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A Division of Orchard Medical

Lipase

IVD

Order Information

Cat. No.	Kit Configuration
OAR1127	Reagent 1: 2 x 20 mL Reagent 2: 1 x 10 mL
OAR1127	Reagent 1: 1 x 40 mL Reagent 2: 1 x 10 mL

Summary

Lipase (LPS) is a pancreatic enzyme essential for the absorption and digestion of nutrients. It hydrolysis the glycerol esters of fatty acids. Estimation of lipase is used for diagnosis of pancreatic disorders such as chronic and acute pancreatitis and obstruction of the pancreatic duct.

Method

Enzymatic Test

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.

1, 2-o-Dilauryl-rac-glycero-3-glutaric acid (6-methylresorufin) ester

Lipase/Co-lipase

→ 1, 2-o-Dilauryl-rac-glycerin+Glutaric acid-(6 methylresorufin)-

[OH^-]

→ ester Glutaric acid + Methylresorufin

The rate of formation of Methylresorufin is proportional to the catalytic concentration of Lipase present in the sample.

Reagents

Storage Instructions and Reagent Stability

Reagent and Calibrator are stable up to the end of the indicated month of expiry, if stored at 2°– 8°C, protected from light and contamination is avoided. Do not freeze the reagents!

Reagent 1: Enzyme
Solution Reagent 2:
Substrate Solution
Calibrator: Lyophilized Calibrator (Value on Label)

Composition

Reagent: N, N-bis (2-hydroxyethyl) Glycine buffer: 50 mmol/L, pH 8.0; colipase (porcine pancreas): ≥ 0.9 mg/L; Na-deoxycholate: 1.6 mmol/L; calcium chloride: 10 mmol/L, Tartrate buffer: 10 mmol/L, pH 4.16; 1,2-O-dilauryl-racglycero-3-glutaric acid-(6- methylresorufin) ester: 0.27 mmol/L; taurodeoxycholate: 8.8 mmol/L; detergent; preservative.

Warnings and Precautions

1. Many other clinical reagents contain lipase or high concentrations of detergents. Avoid contamination and carry over! Special care should be taken in combination with triglycerides, HDL and LDL reagents.
2. Cuvette and other glassware must be cleaned thoroughly after being used for other assays. In case of automated measurement refer to the instrument manual for special washing programs.
3. In very rare cases, samples of patient's with gammopathy might give falsified results.

Waste Management

Please refer to local legal requirements.

Reagent Preparation

The reagents are ready to use. Lipase Calibrator is in lyophilized form and need to be reconstituted with 3.0 mL of distilled water before use. Close the vial carefully and allow the calibrator to stand for 30 minutes swirling occasionally.
Avoid foaming! Do not shake!
Calibrator after reconstitution is stable till 14 days if stored at 2° – 8°C and for 28 days at –20°C, if protected from light and contamination is avoided.

Materials required but not provided

NaCl solution 9 g/L
General laboratory equipment

Specimen

Serum, heparin plasma or EDTA plasma separate at the latest 1h after blood collection from cellular contents.
7 days at 2° –8°C
30 days at –20°C
Only freeze once! Discard contaminated specimens.

Assay Procedure

Wavelength	578 nm
Optical path	10 mm
Temperature	37°C

	Blank	Sample/Calibrator
Reagent 1	800 µL	800 µL
Distilled Water	20 µL	--
Sample/ Calibrator	--	20 µL
Mix and incubate for 5 minute		
Reagent 2	200 µL	200 µL
Mix, Incubate for 2 min. and read absorbance after every 1 min. for 2 min.		

Calculations

ΔA/min = [ΔA/min sample or calibrator] – [ΔA/min blank]

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

Conversion Factor

Conversion factor: Lipase [U/L] x 0.01667= Lipase [µkat/L].

Quality Controls

For internal quality control any normal and abnormal controls should be assayed with each batch of samples. Each laboratory should establish corrective action in case of deviations in control recovery.

Performance Characteristics Measuring Range

The test has been developed determine Lipase activities within a measuring range from 5 – 300 U/L. If such value is exceeded the sample should be diluted 1 + 9 with NaCl solution (9 g/L) and results multiplied by 10.

Interferences

No interference was observed by, Ascorbic acid up to 30 mg/dL, Bilirubin up to 40 mg/dL and Triglycerides up to 1000 mg/Dl.

Sensitivity/Limit of Detection

The lower limit of detection is 5 U/L.

Linearity

The higher limit of detection is 300 U/L.

Precision

Intra-assay n = 20	Mean (U/L)	SD (U/L)	CV (%)
Sample 1	25.77	1.12	4.35
Sample 2	75.30	1.50	1.99

Inter-assay n = 20	Mean (U/L)	SD (U/L)	CV (%)
Sample 1	35.43	1.09	3.07
Sample 2	68.29	1.26	1.84

Method Comparison

A comparison of Nucleus Diagnosys Lipase (y) with a commercially available test (x) using 15 samples gave following results:
$y = 1.002x - 0.596$, $R^2 = 0.990$

Reference Range

Adults: 13 - 60 U/L (0.22–1.00 µkat/L)
Each laboratory should check if reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Literature

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MANUFACTURED BY: NUCLEUS DIAGNOSYS LLP, INDIA

Marketed By: ORCHARD MEDICAL,

DIAMOND ARCADE, 68 JESSORE ROAD,

1st FLOOR, UNIT No. 110 & 112, KOLKATA – 700 055

CUSTOMER CARE No: 84200 69980

CUSTOMER CARE E-MAIL: sales.orchardmedical@gmail.com