ARENA BioScien

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LIPASE (4+1)

Reagent for the in-vitro quantitative determination of lipase in human serum and plasma.

REF: BS.1/LIP02.020.0040	80 test	REF: BS.1/LIP02.025.0050	100 test
REF: BS.1/LIP02.050.0100	200 test		

CLINICAL SIGNIFICANCE

Lipase enzyme and its cofactor "colipase" are produced in the pancreas. Lipase hydrolyze glycerol esters of long chain fatty acids. The enzyme being also secreted in small amounts by the salivary gland, the gastric, pulmonary and intestinal mucosa. Determination of lipase is used for diagnosis of diseases of pancreas such as acute and chronic pancreatitis and obstruction of the pancreatic duct.

METHOD PRINCIPLE

The pancreatic lipase in 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 the following:

1-2-O-dilauryl-rac-glycero-3-glutaric-(6' -methylresorufin)-ester

Lipase/Colipase → 1-2-O-dilauryl-rac-glycerol + Glutaric-6'-methylresorufin-ester → Glutaric acid + Methylresorufin OH (unstable)

REAGENT COMPOSITION

R1: Buffer Reagent	
Goods Buffer (pH 8.0)	40 mmol/L
Taurodesoxycholate	3.4 mmol/L
Desoxycholate	2.6 mmol/L
Calcium chloride	12 mmol/L
Colipase	1 mg/dl
R2: Substrate	
Tartrate Buffer (pH 4.0)	1.5 mmol/L
Taurodesoxycholate	3.4 mmol/L
DGMRE	0.13 mmol/L
Calibrator	Standard Lyophilized human serum. concentration is stated on the vial label.

PRECAUTIONS AND WARNINGS

Reagent to be handled by entitled and professionally educated person.
Good Laboratories practices using appropriate precautions should be followed in:

- Wearing personnel protective equipment (overall, gloves, glasses,).
- Do not pipette by mouth.
- In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.
- Respect country requirement for waste disposal.
  S56: dispose of this material and its container at hazardous or special waste collection point.
  S57: use appropriate container to avoid environmental contamination.
  S61: avoid release in environment.

For further information, refer to the lipase reagent material safety data sheet.

REAGENT PREPARATION, STORAGE AND STABILITY

BioScien lipase reagent are stable until expiration date stated on label when properly stored refrigerated at 2-8°C.

Calibrator: The calibrator is vacuum sealed; therefore, the vial should be reconstituted carefully with exactly 0.5 ml of distilled water.
Close the vial carefully and allow the calibrator to stand for 30 minutes swirling occasionally. Avoid foaming! Do not shake!
After reconstitution the tightly closed calibrator can be used within 30 days at – 25°C.

Deterioration
The ***BioScien*** lipase reagent is normally clear, do not use reagent if it is turbid.

SPECIMEN COLLECTION AND PRESERVATION

Serum free of hemolysis, heparinized plasma.
Stability: 24 hrs. at 15 - 25 °C
5 days at 2 - 8 °C
1 year at -20 °C

SYSTEM PARAMETERS

Wavelength	580 nm (578 nm)
Optical path	1 cm
Assay type	Kinetic
Direction	Increase
Temperature	37°C
Zero adjustment	Against air
Sensitivity	3.0 U/l
Linearity	300 U/l

EQUIPMENT REQUIRED NOT PROVIDED

- Sterile Syringe
- Analytical tubes, automatic pipet
- Centrifuge and spectrophotometer

ASSAY PROCEDURE

	Blank Reagent	*Calibrator/Specimen*
Calibrator/Specimen	---	10 µl
Dist. Water	10 µl	
Reagent 1	0.5 ml	0.5 ml
Mix carefully (do not shake), incubate 1 to 5 min, then add		
Reagent 2	125 µl	125 µl

Mix carefully (do not shake), incubate for 2 min at 37 °C, read absorbance and start stopwatch. After 1 min and after 2 min read absorbance again.

CALCULATION

ΔA/min = [A/min Sample / Calibrator] – [A/min Reagent Blank]

Lipase (U/l) = A/min Sample .x Conc. Calibrator
A/min Calibrator

QUALITY CONTROL

To ensure adequate quality control, it is recommended that normal and abnormal commercial control serum of known concentrations included in each run. If control values are found outside the defined range, check the instrument calibration, and reagent for problems. If control still out of range please contact ***BioScien*** technical support.

PERFORMANCE CHARACTERISTICS

Precision	Within run (Repeatability)		Run to run (Reproducibility)	
	Normal level	High level	Normal level	High level
n	40	40	40	40
Mean U/L	13.4	103	13.4	103
SD.	0.24	1.50	0.24	0.65
CV. %	1.81	1.45	1.81	0.63

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

Accuracy (Methods Comparison)
Result obtained from ***BioScien*** lipase reagent compared with commercial reagent of the same methodology performed on 40 human sera give a correlation of 0.999.

Sensitivity
When run as recommended, the minimum detection limit of the assay is 3 U/l lipase.

Linearity
The reaction is linear up to lipase concentration of 300 U/l. Specimens showing higher concentration should be diluted 1+1 using physiological saline and repeat the assay (result×2).

INTERFERING SUBSTANCES

Hemolysis
No significant interference up to 500 mg/dl.

Icterus
No significant interference up to 60 mg/dl.

Ascorbic Acid
No significant interference up to 30 mg/dl.

Triglycerides
No significant interference up to 1000 mg/dl.

EXPECTED VALUES

<60 U/l

It is recommended for each laboratory to establish and maintain its own reference values.

DYNAMIC RANGE

3 - 300 U/l.

REFERENCES

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3.Lott J, Patel ST, Sawhney AK, Kazmierczak SC, Love JE. Assays of serum lipase: analytical and clinical considerations. Clin Chem 1986; 32:1290-1302.
4.Gargouri Y, Julien R, Bois A, Verger R, Sarda L. Studies on the detergent inhibition of pancreatic lipase activity. J of Lipid Research 1983; 24:1336-42.
5.Lorentz K. Lipase. In: Thomas L, editor. Clinical laboratory diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 95-7.
6.Moss DW, Henderson AR. Digestive enzymes of pancreatic origin. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry.

SYMBOLS IN PRODUCT LABELLING			
IVD	For in-vitro diagnostic use	Σ	Number of <n> test in the pack
LOT	Batch Code/Lot number		Caution
REF	Catalogue Number		Do not use if package is damaged
	Temperature Limitation		Consult Instruction for use
	Expiration Date		
	Manufactured by		

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CE