INTENDED USE
This in vitro diagnostic reagent is intended for the quantitative determination of alanine aminotransferase (ALT) in human serum and plasma samples on Selectra Mach Series analyzers.
This in vitro diagnostic reagent is for professional use only.

CLINICAL SIGNIFICANCE
Alanine aminotransferase (ALT) is a transaminase also known as glutamate pyruvate transaminase (GPT). ALT catalyzes the transfer of the amino group of L-alanine to α-ketoglutarate to give L-glutamate. The highest levels are found in the liver and the kidneys.
ALT levels are markedly increased in acute hepatitis (viral or toxic), and to a lesser extent in chronic hepatitis, cirrhosis, icterus, liver carcinoma or following various drugs.
ALT levels can also be increased in heart diseases. ALT is more liver specific than AST (aspartate aminotransferase). Measurement of AST and ALT may assist in differentiating hepatitis from extrahepatic cell damage.
ALT measurement is indicated to screen patients at risk of liver diseases and to help diagnose or monitor liver diseases.

LIMITATION OF USE
The quantitative assay of alanine aminotransferase alone can not be used to diagnose a disease or a specific pathology. The results must be interpreted in conjunction with other diagnostic test results, clinical findings and the patient’s medical history.

METHOD & PRINCIPLE
IFCC method without pyridoxal phosphate (P-5'-P) - Kinetic.
L-Alanine + α-Ketoglutarate  \(\rightarrow\) Pyruvate + L-Glutamate

\[
\text{LDH} = \frac{\text{L-Lactate} + \text{NAD}^+}{\text{NADH} + \text{H}^+}
\]

COMPOSITION
Reagent 1: R1
Tris buffer, pH 7.50 (30°C)
L-Alanine  680 mmol/L
LDH  ≥ 2000 U/L
Sodium azide  < 0.1 % (w/w)
Reagent 2: R2
α-Ketoglutarate  97 mmol/L
NADH  1.1 mmol/L
Sodium azide  < 0.1 % (w/w)

MATERIALS REQUIRED BUT NOT PROVIDED
- CALI-0650  ELICAL 2
- CONT-0060  ELITROL I
- CONT-0160  ELITROL II
- Normal saline solution (NaCl 9 g/L)
- General Laboratory equipment (e.g. pipette).
- Selectra Mach analyzer and accessories.
- Do not use materials that are not required as indicated above.

PRECAUTIONS OF USE AND WARNINGS
- Take normal precautions and adhere to good laboratory practice.
- Use clean or single use laboratory equipment only to avoid contamination.
- The reagents contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of these reagents always flush with copious amounts of water to prevent azide buildup.
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- Consult Safety Data Sheet (SDS) for a proper handling.
- Do not interchange reagent vials from different kits.

STABILITY
Store at 2-8 °C and protect from light. Do not freeze.
Do not use after expiration date indicated on the vial labels.
On board stability : 8 weeks.

PREPARATION
The device is ready to use.

PRODUCT DETERIORATION
- The product should be clear. Cloudiness would indicate product deterioration.
- Do not use the product if there is visible evidence of contamination or damage (e.g. particle matter).
- Damage to the reagent container may impact on product performance. Do not use the reagent if there is physical evidence of deterioration (e.g. leakages or punctured container).

SAMPLES
Specimens required
- Serum.
- Plasma (lithium heparin).
- Using any other specimen type should be validated by the laboratory.

WARNINGS AND PRECAUTIONS
- Samples must be free from hemolysis.
- Samples should be collected in accordance with Good Laboratory Practice and appropriate guidelines that may be in place.

Storage and stability
- 3 days at room temperature.
- 7 days at 2-8°C.
- For a longer stability, store at -70°C.

REFERENCE VALUES
Serum/plasma  U/L  μkat/L
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Men ≤ 45 ≤ 0.74
Women ≤ 34 ≤ 0.56

Note: The quoted range should serve as a guide only. It is recommended that each laboratory verifies this range or establishes a reference interval for the intended population.

INSTALLATION AND USE
Consult Selectra Mach operator manual.

Programming of special washes: Use of special wash steps is mandatory when some combinations of tests are performed together on the analyzer. For more information on required special wash steps, please refer to instructions for use PIMAC-WASH.

PROCEDURE
The application is included in the 2D barcode on this insert.

CALCULATION
Calculations and/or unit conversions are performed by the analyzer.

CALIBRATION
ELICAL 2 is traceable to IFCC reference method.
Calibration frequency: 4 weeks.
Recalibrate when reagent lots change, when quality control results fall outside the established range and after a maintenance operation.

QUALITY CONTROL
It is recommended that quality control sera such as ELITROL I and ELITROL II be used to monitor the performance of the assay.
Controls have to be performed:
- prior to assaying patient samples,
- at least once per day,
- after every calibration,
- and/or in accordance with laboratory and regulatory requirements.
Results should be within the defined ranges. If values fall outside of the defined ranges, each laboratory should take necessary corrective measures.

WASTE MANAGEMENT
Disposal of all waste material should be in accordance with local, state and federal regulatory requirements (please refer to the Safety Data Sheet (SDS)).
- Measuring range
10.0–450.0 U/L (0.17–7.50 μkat/L)
Samples having greater concentrations will automatically be diluted 1:10 with NaCl 9 g/L solution and re-assayed. Results take the dilution into account. This procedure extends the measuring range up to 4 500.0 U/L (75.00 μkat/L). Do not report results outside this extended range.

- Limit of Detection (LoD) and Limit of Quantification (LoQ)
LoD : 2.6 U/L (0.04 μkat/L)
LoQ : 5.0 U/L (0.08 μkat/L)

- Precision
Imprecision data has been obtained on 2 Selectra Mach5 analyzers over 20 days (2 runs per day, tests performed in duplicate). Representative results are presented in the following table.

<table>
<thead>
<tr>
<th>Level</th>
<th>n</th>
<th>U/L</th>
<th>μkat/L</th>
<th>CV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td>80</td>
<td>38.7</td>
<td>0.65</td>
<td>1.0</td>
</tr>
<tr>
<td>Level 2</td>
<td>80</td>
<td>76.2</td>
<td>1.27</td>
<td>2.0</td>
</tr>
<tr>
<td>Level 3</td>
<td>80</td>
<td>374.1</td>
<td>6.24</td>
<td>0.4</td>
</tr>
</tbody>
</table>

- Correlation
A comparative study has been performed between ALT/GPT reagent on a Selectra Mach5 analyzer and a similar commercially available system on 100 human serum samples. The sample concentrations ranged from 9.1 to 459.0 U/L (0.15 - 7.65 μkat/L). The results are as follows:
Correlation coefficient : (r) = 0.999
Linear regression: y = 0.990x - 0.2 U/L (0.00 μkat/L).

- Limitations/Analytical interferences
- ALT can be underestimated in case of severe vitamin B6 deficiency. [3]
- Hemolyzed samples should not be used since significant hemolysis may increase ALT concentration because of high levels of ALT in erythrocytes. [3]
- Studies have been performed to determine the level of interference from different compounds. The following alanine aminotransferase levels were tested: 35.0 U/L and 350 U/L. No significant interference is defined by a recovery ± 10% of the initial value.

- Triglycerides: No significant interference up to 2 000 mg/dL (22.6 mmol/L).
- Unconjugated bilirubin: No significant interference up to 30.0 mg/dL (513 μmol/L).
- Conjugated bilirubin: No significant interference up to 29.5 mg/dL (505 μmol/L).
- Pyruvate: No significant interference up to 2.0 mg/dL (227 μmol/L).
- Ascorbic acid: No significant interference up to 20.0 mg/dL.
- Acetaminophen: No significant interference up to 30 mg/dL.
- Acetylsalicylic acid: No significant interference up to 200 mg/dL.

- In very rare cases, monoclonal gammopathies (multiple myeloma), in particular IgM type (Waldenstrom's macroglobulinemia) can cause unreliable results. [4]
- Many other substances and drugs may interfere. Some of them are listed in reviews published by Young. [3, 4]

DECLARATION OF SERIOUS INCIDENT
Please notify the manufacturer (through your distributor) and competent authority of the Member State of the European union in which the user and/or the patient is established, of any serious incident that has occurred in relation to the device. For other jurisdictions, the declaration of serious incident should be in accordance with local, state and federal regulatory requirements. By reporting a serious incident, you provide information that can contribute to the safety of in vitro medical devices.

SYMBOLS
Symbols used are defined in ISO 15223-1 standard, except those presented below:

- MODIFICATION FROM PREVIOUS VERSION
- EUROPEAN CONFORMITY

TECHNICAL ASSISTANCE:
Contact your local distributor or ELITech Clinical Systems SAS (CCsupport@elitechgroup.com).

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