Lipase. Ref.: LIP-500A
Quantitative determination of Lipase
Only for in vitro use in clinical laboratory
Store at 2-8ºC R1: 1x24mL + R2: 1x6mL
CAL: 2 x 4 mL

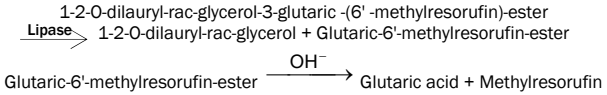
LIPASE

PRINCIPLE OF THE METHOD
Lipase is applied for the determination of Lipase concentration in human serum and plasma.

CLINICAL SIGNIFICANCE
Lipase measurements are used in the diagnosis and treatment of pancreatic diseases such as acute pancreatitis and obstruction of the pancreatic tract.

After acute pancreatitis, lipase activity rises within 4 to 8 hours, peaks after 24 hours, and decreases after 8 to 14 days. However, there is no correlation between the lipase activity determined in serum and the degree of damage to the pancreas.

The colorimetric substrate 1,2-O-Dilauryl-rac-glycero-3- glutaric acid-(6'methyl-resorufin)-ester is cleaved by pancreatic lipase and the carboxylic acid ester hydrolyses in the alkaline test medium to yield the chromophore methyl resorufin product. The kinetic of colour formation at 580 nm is monitored and it is proportional to lipase activity in sample.



REAGENTS

R1	Tris buffer pH 8.30	40 mmol/L
	Colipase	≥ 1mg/L
	Deoxycholate	≥ 1.8 mmol/L
	Taurodeoxycholate	≥ 7.0 mmol/L
R2	Tartrate buffer pH4.00	15 mmol/L
	Lipase substrate	≥ 0.7 mmol/L
	Calcium ions	≥ 1 mmol/L

PRECAUTIONS
Do not use expired reagents.
Reagents with two different lot numbers should not be interchanged.
For professional use.
Follow Good Laboratory Practice (GLP) guidelines.
CAUTION: Human source samples are processed with this product. All human source samples must be treated as potentially infectious materials and must be handled in accordance with OSHA standards.

PREPARATION
The reagent is ready to use.

STORAGE AND STABILITY
Reagents are stable at +2/+8˚C till the expiration date stated on the label which is only for closed vials.
Once opened vials are stable for 30 days at +2/+8ºC in optimum conditions. On board stability is strongly related to auto-analyzers' cooling specification and carry-over values.

Reagent stability and storage have been verified by using Clinical and Laboratory Standards Institute (CLSI) EP25-A protocol.

ADDITIONAL EQUIPMENT
- Spectrophotometer or colorimeter measuring at 572 nm.
- Matched cuvettes 1,0 cm light path.
- General laboratory equipment (Note 2).

SAMPLES
Serum and plasma are collected according to the standard procedure.
Lipase in serum is stable for: 7 days at +20/+25ºC, 7 days at +2+8ºC, 1 year at -20ºC

PROCEDURE
1. Assay conditions:
   Wavelength: . . . . . 572 nm
   Cuvette: . . . . . 1 cm light path
   Temperature . . . . . 37ºC / 15-25ºC
2. Adjust the instrument to zero with distilled water.
3. Pipette into a cuvette(Note 4):

	Standard	Sample
R1(µL)	500	500
R2(µL)	125	125
Standard(Note 3) (µL)	10	--
Sample (µL)	--	10

4. After adding sample or standard mix well and aspirate immediately to photometer within 5 seconds.
5. Read absorbance after 80 sec. incubation (A1) and absorbance exactly after 150 seconds incubation (A2)

CALCULATIONS
$$\frac{(A)Sample}{(A)Standard} \times (\text{Standard conc.}) = U/L$$

Conversion factors:
U/L x 0,0167 = µkat/L

QUALITY CONTROL
Control sera are recommended to monitor the performance of assay procedure.
The assay requires the use of a Lipase Calibrator Lyophilized. We recommend: Lipase Calibrator SET Lyophilized, REF: LIC-500C

Calibration Stability: It strongly depends on the application characteristics of in-use auto-analyzer and capacity of cooling. Calibration stability is 15 days.

Each laboratory should establish its own internal Quality Control scheme and procedures for corrective and preventive action if controls do not recover within the acceptable tolerances.

Quality control is recommended every morning. Calibration is not recommended if Quality control values are acceptable. Reagent should be calibrated after lot changes.

REFERENCE VALUES[1]
Adults : ≤ 60 U/L
It is recommended that each laboratory establish its own normal range.

PERFORMANCE CHARACTERISTICS
Limit of Detection (LoD): The limit of detection is 2 U/L.

Limit of Quantitation [LoQ values are based on Coefficient of Variation Percentage (CV) %≤ 20%: 5 U/L

LoD and LoQ values have been verified by using CLSI EP17-A protocol.

High Linearity: The method is linear up to 600 U/L.
For values above high linearity, dilute sample with 0.9% saline, repeat the test and multiply the result by the dilution factor.

Linearity may considerably vary depending on the instrument used.
Precision:

	Repeatability (n=80)		Reproducibility (n=80)	
Mean (U/L)	31	224	31	224
SD	0.48	4.63	1.15	3.71
CV (%)	1.56	2.06	11.5	5.15

±10% CV% differences can be observed between devices.

Accuracy: Results obtained using Sorachim reagents (y) did not show systematic differences when compared with other commercial reagents (x).
The results obtained were the following:
Correlation coefficient (r): 0,989
Regression equation: y=1.096x – 4.45
The results of the performance characteristics depend on the analyzer used.

INTERFERENCES
No significant interference was observed for haemoglobin, conjugated bilirubin, lipemia up to the interference concentration given in the table.

Interfering Substance and Concentration	Lipase Target (U/L)	N	Observed Recovery %
Hemoglobin 1260 mg/dL	31	3	97
Bilirubin 9,47 mg/dL	33	3	94
Lipemia 570 mg/dL	26	3	100

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The acceptable interference limit is set 10% below the highest interference concentration within ± 10% recovery of the target.
Interferences may affect the results due to medication or endogenous substances.
These performance characteristics have been obtained by using an analyzer. Results may vary if a different instrument or manual procedure is used.

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