APPLICATION PARAMETERS

PRIMARY PARAMETERS

Code	LIP
Bar-Code	Active
Code for Bar-Code	345
Test Methodology	Enzyme
Method	Kinetic
Kind of Process	Linear
1st Filter	578
2nd Filter	700
Reaction direction	Increasing

REAGENTS

Number of reagents	2
Reagent 1 Volume µL	200
Concentrated	Inactive
Reagent 2 Volume µL	120
Concentrated	Inactive

SAMPLE	Serum	Urine
Name	Lipase	N/A
Sample µL	4	N/A
Pre-Dilution 1:	1	N/A
Post-Dilution 1:	10	N/A

TIMES

Sample Starter	Inactive
Delay Time	0
Reading Time	180
Reagent 1 Incubation Time	240
Reagent 2 Incubation Time	60

CHECK PARAMETERS

Reagent Limit (mABS)	280
Curve Acceptance (%)	100

RE-RUN SERUM

Test Limit (Conc)	300	
Low Test Limit (Conc)	0.8	
Initial ABS (mABS)	280	
Final ABS (mABS)	1000	
Max ABS Delta (mABS)	300	
Prozone Check	Inactive	
Normal Range	Min	Max
Man	[User defined]	
Woman	[User defined]	
Child	[User defined]	
Re-run hyperactive	Active	
Re-run pathological	Inactive	

RE-RUN URINE

Test Limit (Conc)	N/A	
Low Test Limit (Conc)	N/A	
Initial ABS (mABS)	N/A	
Final ABS (mABS)	N/A	
Max ABS Delta (mABS)	N/A	
Prozone Check	Inactive	
Normal Range	Min	Max
Man	N/A	
Woman	N/A	
Child	N/A	
Re-run hyperactive	Inactive	
Re-run pathological	Inactive	

SECONDARY PARAMETERS

1st Unit Serum	U/L
2nd Unit Serum	Inactive
1st Unit Urine	N/A
2nd Unit Urine	Inactive
Dynamic Blank	Active
Needle washes	[From Settings Table]
Cuvette washes	[From Settings Table]
Special Wash	[From Settings Table]
Instrumental Factor	1.000
Shift	0.000
Reagent Blank	Every Day
Decimals	0

STANDARD PARAMETERS

Factor	[Determined by Calibration]
Minimum	1500
Maximum	2500
Number of Samples	1
Max Var. (%)	10
Timed Re-run	Each / 28 days
N. replicates	3
Reagent ABS	[Determined by Envoy]
Pos.	[From settings table]
Conc.	[From calibrator labeling]
ABS	[Determined by Envoy]
% last calibration	100

PROGRAMMING INSTRUCTIONS

Detailed instructions for programming reagent parameters are provided in the Envoy 500 Operator Manual and Envoy500 Settings Table.

If the Envoy 500 Chemistry System is not pre-programmed, a LIP code must first be added before the parameters can be entered. On the menu bar, select «Test → Test Directory.» A new window will open up listing all the codes for the tests that are installed on the instrument. Click on the «New Code» button, type «LIP» into the Code field and select «Save.»

To program the application parameters, check the box next to the code for the Lipase test, and select the «Parameters» button located at the bottom of the window. To program standard information, click the «Standards» button located at the bottom of the window.

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LIPASE ENVOY

Product no. LPSL-0850

For *in vitro* diagnostic use

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

INTENDED USE

LIPASE ENVOY is for the quantitative *in vitro* diagnostic determination of Lipase in human serum and plasma on Envoy 500 Series Analyzers. 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.

METHODOLOGY [4,5]

Colorimetric- Kinetic.

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 (DGGM) 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.

Pancreatic Lipase
1,2-O-dilauryl-rac-glycero-3-glutaric acid - (6'-methylresorufin)-ester ⟶
1,2-O-dilauryl-rac-glycerol + glutaric acid-(6'-methylresorufin)-ester
Spontaneous reaction
glutaric acid-(6'-methylresorufin)-ester ⟶ glutaric acid + methylresorufin

REAGENTS

COMPOSITION

LIPASE Reagent R1 contains : 50 mmol/L BICIN*buffer, pH 8.0; ≥ 0.9 mg/L Colipase (Porcine Pancreas); 1.6 mmol/L Sodium deoxycholate ; 10 mmol/L Calcium chloride ; < 0.1% Sodium azide; Detergent.

LIPASE Reagent R2 contains : 10 mmol/L Tartrate buffer, pH 4.16 (± 0.15); 0.27 mmol/L 1,2-O-dilauryl-rac-glycero-3-glutaric acid (6'-méthylrésorufin)-ester; 8.8 mmol/L Taurodeoxycholate; Detergent; Preservative.

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

WARNINGS AND PRECAUTIONS

- 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 contaminations.
- The reagent R1 contains sodium azide, which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of these reagent always flush with copious amounts of water to prevent azide buildup.
- Dispose of contents in accordance with all local, state and federal regulations.
- For more information, Safety Data Sheet (SDS) is available on request for professional user.

PREPARATION

LIPASE Reagent is ready for use on the Envoy 500 Analyzer as packaged.

STORAGE AND STABILITY

Store this reagent at 2 to 8 °C and protected from light. Do not freeze. Unopened reagents are stable to the expiration dates on the bottle labels. The reagent is stable for 28 days onboard the Envoy 500 Analyzer.

SPECIMENS [6]

COLLECTION AND STORAGE

Fresh unhemolyzed serum or lithium heparinized plasma are preferred specimens. Do not analyze whole blood.

According to Good Laboratory Practice venipuncture should be performed prior to the administration of drugs.

For best results, use only fresh specimens. Lipase in samples are stable 7 days at room temperature, 3 weeks at 2-8 °C and 1 year at – 20 °C.

PROCEDURE

MATERIALS PROVIDED

The LIPASE ENVOY Reagent Kit includes the following components:

2 x 19.2 mL boats of Envoy 500 LIPASE Reagent 1
2 x 11.8 mL bottles of Envoy 500 LIPASE Reagent 2

MATERIALS REQUIRED BUT NOT PROVIDED

- ELICAL 2, calibrator (product no. CALI-0580).
- ELITROL I, control serum (product no. CONT-0080).
- ELITROL II, control serum (product no. CONT-0180).
- Envoy 500 Wash Solution Kit (product no. 55152).
- Normal saline.
- Analyzer specific consumables
- General Laboratory Equipment.

REAGENT INSTALLATION AND USE

Program the instrument using the application parameters and programming instructions provided at the end of this Instructions For Use.

Refer to the Operator Manual for additional information on installing reagents and programming the analyzer, and running samples, and controls.

The LIPASE ENVOY is pre-assembled and ready to use as packaged.

Envoy 500 Wash Solution Kit (product no. 55152) must be installed in the Basic wash position and Special Wash must be programmed as indicated in the Envoy 500 Settings Table.

Small bottles may become separated from large boats during shipping. If this occurs snap the small bottle back onto the large reagent boat before continuing.

Do not remove the caps from the bottles until you are ready to install the reagent on the analyzer. Before installing, mix the reagents by gently inverting the reagent boats several times. Record the installation date on the label and insert the unit into the designated position on the reagent tray. Let the reagent equilibrate on the instrument for at least 30 minutes before use.

CALIBRATION

Calibrate the instrument after loading new reagent lot, after maintenance and whenever quality control results fall outside established limits. Under typical use conditions, calibration factors for this test are valid for 28 days. Refer to the Operator Manual for calibration procedures.

.../...

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QUALITY CONTROL

Quality control requirements should be established in accordance with local, state and/or federal regulations or accreditation requirements.

Assay at least two levels of serum control daily. Serum Controls for Envoy 500 level 1 and level 2 may be used. Controls should also be assayed after maintaining the instrument and after loading a new reagent unit.

Controls may be assayed more frequently based on laboratory work-flow and the discretion of the user.

CALCULATIONS

All calculations are performed by the instrument.

To calculate the result in SI units (µkat/L), multiply the result in conventional units (U/L) by 0.0167.

PERFORMANCE CHARACTERISTICS

MEASURING RANGE

Determined according to CLSI[8] EP6-A protocol, the measuring range is listed below. Samples that exceed the upper limit should be diluted 1:10 with NaCl 9 g/L solution (normal saline) and re-assayed. 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%.

The «Re-run hyperactive» function performs the dilution automatically. Results take the dilution into account.

Range	Conventional Units	SI Units
Default	5.0 to 300.0 U/L	0.08 to 5.00 µkat/L
Hyperactive	300.0 to 3000.0 U/L	5.00 to 50.00 µkat/L

LIMIT OF DETECTION (LOD) AND LIMIT OF QUANTIFICATION (LOQ)

Determined according to CLSI[9] EP17-A protocol, the LoD is 0.8 U/L (0.01 µkat/L) and LoQ is 5.0 U/L (0.08 µkat/L).

EXPECTED VALUES [7]

Published Lipase reference ranges are listed below. Use these ranges only as guides. Each laboratory should establish its own reference ranges.

Reference Range	Conventional Units	SI Units
Serum/plasma (37°C)	13 - 60 U/L	0.22 - 1.00 µkat/L

PRECISION

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

Sample		Mean		Within-run	Total
	n	U/L	µkat/L	CV (%)	
Level 1	80	31	0.52	1.9	5.5
Level 2	80	58	0.97	1.9	4.6
Level 3	80	232	3.87	1.5	5.3

METHOD COMPARISON

A comparative study has been performed between an Envoy500 Analyzer and an FDA-approved system equipment (IFCC method) on 101 human serum samples according to CLSI[11] EP9-A2 protocol.
The sample activity was between 5.0 and 298.0 U/L (0.08 and 4.97 µkat/L).

The parameters of the linear regressions are as follows :
Correlation coefficient: (r) = 0.999
Linear regression: y = 1.027x + 1 U/L (0.02 µkat/L)

LIMITATIONS / INTERFERING SUBSTANCES

- Do not report results outside of the usable range.

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

- Studies have been performed to determine the level of interference from different compounds according to CLSI[12] EP7-A2 protocol. Recovery is within ± 10% of initial value of Lipase activity of 30.0, 40.0 and 240.0 U/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 (504 µmol/L).
Triglycerides:	No significant interference up to 2082 mg/dL (23.53 mmol/L).
Hemoglobin:	No significant interference up to 50.0 mg/dL.
Ascorbic acid:	No significant interference up to 20.0 mg/dL (1136 µmol/L).
Acetylsalicylic acid:	No significant interference up to 200 mg/dL.
Acetaminophen:	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 compounds may interfere.[14-16]

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GLOSSARY OF SYMBOLS

CONT	Contents		Manufacturer	REF	Catalog No.
LOT	Batch Code		See instruction for use		Use by
OPENED	Date opened /Installation date	IVD	*In vitro* diagnostic device		Temperature Limitation
STAB DAYS	Number of days onboard stability	R1	Reagent 1	R2	Reagent 2
	Keep away from sunlight				

☛ : Modification from previous version

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