


Lipase-LQ Kinetic Colorimetric Liquid

IVD For In-Vitro diagnostic and professional use only

2°C  8°C Store at 2° to 8° C

INTENDED USE

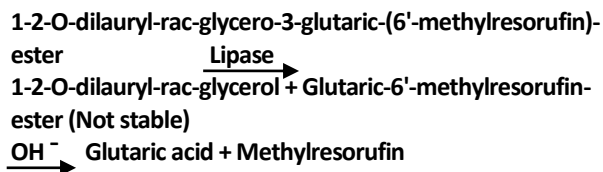
For the quantitative determination of lipase concentration in human serum or plasma.

INTRODUCTION

Lipase is one of several enzymes produced by the pancreas to help digest dietary fats. This test measures the amount of lipase in blood. Lipase is transported through the pancreatic duct and into the first part of the small intestine (duodenum), where it helps break down dietary triglycerides (a form of fat) into fatty acids. Determination of LPS is used for diagnosis of diseases of pancreas such as acute and chronic pancreatitis and obstruction of the pancreatic duct. Clinical diagnosis should not be based on a single test result; it should integrate clinical and other laboratory data.

PRINCIPLE

Pancreatic lipase, in the presence of colipase, desoxycholate and calcium ions, hydrolyses the substrate 1-2-O-dilauryl-rac-glycero-3-glutaric acid-(6'-methylresorufin)-ester. The sequence of reactions involved in the enzymatic direct lipase determination is as follows:



The rate of methylresorufin formation, measured photometrically, is proportional to the catalytic concentration of lipase present in the sample.

REAGENTS

Reagent	Composition	Con.
R1 (Buffer)	TRIS pH 8.3	40mmol/L
	Colipase	≥1 mg/L
	Desoxycholate	1.8mmol/L
	Taurodeoxycholates	7.2mmol/L
R2 Substrate (micro-emulsion)	Tartrate pH4.0	15mmol/L
	Lipase Substrate	≥0.7mmol/L
	Calcium chloride (CaCl ₂)	0.1mmol/L
LIPASE CAL	Standard Lyophilized human serum. The LPS activity (U/L methylresorufin at 37°C) is Indicated on the label of the vial.	

EQUIPMENTS NEEDED BUT NOT PROVIDED

- Spectrophotometer or colorimeter measuring at 580 nm.
- Thermostatic bath at 37° C (±0.1°C).
- Matched cuvettes 1.0 cm light path.
- General laboratory equipment.

PREPARATION

- **R1 and R2** are ready to use. The reagents are stable after opening for 90 days at 2-8° C.
- **R2** Mix gently before use.
- **LIPASE CAL**: Dissolve in 1 mL of distilled water then cap and mix gently to dissolve contents. The reagent is stable for 7 days at 2-8°C or 3 months at -20°C

PRECAUTIONS

- **LIPASE CAL** Components from human origin have been tested and found to be negative for the presence of HBsAg, HCV, and antibody to HIV (1/2). However handle cautiously as potentially infectious.

STORAGE AND STABILITY

- All components of the kit are stable until the expiration date on the label when stored tightly

closed at 2-8°C, protected from light and contaminations prevented during their use.

- Do not use reagents over the expiration date.
- **Signs of reagent deterioration:**
 - Presence of particles and turbidity.
 - Blank absorbance (A) at 580 nm ≥1.4.
 - R 2 is a turbid orange-colored micro-emulsion, discard if turning to red.

SAMPLES

Serum or plasma with sodium citrate, EDTA or heparin. Avoid repeated thawing. The sample is stable for 2 days at 2-8°C.

PROCEDURE

1. Assay conditions:
Wavelength:.....580 nm
Cuvette light path:..... 1 cm
Constant temperature.....37°C
2. Adjust the instrument to zero with distilled water.
3. Pipette into a cuvette:

	Blank	Standard /Sample
R 1 (mL)	1.0	1.0
R 2 (μL)	200	200
Distilled water (μL)	10	--
Standard/Sample(μL)	--	10

4. Mix then incubate at 37°C for 1 minute.
5. Read initial absorbance (A) of the sample then start the stopwatch and read absorbances at 1 minute intervals thereafter for 2 minutes.
6. Calculate the difference between absorbance and the average absorbance differences per minute (ΔA/min).

CALCULATIONS

(ΔA/min) Sample - (ΔA /min) Blank = (ΔA /min) of sample

(ΔA/min) Standard - (ΔA/min) Blank= (ΔA/min) of Standard

$\frac{\Delta A/\text{min Sample}}{\Delta A/\text{min Standard}} \times \text{Calibrator activity} = \text{U/L of lipase in the sample}$

Conversion factor: LPS [U/L] x 0.01667= LPS [μkal/L]

Units: One international unit (IU) is the amount of enzyme that transforms 1 μmol of substrate per minute, under standard conditions. The concentration is expressed in units per litre of sample (U/L).

QUALITY CONTROL

- If control values are found outside the defined range, check the instrument, reagents and technique for problems.
- Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

REFERENCE VALUES

Normal range: ≤ 38 U/L (U/L methylresorufin at 37°C).

These values are for orientation purposes; each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS

1. Measuring range:

From *detection limit* of 5 U/L to *linearity limit* of 250 U/L.

2. Precision:

	Intra-assay (n=20)		Inter-assay (n=20)	
Mean	40.2	59.35	38.5	58.9
SD	0.410	0.875	1.10	1.25
CV %	1.02	1.47	2.86	2.13

3. Sensitivity:

1 U/L = 0.00059792 (A).

4. Accuracy:

Results obtained using ATLAS reagents (y) did not show systematic differences when compared with other commercial reagents (x). The results obtained using 101 samples were as follows:

Correlation coefficient (R)²: 0.99732.

Regression equation: $y = 0.50054x + 3.9443$.

The results of the performance characteristics depend on the analyzer used.

INTERFERENCES

Triglycerides at 300 mg/dL interfere with the assay reducing the activity of enzyme by 6%. Hemoglobin concentration lower than 150 mg/dL and Bilirubin lower than 20 mg/dL do not interfere. A list of drugs and other substances interfering with lipase determination has been reported.

NOTES

1. In some storage conditions (i.e. storage at a temperature lower than that indicated) a precipitate may appear in the vial that will not influence that the reagent performance; however, it is recommended to resuspend the product by gentle mixing.
2. In order to avoid contamination, it is recommended to use disposable material.

















REFERENCES

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 REF	Catalogue Number		Temperature limit
 IVD	In Vitro diagnostic medical device		Caution
	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
 LOT	Batch code		Manufacturer
	Fragile, handle with care		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry