INTENDED USE
ELITech Clinical Systems AST/GOT 4+1 L is intended for use in the quantitative in vitro diagnostic determination of aspartate aminotransferase (AST) in human serum and plasma on ELITech Clinical Systems Selectra Pro Series, Analyzers. Aspartate aminotransferase (AST) measurements are used in the diagnosis and treatment of certain types of liver and heart diseases.

It is not intended for use in Point of Care settings.

CLINICAL SIGNIFICANCE
Aspartate aminotransferase (AST), also known as glutamate oxaloacetate transaminase (GOT), is a transaminase. AST catalyses the transfer of the amingroup of L-Aspartate to α-ketoglutarate to give L-glutamate. AST is widely distributed in the body, but the highest levels are found in heart, liver, skeletal muscles and kidneys.

Damage to cells of these tissues induces AST increase in serum. In case of luminum forms of hepaties, especially viral hepatitis the enzyme level is markedly elevated. In case of myocardial infarction, AST activity increases and reaches a peak after 18-24 hours. The activity falls back to normal after 4-5 days, provided no reinfarct has occurred.

The following pathological states are examples of disorders also resulting in an increase of enzyme activity: liver cell necrosis or injury of any cause (for example intake of alcohol, delirium tremens, and administration of drug induce moderate AST elevation), alcoholic hepatitis, muscular dystrophy and gangrene, infectious mononucleosis, acute viral hepatitis the enzyme level is markedly elevated. In case of myocardial infarction, AST activity increases and reaches a peak after 18-24 hours. The activity falls back to normal after 4-5 days, provided no reinfarct has occurred.

Samples are stable 24 hours at room temperature, 7 days at 2-8°C and 3 months at -20°C.

REFERENCE VALUES
- Serum free from hemolysis.

AST serum level can be decreased in case of vitamin B6 deficiency.

METHOD
IFCC method without pyridoxal phosphate (P-5-P).

PRINCIPLE
Kinetic determination of aspartate aminotransferase (AST) activity:

Reagents Composition

Reagent 1: R1
- L-Aspartate: 100 mMol/L
- α-Ketoglutarate: 330 mMol/L
- Lactate dehydrogenase (LDH) (microorganisms): 2000 U/L
- Malate dehydrogenase (MDH) (bacterial): 1000 U/L
- Sodium azide: < 0.1 %

Reagent 2: R2
- α-Ketoglutarate: 78 mMol/L
- NADH: 1.1 mMol/L
- Sodium azide: < 0.1 %

Material Required But Not Provided
- ELITOL A2, calibrator, ref. CALI-0250, 4 x 55 mL
- ELITOL D2, control serum, ref. CONT-0090, 10 x 5 mL
- ELITOL D2, control serum, ref. CONT-0180, 10 x 5 mL
- General Laboratory equipment.

Waste Management
- Disposal of all waste material should be in accordance with local, state and Federal regulatory requirements.

Stability of Reagents
- Store at 2-8 °C and protect from light.
- The reagents are stable until the expiry date stated on the label.
- On board stability. Refer to § PERFORMANCE DATA.

Preparation
- The reagents are ready to use.

Reagent Deterioration
- The reagent solutions should be clear. Cloudiness would indicate deterioration.

Samples
- Specimen
- Serum free from hemolysis.
- Lithium heparinized plasma, free from hemolysis.
- Storage
- Samples are stable 24 hours at room temperature, 7 days at 2-8°C and 3 months at -20°C.

Reference Values
- Serum, plasma (37°C) < 40 μkat/L
- Reference values for infants are higher than for adults.

Note: If the results are higher than the provided reference range, it is recommended that each laboratory establishes and maintains its own reference values. The data given here are only for information.

References
- Conversion factor: U/L x 0.0167 = μkat/L

Procedure
See application included in the barcode indicated at the end of the insert.

Calibration
For calibration, multiparameter calibrator Elisal 2 must be used. Its value is traceable to IFCC reference method 14.

Quality Control
To ensure adequate quality, control sera such as ELITROL I (normal control) and ELITROL II (abnormal control) should be used. These controls should be assayed together with patient samples, at least once a day and after each calibration.

The control should be adapted to Quality Control procedures of each laboratory and the regulatory requirements. Results should be within the defined ranges. If values fall outside of the defined range, each laboratory should take corrective measures. Quality control materials should be used in accordance with local, state, and/or federal guidelines.

Performance Data at 37°C
A) On ELITech Clinical Systems Selectra ProM Analyzers

- Measuring range
- Determined according to CLSI® EP4-A protocol, the measuring range is from 10.0 to 250.0 U/L (0.17 to 4.17 μkat/L).

- Interferences
- Samples exceeding 250.0 U/L should be diluted 1:10 with NaCl 9 g/L solution (normal saline) and re-assayed. Use of this procedure extends the measuring range to 250.0 to 2500.0 U/L (4.17 to 41.67 μkat/L).

- Precision
- Determined according to CLSI® EP7-A2 protocol.

- Correlation
- A comparative study has been performed between an ELITech Clinical Systems Selectra ProM Analyzer and another FDA-Approved system equipment (IFCC method without pyridoxal phosphate) on 100 human serum samples according to CLSI® EP9-A2 protocol.

- Interferences
- Studies have been performed to determine the level of interference from different compounds according to CLSI(71) EPT-A2 protocol and SFBC recommendations(66).

- Storage
- -20 °C.
- 2-8 °C.

- Recalibrate when reagent lots change, when quality control results fall outside the established range, and after a maintenance operation.

B) On ELITech Clinical Systems Selectra ProS Analyzers

- Measuring range
- Determined according to CLSI® EP4-A protocol, the measuring range is from 10.0 to 250.0 U/L (0.17 to 4.17 μkat/L).

- Interferences
- Samples exceeding 250.0 U/L should be diluted 1:10 with NaCl 9 g/L solution (normal saline) and re-assayed. Use of this procedure extends the measuring range to 250.0 to 2500.0 U/L (4.17 to 41.67 μkat/L).

- Precision
- Determined according to CLSI® EP7-A2 protocol.

- Correlation
- A comparative study has been performed between an ELITech Clinical Systems Selectra ProS Analyzer and another FDA-Approved system equipment (IFCC method without pyridoxal phosphate) on 100 human serum samples according to CLSI® EP9-A2 protocol.

- Interferences
- Studies have been performed to determine the level of interference from different compounds according to CLSI(71) EPT-A2 protocol and SFBC recommendations(66).
In vitro diagnostic reagent, for professional use only

- Limit of Detection (LoD) and Limit of quantification (LoQ)
  Determined according to CLSI(15) EP7-A2 protocol.
  LoD = 1.8 U/L (0.03 μkat/L)
  LoQ = 5.0 U/L (0.08 μkat/L)

- Precision
  Determined according to CLSI(15) EP5-A2 protocol.

<table>
<thead>
<tr>
<th>Level</th>
<th>Mean</th>
<th>Within-run CV (%)</th>
<th>Total CV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>18.8</td>
<td>0.31</td>
<td>2.9</td>
</tr>
<tr>
<td>Medium</td>
<td>43.3</td>
<td>0.72</td>
<td>1.4</td>
</tr>
<tr>
<td>High</td>
<td>197.5</td>
<td>3.29</td>
<td>0.7</td>
</tr>
</tbody>
</table>

- Correlation
  A comparative study has been performed between an ELITech Clinical Systems Selectra ProS Analyzer and another FDA-Approved system equipment (IFCC method without pyridoxal phosphate) on 100 human serum samples according to CLSI(26).
  The sample concentrations were between 10.5 and 244.2 U/L (0.18 and 4.08 μkat/L).
  The parameters of the linear regressions are as follows:
  Correlation coefficient: \( r = 0.999 \)
  Linear regression:
  \[ y = 0.999 x + 0.01 \mu \text{kat/L} \]

- Interferences
  Studies have been performed to determine the level of interference from different compounds according to CLSI(27).
  - Ascorbic acid: No significant interference up to 20 mg/dL (1136 μmol/L).
  - Turbidity: No significant interference up to 614 mg/dL (6.94 mmol/L).
  - Conjugated Bilirubin: No significant interference up to 29.5 mg/dL (504 μmol/L).
  - Unconjugated Bilirubin: No significant interference up to 30 mg/dL (513 μmol/L).
  - Protein: No significant interference up to 20 g/dL (1136 μmol/L).
  - Conjugated Protein: No significant interference up to 3 mg/dL (340 μmol/L).
  - Other compounds may interfere.(28,29)

- On board stability/Calibration frequency
  On Board Stability: 28 days
  Recalibration frequency: 28 days
  Recalibrate when reagent lots change, when quality control results fall outside the established range, and after a maintenance operation.

BIBLIOGRAPHY


SYMBOLS

- In vitro diagnostic medical device
- Temperature limitation
- Consult instruction for use
- Batch code
- Manufacturer
- Use by
- Catalogue number
- European Conformity

AST/GOT 4+1 SL

<table>
<thead>
<tr>
<th>Component</th>
<th>Kit composition</th>
<th>LoD</th>
<th>LoQ</th>
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<tbody>
<tr>
<td>R1</td>
<td>8 x 10 mL</td>
<td>0.01 μkat/L</td>
<td>0.08 μkat/L</td>
</tr>
<tr>
<td>R2</td>
<td>8 x 5 mL</td>
<td>0.01 μkat/L</td>
<td>0.08 μkat/L</td>
</tr>
</tbody>
</table>

- LoD = 1.8 U/L (0.03 μkat/L)
- LoQ = 5.0 U/L (0.08 μkat/L)

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