test y | ALAT FS (BX-4000) |
| Slope | 0.991 |
| Intercept | 0.841 U/L (0.014 μ kat/L) |
| Coefficient of correlation | 0.9995 |

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

Conversion Factor

ALAT [U/L] \times 0.0167 = ALAT [μ kat/L]

Reference Range [7,8]

| | | |
|-------|----------|--------------------|
| Women | < 31 U/L | < 0.52 μ kat/L |
| Men | < 41 U/L | < 0.68 μ kat/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.
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3. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240-1243.
4. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; 14-5.
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7. Lorentz K, Röhle G, Siekmann L. Einführung der neuen Standardmethoden 1994 zur Bestimmung der katalytischen Enzymkonzentrationen bei 37 °C. DG Klinische Chemie Mitteilungen 1995; Heft 4.
8. Zawta B, Klein G, Bablok W. Temperature Conversion in Clinical Enzymology? Klin. Lab. 1994; 40: 33-42.



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

* Fluid Stable

| Chemistry Parameters 1 | | | | Sysmex BX-3010 Chemistry Analyzer Analytical Parameters | | |
|---|--------------------|---------------------|--------------|---|-------------------|--------------------|
| Method No. | * | Method Name | ALAT | Reagent Name | Reagent (μL) | Water (μL) |
| Print Name | ALT | MethodColor | | R1 | ALAT 100 | |
| Sample Type | Serum | | | R2 | ALAT 25 | |
| Unit | U/L | | | Diluent | Disable | |
| Assay Type | Rate | | | Sample Ppt. Wash | Disable | |
| Measuring points | | Start | End | Stirring Speed R1 | Middle | R2 Fast |
| | | 1 | 30 - 46 | | | |
| | | 2 | Disable - | | | |
| Wave Length | Prim. 340 | Sec. 415 | | Normal Range | | |
| | | | | No. | Normal Range Name | Min Max |
| | | | | 1 | Male-G1 | * * |
| | | | | 2 | Male-G2 | * * |
| | | | | 3 | Male-G3 | * * |
| | | | | 4 | Female-G1 | * * |
| Normal | Sample Volume (μL) | Diluted Sample (μL) | Diluent (μL) | Technical Range | | |
| | Low Normal High | | | (Conc) | 3 - 600 | |
| <input type="checkbox"/> Diluent | 0.0 < 7.5 < 0.0 | | | (mAbs/10) | * - * | |
| <input type="checkbox"/> Rerun (High/Prozone) | | | | Previous Result Comparison (%) | * - * | % |
| <input type="checkbox"/> Diluent | 0.0 < 7.5 < 0.0 | | | Abnormal Range (Conc) | * - * | |
| <input type="checkbox"/> Rerun (Low) | | | | Panic Range (Conc) | * - * | |
| <input type="checkbox"/> Diluent | 0.0 < 7.5 < 0.0 | | | Decimal Point | 0 | Profile SI Disable |

*Entered by user

| Chemistry Parameters 2 | | | | Sysmex BX-3010 Chemistry Analyzer Analytical Parameters | | |
|---|------------------|-------------|---------------|---|--|--------|
| Method No. | * | Method Name | ALAT | Sample | Serum | |
| Limit Checks | | | | Blank measurement | | |
| <input checked="" type="checkbox"/> Duplicate Limit | | 50 | mAbs/10 | Blank measurement: | Disable reagent blank and C1 blank | |
| <input checked="" type="checkbox"/> Sensitivity Limit | | 250 | mAbs/10 | Measurement of Reagent Blank during Run: | None | |
| <input checked="" type="checkbox"/> Linearity Limit | | 10 | % | Reagent blank measurement at calibration: | Reagent blank (No sample) | |
| | | 220 | (mAbs/10)/min | The number of measurement: | Duplicate | |
| <input type="checkbox"/> Prozone Limit | | Higher | % | Reagent blank limit checks: | <input checked="" type="checkbox"/> Duplicate Limit 20 mAbs/10 | |
| | | | | Instrument Factor | a 1.00 | b 0.00 |
| | | SL1-S | - | | | |
| | | SL1-F | | | | |
| | | SL2-S | - | | | |
| | | SL2-F | | | | |
| | | Sensitivity | | | | |
| <input checked="" type="checkbox"/> Absorbance Limit | | | mAbs/10 | | | |
| | Abs. in reaction | Decrease | | | | |
| | Limit | 4500 | mAbs/10 | | | |

Calibration Registration

**Sysmex BX-3010 Chemistry Analyzer
Analytical Parameters**

Method No.

Method Name

Sample Type

Replication

Check Interval

Test without calibration

Calibration Type

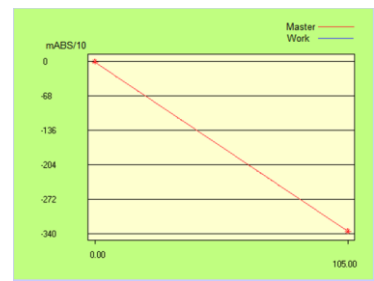
Reagent Lot

Calibrator Name

| | Conc. | WORK | MASTER | Calibr. Lot No. | <input type="checkbox"/> All |
|----|--------------------------------|-----------------|-----------------|-----------------|------------------------------|
| C1 | <input type="text" value="0"/> | Automatic entry | Automatic entry | * | |
| C2 | * | Automatic entry | Automatic entry | * | |
| C3 | * | | | | |
| C4 | * | | | | |
| C5 | * | | | | |
| C6 | * | | | | |
| C7 | * | | | | |

K C1 Blank
 Reagent Blank for C1

Reagent Lot No.
 (R1) Last
 (R2)



The calibration curve is lot dependent

Reagent blank mAbs/10 Last

Blank mAbs/10 Last

Calibration Curve Conc.

Absorbance mAbs/10

*Entered by user

| Chemistry Parameters | | Sysmex BX-4000 Chemistry Analyzer Analytical Parameters | | | |
|-----------------------------------|--|--|--|-----------------------------------|---|
| Method | * <input type="text"/> | Name | <input type="text" value="ALAT"/> | | |
| Print Name | <input type="text" value="ALT"/> | R1 | <input type="text" value="ALAT"/> | <input type="text" value="150"/> | <input type="text"/> |
| Sample | <input type="text" value="Serum"/> | R2 | <input checked="" type="checkbox"/> Enable | <input type="text" value="ALAT"/> | <input type="text" value="38"/> |
| Unit | <input type="text" value="U/L"/> | Diluent | <input type="checkbox"/> Enable | <input type="text"/> | <input type="text"/> |
| Assay Type | <input type="text" value="Rate"/> | Measuring points | Start | End | Decimal Points |
| | | 1 | <input type="text" value="44"/> | - <input type="text" value="68"/> | <input type="text" value="0"/> |
| | | <input type="checkbox"/> Enable | 2 | <input type="text"/> | <input type="text"/> |
| Wave Length | Prim. <input type="text" value="340"/> | Sec | <input type="checkbox"/> Disable | <input type="text" value="415"/> | |
| Normal | Sampling | Sample (μL) | Diluent (μL) | Technical Range | |
| <input type="checkbox"/> Dilution | <input type="text" value="11.3"/> | | | (Conc) | <input type="text" value="3"/> - <input type="text" value="600"/> |
| | Rerun (High/Prozone) | | | (mAbs/10) | <input type="text"/> |
| <input type="checkbox"/> Dilution | <input type="text" value="11.3"/> | | | | |
| | Rerun (Low) | | | | |
| <input type="checkbox"/> Dilution | <input type="text" value="11.3"/> | | | | |
| | | | | SPT Wash | <input type="checkbox"/> Enable <input type="text"/> |
| | | | | Reagent Name | <input type="text"/> |
| | | | | Stirring Speed | R1 <input type="text" value="Middle"/> R2 <input type="text" value="High"/> |

*Entered by user

| Chemistry Parameters | | Sysmex BX-4000 Chemistry Analyzer Analytical Parameters | | | |
|---|----------------------------------|--|------------------------------------|---|---|
| Method No. | * <input type="text"/> | Name | <input type="text" value="ALAT"/> | Sample | <input type="text" value="Serum"/> |
| Limit Checks | | | | | |
| <input checked="" type="checkbox"/> Duplicate Limit | <input type="text" value="50"/> | | | | mAbs/10 |
| <input checked="" type="checkbox"/> Sensitivity Limit | <input type="text" value="250"/> | | | | mAbs/10 |
| <input checked="" type="checkbox"/> Linearity Limit | <input type="text" value="10"/> | % | <input type="text" value="220"/> | | (mAbs/10)/min |
| <input type="checkbox"/> Prozone Limit | <input type="text"/> | % | <input type="text" value="Upper"/> | | |
| | SL1-S | <input type="text"/> | - | SL1-F | <input type="text"/> |
| | SL2-S | <input type="text"/> | - | SL2-F | <input type="text"/> |
| | Sensitivity | <input type="text"/> | | | mAbs/10 |
| <input checked="" type="checkbox"/> Absorbance Limit | | | | | |
| | Reaction | <input type="text" value="Decrease"/> | | | |
| | Limit | <input type="text" value="4500"/> | | | mAbs/10 |
| | | | | Blank measurement | |
| | | | | Blank measurement: | <input type="text" value="Disable reagent blank and S1 blank"/> |
| | | | | Measurement of Reagent Blank during Run: | <input type="text" value="None"/> |
| | | | | Reagent blank measurement at calibration: | <input type="text" value="Reagent blank (No sample)"/> |
| | | | | The number of measurement: | <input type="text" value="Duplicate"/> |
| | | | | Reagent blank limit checks: | |
| | | | | <input checked="" type="checkbox"/> Duplicate Limit | <input type="text" value="20"/> mAbs/10 |
| | | | | Instrument Factor | |
| | | | | a | <input type="text" value="1.00"/> |
| | | | | b | <input type="text" value="0.00"/> |

Registration Calibration

**Sysmex BX-4000 Chemistry Analyzer
Analytical Parameters**

Method Name

Sample

Sampling

Check Interval days

Auto

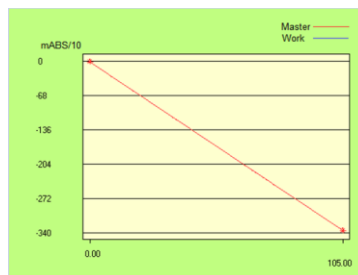
Auto Interval hours

Type Lot

Material Name

R Lot No. R1
R2

Last



The calibration curve is lot dependent

| | Conc. | WORK | MASTER | Lot No. (S) <input type="checkbox"/> All |
|----|-------|-----------------|-----------------|--|
| S1 | 0 | Automatic entry | Automatic entry | |
| S2 | * | Automatic entry | Automatic entry | |
| S3 | * | | | |
| S4 | * | | | |
| S5 | * | | | |
| S6 | * | | | |
| S7 | * | | | |

Reagent blank mAbs/10 Last

Blank mAbs/10 Last

Type Conc.

Absorbance mAbs/10

K S1 Blank Reagent Blank for S1

*Entered by user