

LIPASE

DGGR. Kinetic colorimetric. Liquid

Product information

24LIP01-UN	Meditest LIPASE	4x40 mL 2x16 mL
24LIP01-AU	Meditest LIPASE	4x40 mL 2x16 mL
24LIP01-AB	Meditest LIPASE	4x40 mL 2x16 mL
24LIP01-ER	Meditest LIPASE	4x40 mL 2x16 mL
24LIP01-AR	Meditest LIPASE	4x40 mL 2x16 mL

Purpose

In vitro assay for the quantitative determination of lipase in human serum and plasma.

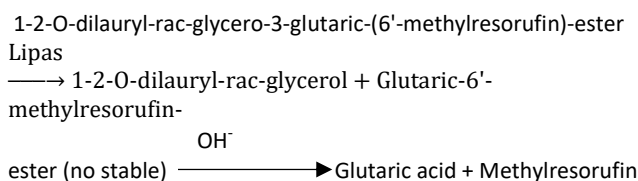
Summary

Lipase (LPS) is a pancreatic enzyme that catalyzes the hydrolysis of glycerol esters of fatty acids, essential for the absorption and digestion of nutrients.

Lipase determination is used in the diagnosis of pancreatic diseases such as acute and chronic pancreatitis and obstruction of the pancreatic duct^{1,7,8}. Clinical diagnosis should not be based on a single test result, but clinical and other laboratory data should be integrated.

Test principle

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



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

Reagents - working solutions

R 1 Buffer	TRIS pH 8.3	40 mmol/L
	Colipase	> 1 mg/L
	Desoxycholate	1.8 mmol/L
	Taurodesoxycholate	> 20 mmol/L
R 2 Substrate	Tartrate pH 4.0	15 mmol/L
	Lipase Substrate	> 0.7 mmol/L
	Calcium chloride (CaCl ₂)	> 0.05 mmol/L

Precautions warnings

It is intended for in vitro diagnostic use by healthcare professionals. Follow the normal precautions necessary in handling all laboratory reagents.

Infectious or microbial waste:

Warning: handle waste as potentially biohazardous. Dispose of waste according to accepted laboratory instructions and procedures.

Environmental hazards: Follow all relevant local disposal regulations to determine that it has been disposed of safely. If requested, a safety data sheet can be provided to professional users.

Inhibit foam formation in all reagents and sample types (sample, calibrator and control).

If there is any damage on the package, do not use. Read the user manual carefully before use, do not use the expired assay kit. Do not mix different lot reagents.

All samples should be considered epidemic material, please dispose of them in accordance with the laboratory working standard of infectious diseases.

Take the necessary protective measures to prevent users from becoming infected during operation.

Use of reagents

Ready to use.

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 contamination is avoided during their use.

Do not use reagents after the expiration date. Signs of reactive deterioration: Presence of particles and turbidity. R2 is a micro-emulsion of a cloudy orange color, discard it if it turns red.

Sample collection and preparation

Fresh serum samples are recommended. Medios does not recommend the use of EDTA and citrated plasma samples. These sample types can only be used if different reference ranges are established by each laboratory using different sample types other than fresh serum. Avoid repeated freezing and thawing.

Stability: 14 days at 2-8°C and -20°C.

Required Materials (not included in the kit)

1. Cat# 24BIO01-DC Meditest Diachem Calibrator
2. Cat# 24BIO01-DQ Meditest Diacheck Control L1
3. Cat# 24BIO02-DQ Meditest Diacheck Control L2
4. General laboratory equipment
5. Distilled or deionized water

Working Procedure

If you are using a spectrophotometer to perform this test, work with the following procedure. Ask your representative for the application data for fully automatic devices.

1. Test Conditions:

Wavelength: . 570 nm

Cuvette: 1 cm light path

Temperature: . 25°C/30°C/37°C

2. Set the appliance to zero with distilled water.

3. Place the pipettes in a cuvette.

4. Mix, incubate for 1 minute.

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5. Read the initial absorbance (A) of the sample, start the stopwatch, and read the absorbances at 1-minute intervals for 3 min.
6. Calculate the difference between absorbances and the average absorbance differences per minute ($\Delta A/\mu\text{iv}$).

Calculation

One international unit (IU) is the amount of enzyme that converts $1\mu\text{mol}$ substrate per minute under standard conditions. The concentration is expressed in units per liter of sample (U/L).
Conversion factor: $\text{U/L} \times 0.0167 = \mu\text{kat/L}$

Expected values

The normal range for pancreatic lipase when measured by the DGGR method is 13-60 U/L⁸
These values are for orientation purposes; Each laboratory should establish its own reference range

Limitations

At Lipase concentrations tested (40 U/L), up to 75 mg/dL bilirubin, up to 110 mg/dL hemoglobin, and up to 120 mg/dL ascorbic acid are immiscible. 600 mg/dL Intralipid (1300 mg/dL triglyceride) is immiscible. A list of drugs and other substances that interfere with lipase determination has been reported^{2, 3}.

Performance characteristics

Measuring range: 4.32-700 U/L
If the results obtained are greater than the linearity limit, dilute the sample by 1/10 with 9 g/L NaCl and multiply the result by 10.

Precision

	Intra-assay (n=80)		Inter-assay (n=20)	
Mean (U/L)	46.8	93.46	49.25	103.2
SD	3.15	10.97	6.23	9.93
CV (%)	3.3	2.4	5.0	4.3

Sensitivity: $1 \text{ U/L} = 0.378 \Delta\text{mAbs/min}$

Accuracy: Results obtained using Meditest reagents (y) showed no systematic differences when compared to other commercial reagents (x). The results obtained using 50 samples are as follows:

Correlation coefficient (r^2): 0.994

Regression equation $y = 1.076x + 1.313$

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

References

1. McNeely M. Lipase. Kaplan A et al. Clin Chem The C.V. Mosby Co. St Louis. Toronto. Princeton 1984; 1130-1134, 892.
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5. Young DS. Effects of drugs on Clinical Lab. Tests, 4th ed AACC Press, 1995.
6. Young DS. Effects of disease on Clinical Lab. Tests, 4th ed AACC 2001.
7. Burtis A et al. Tietz Textbook of Clinical Chemistry, 3rd ed AACC 1999.
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