**CAUTION:** Federal Law restricts this device to sale by or on the order of a licensed healthcare practitioner (Rx Only)

**INTENDED USE**
ELITech Clinical Systems LIPASE SL is intended for the quantitative in vitro diagnostic determination of lipase in human serum and plasma on ELITech Clinical Systems Selectra Pro Series Analyzers. Lipase measurements are used in the diagnosis and treatment of diseases of the pancreas such as acute pancreatitis and obstruction of the pancreatic duct. It is not intended for use in Point of Care settings.

**CLINICAL SIGNIFICANCE**
Lipase is a digestive enzyme of 48 kDa released by the pancreas which catalyzes the hydrolysis of glycerol esters from triglycerides to form a monoglyceride and free fatty acids chains. Analysis of the lipase is mainly used in the diagnosis of the pancreatic disease (acute or chronic pancreatitis and their complication, carcinoma). During acute pancreatitis, a transitory increase of the activity of lipase is observed after 4 to 8h, reaches a peak after 24h, the activity returning normal after 6 to 14 days. However, an increase of the activity of lipase is also observed in other intra-abdominal pathologies: acute cholecystitis, pancreatic duct obstruction. Patients with a reduced glomerular filtration rate have also a increased lipase activity.

**METHOD**
- **Substrate: 1,2-Diaryl-rac-glycero-3-Glutaric acid (6'-methylresorufin) ester (DGGM).**
- **Colorimetric: Kinetic.**

**PRINCIPLE**
The method for the determination of lipase is based on the cleavage of specific chromogenic lipase substrate 1,2-Diaryl-rac-glycero-3-glutaric acid (6'-methylresorufin) ester emulsified in stabilized micro-particles. In the presence of specific activators of pancreatic lipase as colipase, calcium ions and bile acids, the substrate is converted to 1,2-Diaryl-rac-glycero-3-glutaric acid (6'-methylresorufin)ester which decomposes spontaneously to glutaric acid and methylresorufin.

The increase of absorbance at 578 nm, due to methylresorufin formation, is proportional to the activity of lipase in the sample.

![Reagents Composition](image)

**MATERIAL REQUIRED BUT NOT PROVIDED**
- EL TRO 1 calibrator, ref.CAL-0190, 1 x 3 mL.
- ELITROL I, control serum, ref.CONT-0990, 10 x 5 mL.
- ELITROL II, control serum, ref.CONT-0190, 10 x 5 mL.
- General Laboratory equipment.

**PRECAUTIONS AND WARNING**
- This test is for professional in vitro diagnostic use only.
- Take normal precautions according to good laboratory practice.
- Use clean or single use laboratory equipment only to avoid contamination.
- The reagent R1 contains 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.
- For more information, refer to the Safety Data Sheet (SDS).

**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. Do not freeze.

**PREPARATION**
The reagents are ready to use.

**REAGENT DETERIORATION**
The reagent solutions should be clear. Cloudiness would indicate deterioration. Any reagent showing evidence of contamination should be discarded.

**SAMPLES**
- **Specimen:** Serum or lithium heparinized plasma free from hemolysis.
- **Unconjugated Bilirubin:** No significant interference up to 30.0 mg/dL (513.1 μmol/L).
- **Conjugated Bilirubin:** No significant interference up to 29.5 mg/dL (504.6 μmol/L).
- **Hemoglobin:** No significant interference up to 50 mg/dL.
- **Triglycerides:** No significant interference up to 3000 mg/dL (33.90 mmol/L).
- **Ascorbic acid:** No significant interference up to 20 mg/dL (1136 μmol/L).
- **Alanine transaminase:** No significant interference up to 200 mg/dL.

**REFERENCES**
- Guidelines for diagnostic use of enzymes.
- **Quality control materials: normal control and abnormal control**
- **Performance Data at 37 °C**
- **Precision**
- **Correlation**
- **Limit of Detection (LoD) and Limit of Quantification (LoQ)**
- **Warrantings and Precautions**
- According to Good Laboratory Practice, venipuncture should be performed prior to the administration of drugs.
- **Storage**
The samples are stable 7 days at room temperature, 3 weeks at 2-8 °C and 1 year at ~ 20 °C.

**REFERENCES**
- Serum, plasma (37 °C): 13-60 U/L

**Notes**
- It is recommended for each laboratory to establish and maintain its own reference values. The data given here are only for information.
- Conversion factor: U/L x 0.0167 = μkat/L

**PROCEDURE**
- See application included in the barcode indicated at the end of the insert.

In the application, the offset must be set to: - 2 U/L (-0.03 μkat/L).

**Lipase SL reagent is strongly contaminated by Triglycerides SL reagent.**
In order to avoid cuvette contamination on Selectra instruments, program the following incompatibilities:
- **Software**
  - TouchPro
  - Other
  - Parameter
  - Test incompatibilities
  - Link / Triglycerides SL – Acid Solution
- For Selectra TouchPro users, the venus dilution function performs the sample dilution automatically. Results take the dilution into account.
- **Limit of Detection (LoD) and Limit of Quantification (LoQ)**
  - Determined according to CLSI EP7-A protocol, LoD 1 U/L (0.02 μkat/L).
  - LoQ 9 U/L (0.08 μkat/L).
- **Precision**
  - Determined according to CLSI EP5-A2 protocol

<table>
<thead>
<tr>
<th>Mean</th>
<th>Within-run</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>n U/L</td>
<td>μkat/L</td>
<td>CV (%)</td>
</tr>
<tr>
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<tr>
<td>Level 2</td>
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<tr>
<td>Level 3</td>
<td>80</td>
<td>229</td>
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</table>

**Correlation**
A comparative study has been performed between an ELITech Clinical Systems Selectra ProF Analyzer and another FDA-Approved system equipment (Colorimetric method) on 100 human serum samples according to CLSI EP/A2 protocol.

The sample activities were between 6 and 284 U/L (0.10 and 4.73 μkat/L).

The parameters of the linear regression are as follows:
- Correlation coefficient: (r) = 0.999
- Linear regression: y = 0.003 x + 1 U/L (0.02 μkat/L)
- Limitations/Interferences:
  - Do not report results outside of the usable range.
  - Studies have been performed to determine the level of interference from different compounds according to EP7-A2 1/2 protocol of CLSI. Recovery within a % of initial value of lipase of 30, 80 and 240 U/L.

**For Technical questions, Please call or contact**
(855) 354-8324 - www.elitechgroup.com
27 Wellington Road, Lincoln, Rhode Island 02865 - U.S.A.

(04/2016)
FTNA-LPSL-v3
- In very rare cases, monoclonal gammopathies (multiple myeloma), in particular IgM type (Waldenstrom’s macroglobulinemia) can cause unreliable results.\(^{(13)}\)
- Many other substances and drugs may interfere. Some of them are listed in Young and in Glick.\(^{(14-16)}\)
- The results of this assay should be interpreted in conjunction with other diagnostic test results, clinical findings and the patient’s medical history.
- On board stability/Calibration frequency
  On Board Stability: 14 days
  Calibration frequency: 7 days

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

**PERFORMANCE DATA at 37 °C on ELITech Clinical Systems Selectra ProS Analyzers**

- Measuring range

  Determined according to CLSI EP6-A\(^{8}\) protocol, the measuring range is from 5 to 300 U/L (0.08 to 5.00 \(\mu\)kat/L).

  Samples exceeding 300 U/L (5.00 \(\mu\)kat/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 from 300 to 3000 U/L (5.00 to 50.00 \(\mu\)kat/L).

  This extended measuring range was confirmed in a study where a high activity of lipase was spiked into native serum samples. The recovery observed did not exceed the expected recovery by  \( \pm 10\% \).

  For Selectra TouchPro users, the «rerun dilution» function performs the sample dilution automatically. Results take the dilution into account.

- Limit of Detection (LoD) and Limit of Quantification (LoQ)

  Determined according to CLSI EP7-A\(^{2}\) protocol,
  - LoD = 1 U/L (0.02 \(\mu\)kat/L)
  - LoQ = 5 U/L (0.08 \(\mu\)kat/L)

- Precision

  Determined according to CLSI EP2-A2 protocol\(^{(11)}\)

<table>
<thead>
<tr>
<th>Level</th>
<th>n</th>
<th>Mean(\mu)kat/L</th>
<th>Within-run CV (%)</th>
<th>Total CV (%)</th>
</tr>
</thead>
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<td>1.5</td>
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<td>3</td>
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</table>

- Correlation

  A comparative study has been performed between an ELITech Clinical Systems Selectra ProS Analyzer and another FDA-Approved system equipment (Colorimetric method) on 100 human serum samples according to CLSI EP7-A2 protocol\(^{(11)}\).

  The sample activities were between 7 and 294 U/L (0.12 and 4.90 \(\mu\)kat/L).

  The parameters of the linear regressions are as follows:
  - Correlation coefficient: \( r = 1.000 \)
  - Linear regression: \( y = 1.036 x \)

  - Limitations/ Interferences

  - Do not report results outside of the usable range.
  - Studies have been performed to determine the level of interference from different compounds according to EP7-A2\(^{(11)}\) protocol of CLSI. Recovery within a 10 % of initial value of lipase of 30, 60 and 240 U/L.

  - Unconjugated Bilirubin: No significant interference up to 30.0 mg/dL (513.1 \(\mu\)mol/L).
  - Conjugated Bilirubin: No significant interference up to 29.5 mg/dL (0.044 \(\mu\)mol/L).
  - Hemoglobin: No significant interference up to 50 mg/dL.
  - Aspartate aminotransferase: No significant interference up to 3000 mg/dL (33.90 mmol/L).
  - Alkaline phosphatase: No significant interference up to 20 mg/dL (1136 \(\mu\)kat/L).
  - Amylase: No significant interference up to 200 \(\mu\)kat/L.
  - Acanthomypi: No significant interference up to 30 mg/dL.

  - In very rare cases, monoclonal gammopathies (multiple myeloma), in particular IgM type (Waldenstrom’s macroglobulinemia) can cause unreliable results.\(^{(13)}\)

  - Many other substances and drugs may interfere. Some of them are listed in Young and in Glick.\(^{(14-16)}\)

  - The results of this assay should be interpreted in conjunction with other diagnostic test results, clinical findings and the patient’s medical history.

  - On board stability/Calibration frequency

    On Board Stability: 14 days
    Calibration frequency: 7 days

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

**BIBLIOGRAPHY**


**SYMBOLS**

- \( \mu \)kat/L

**IMPORTANT NOTE/ see § PROCEDURE:**

- Manual entry required
- Contamination risk

**REFERENCES:**

- Kit composition:
  - R1 4 x 5.6 mL  
  - R2 4 x 3.6 mL

- Manufacturer
  - ELITech Clinical Systems SAS
  - Zone Industrielle 61500 SEES
  - France
  - For Technical questions, Please call or contact (855) 354-8324 - www.elitechgroup.com
  - 27 Wellington Road
  - Lincoln, Rhode Island 02865 - U.S.A.
  - Temperature limitation
  - Batch code
  - Use by
  - Catalogue number
  - Reagent 1
  - Reagent 2
  - Keep away from sunlight

- Content

- LPSL-0230 4 x 9.2 mL
  - LPSL-0230
  - FTNA-LPSL

- Manufacturer
  - ELITech Clinical Systems
  - Selectra Pro Series Analyzer
  - LIPASE SL

- Use by

- Temperature limitation