ELITechGroup
CLINICAL SYSTEMS

In vitro diagnostic reagent, for professional use only

ELITech Clinical Systems
Selectra Pro Series Analyzers
LIPASE SL

References :
LPSL-0230 4 x 9.2 mL

Kit composition :
R1 4 x 5.6 mL + **R2** 4 x 3.6 mL

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 [1-3]
Lipase is a digestive enzyme of 48 kDa released by the pancreas which catalyses the hydrolysis of glycerol esters from triglycerides to form a monoglyceride and free fatty acids chains. Analysis of the activity 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 8 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 [4]
Substrate: 1,2-O-Dilauryl-rac-Glycero-3-Glutaric acid-(6-methylresorufin) ester (DGGM).
Colorimetric- Kinetic.

PRINCIPLE [4,5]
The method for the determination of lipase is based on the cleavage of specific chromogenic lipase substrate 1,2-O-dilaurylrac-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-O-dilauryl-rac-glycerol and 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

1,2-O-dilauryl-rac-glycero-3-glutaric acid - (6'-methylresorufin)-ester —*Pancreatic Lipase*→ 1,2-O-dilauryl-rac-glycerol + glutaric acid-(6'-methylresorufin)-ester

glutaric acid-(6'-methylresorufin)-ester —*Spontaneous reaction*→ glutaric acid + methylresorufin

REAGENTS COMPOSITION
Reagent : R1

BICIN*buffer, pH 8.0		50	mmol/L
Colipase (Porcine Pancreas)	≥	0.9	mg/L
Sodium deoxycholate		1.6	mmol/L
Calcium chloride		10	mmol/L
Sodium azide	<	0.1	%
Detergent			

Reagent : R2

Tartrate buffer, pH 4.16 (± 0.15)		10	mmol/L
1,2-O-dilauryl-rac-glycero-3-glutaric acid (6'-méthylrésorufin)-ester		0.27	mmol/L
Taurodeoxycholate		8.8	mmol/L
Detergent			
Preservative			

*BICIN= N,N-bis(2-hydroxyethyl)glycine

MATERIAL REQUIRED BUT NOT PROVIDED
- ELICAL 2, calibrator, ref.CALI-0580, 4 x 3 mL.
- ELITROL I, control serum, ref.CONT-0080, 10 x 5 mL.
- ELITROL II, control serum, ref.CONT-0180, 10 x 5 mL.
- General Laboratory equipment.

PRECAUTIONS AND WARNING
- This reagent is for professional *in vitro* diagnostic use only.
- Take normal precautions and adhere 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.
The reagent is 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. Any reagent showing evidence of contaminaion should be discarded.

SAMPLES [6]
- Specimen
Serum or lithium heparinized plasma free from hemolysis.

- Warnings 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.

REFERENCE VALUES [7]
Serum, plasma (37 °C): 13-60 U/L

Note : *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	Menu	Parameter
TouchPro	Test incompatibilities	Link / Triglycerides SL – Acid Solution
Other	Cuvette incompatibility	Triglycerides SL <<HCl

In order to avoid needle contamination on Selectra instruments, do not program Lipase SL and Triglycerides SL in the same run. Ensure the instrument goes back to "stand-by" status before launching a run containing Lipase SL.

CALIBRATION
For calibration, multiparametric calibrator Elical 2 must be used. Its value is traceable to the manual measurement.
Calibration frequency: refer to § PERFORMANCE DATA.

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 frequency 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 ranges, 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 on ELITech Clinical Systems Selectra ProM 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 µkat/L). Samples exceeding 300 U/L (5.00 µkat/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 µkat/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 > ± 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 EP17-A [9] protocol,
LoD = 1 U/L (0.02 µkat/L).
LoQ = 5 U/L (0.08 µkat/L).

- Precision
Determined according to CLSI EP5-A2 protocol[10].

		Mean		Within-run	Total
	n	U/L	µkat/L	CV (%)	
Level 1	80	28	0.47	0.8	3.9
Level 2	80	55	0.92	0.7	4.0
Level 3	80	229	3.82	0.4	4.4

- Correlation
A comparative study has been performed between an ELITech Clinical Systems Selectra ProM Analyzer and another FDA-Approved system equipment (Colorimetric method) on 100 human serum samples according to CLSI EP9-A2 protocol[11].
The sample activities were between 6 and 284 U/L (0.10 and 4.73 µkat/L).

The parameters of the linear regressions are as follows:
Correlation coefficient : (r) = 0.999
Linear regression : y = 1.063 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[12] protocol of CLSI. Recovery within ± 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 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).
Acetylsalicylic acid:No significant interference up to 200 mg/dL.
Acetaminophen: No significant interference up to 30 mg/dL.

*:US FDA only
☛: Modification from previous version

(04/2016)
FTNA-LPSL-v3

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.

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References :
LPSL-0230 4 x 9.2 mL

Kit composition :
R1 4 x 5.6 mL + **R2** 4 x 3.6 mL

- 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 µkat/L). Samples exceeding 300 U/L (5.00 µkat/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 µkat/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 > ± 10%

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

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LoD = 1 U/L (0.02 µkat/L).
LoQ = 5 U/L (0.08 µkat/L).

- Precision
Determined according to CLSI EP5-A2 protocol[10].

		Mean		Within-run	Total
	n	U/L	µkat/L	CV (%)	
Level 1	80	31	0.52	1.5	4.4
Level 2	80	55	0.92	0.9	3.0
Level 3	80	246	4.10	1.2	4.2

- 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 EP9-A2 protocol[11].
The sample activities were between 7 and 294 U/L (0.12 and 4.90 µkat/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[12] protocol of CLSI. Recovery within ± 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 µmol/L).
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Ascorbic acid: No significant interference up to 20 mg/dL (1136 µmol/L).
Acetylsalicylic acid:No significant interference up to 200 mg/dL.
Acetaminophen: No significant interference up to 30 mg/dL.

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- Many other substances and drugs may interfere. Some of them are listed in Young and in Glick. [14-16]

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Calibration frequency: 7 days

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BIBLIOGRAPHY

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☞**SYMBOLS**

IVD In vitro diagnostic medical device	Temperature limitation
Consult instruction for use	LOT Batch code
Manufacturer	Use by
REF Catalogue number	R1 Reagent 1
Keep away from sunlight	R2 Reagent 2
CONT Content	

☞ **IMPORTANT NOTE/ see § PROCEDURE:**
- Manual entry required
- Contamination risk

LIPASE 0
820 FTNA-LPSL

☞: Modification from previous version

(04/2016)
FTNA-LPSL-v3

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.