Lipase DC FS

Lipase Reagent Test Kit

Intended Use
Diagnostic reagent for in vitro quantitative determination of lipase in human serum on photometric analyzers.

Reagent Kits

Item Code	Pack size
143219934841	R1: 2 x 20 mL ; R2 : 1 x 10 mL

Summary
Lipases are enzymes which hydrolyze glycerol esters of long fatty acids. The enzyme and its cofactor colipase are produced in the pancreas, lipase being also secreted in small amounts by the salivary glands as well as by gastric, pulmonary and intestinal mucosa. Bile acids and colipase form micellar complexes with the lipids and bind lipase on the substrate/water interface. Determination of lipase is used for investigation of pancreatic disorders. In acute pancreatitis, lipase concentrations rise to 2 – 50 fold the upper reference limit within 4 – 8 hours after the beginning of abdominal pain peaking at 24 hours and decrease within 8 to 14 days. Elevated lipase values may also be observed in chronic pancreatitis and obstruction of the pancreatic duct.

Principle
Lipases are enzymes which hydrolyze glycerol esters of long fatty acids. The enzyme and its co-factor colipase are produced in the pancreas and small amount is secreted in the Liver. The combination of Lipase and bile acids make this specific and reliable for pancreatic lipase without any reaction due to lipolytic enzymes or esterases.

1,2-o-Dilauryl-rac-glycerol-3 glutaric acid (6-methylresorufin)
lipase/Colipase
Ester ⟷ 1,2-o-Dilauryl-rac-glycerin + glutaric acid -

. spontaneous degradation
(6-methylresorufin) ester ⟷ Glutaric Acid + Methylresorufin

The increase in absorbance is determined photometrically.

Storage Instruction and Reagent Stability
Reagents are stable until their expiration date when stored at 2-8°C.

Reagent Preparation
Lipase reagent comes in a two-reagent system, ready- to-use for both manual method and automated chemistry analyzers

Reagent Composition

Reagent 1 :	Good's Buffer pH 8.0	50 mol/L
	Taurodesoxycholate	4.3 mmol/L
	Desoxycholate	8.0 mmol/L
	Calcium Chloride	15 mmol/L
	Colipase	2.2 mg/L
	Preservative	Q.S.
Reagent 2 :	Tartarate Buffer	7.5 mmol/L
	Taurodesoxycholate	17.2 mmol/L
	Color Substrate	0.65 mmol/L
	Stabilizer	Q.S.
	Preservative	Q.S.

Traceability
Calibrator values have been made traceable to the molar extinction coefficient of an available measuring method.

Sample Material

Sample	Storage condition	Stability
Serum/ Heparin Plasma	20'C - 24°C	5 days
	4"C - 8°C	7 days
	-20°C	1 year

Assay Procedure
Wavelength 578 nm
Light path 10 mm
Temperature 37°C

	Blank	Sample/Calibrator
Reagent 1	2000 µL	200 µL
Sample/Calibrator	-	4 µL
Distilled water	20 µL	
Mix (Do not shake), incubate for 2 min.		
Reagent 2	50 µL	50 µL
Mix, incubate 2 min. at 37°C, read absorbance after exactly 1 and 2 min.		

Calculation

$$\text{Lipase (U/L)} = \frac{\Delta \text{ A/ min sample}}{\Delta \text{ A/ min calibrator}} \times \text{cone, calibrator (U/L)}$$

Calibrators and Controls
DiaSys TruCal U is recommended for calibration. Calibrator values have been made traceable to the molar extinction coefficient of an available measuring method. Use DiaSys TruLab N and P for internal quality control. Use of human based controls is strictly recommended. Each laboratory should establish corrective action in case of deviations in control recovery.

REFRANE RAGE
Normal Rage < 60 U/L
"Each laboratory should check if reference ranges are transferable to its own patient population and determine own reference ranges if necessary".

Performance Characteristics
Measuring Range
If the sample Lipase activity is greater than 300 U/L,the sample should be diluted with saline before measurement. The result should be multiplied by the dilution factor. Assay is specific for Lipase and has no detectable reaction with other nucleosides. The reagent solution should be clear. If turbid, the reagent may have deteriorated.

Sensitivity/Limit of Detection
The lower limit of detection is 3 U/L

Linearity
The linearity of the procedure is 300 U/L

Precision

Intra-assay Precision n=20	Mean [U/L]	SD [U/L]	CV [U/L]
Sample 1	38.1	1.75	4.6
Sample 2	66.7	1.77	2.65
Sample3	94.3	1.19	1.26

Inter-assay Precision n=20	Mean [U/L]	SD [U/L]	CV [U/L]
Sample 1	40.6	0.80	1.96
Sample 2	60.0	0.97	1.61
Sample3	108	1.52	1.40

Method Comparison
Add from DiaSys PI

Interference
No interference was observed by

Ascorbic acid	up to	30 mg/dL.
Bilirubin	up to	60 mg/dL,
Hemoglobin	up to	500 mg/dL,
Triglycerides	up to	1050 mg/dL,

Warning and Precautions

1. R1 is light - sensitive and should be stored in a dark place.
2. Keep out of reach of children. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
3. Take off immediately all contaminated clothing.
4. Wear suitable gloves and eye/face protection.
5. Always use safety pipettes to pull the reagents into a pipette.
6. Reagents may contain some non-reactive and preservative components. It is suggested to handle carefully, avoid direct contact with skin and do not swallow.
7. Perform the test according to the "Current Good Laboratory Practice" (cGLP) guidelines.

Clinical Interpretation

An elevated lipase usually indicates a problem with the pancreas. Evaluating the results of the two tests together helps to diagnose or rule out pancreatitis and other conditions. Lipase testing is also occasionally used in the diagnosis and follow-up of cystic fibrosis, celiac disease, and Crohn disease.

Limitations

To avoid contamination, use clean laboratory materials, use clean, dry disposable pipette tips for dispensing. Close reagent and calibrator bottles immediately after use. Avoid direct exposure of working reagent to light.

Literature

1. Kobayashi F, Ike da T, Marumo F, Sato C: Adenosine deaminaseisoenzymes in liver disease. Am. J. Gastroenterol. 88: 266-271(1993)
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4. Boonyagars L., Kiertiuranakul S.: Use of Adenosine Deaminase for the Diagnosis of Tuberculosis: A Review. J. Infect. Dis Antimicrob Agents 2010: 27:111-8.
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7. Porcel, JM.: Handling Pleural Fluid Samples for Routine Analyses. Derleme. June 2013:19-22.

Notes on Symbols and Marks

	Consult instructions for use
	Use-by date
LOT	Batch code
REF	Catalouge number
	Caution
	Manufacturer
IVD	*In vitro diagnostic* medical device
	Temperature limit
	Do not re-use
CONT.	The pack contains
	Recycle
	Date of manufactures

ISO 9001, ISO 13485 and ICMED 13485 Certified Company

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Revision No. :02
May. : 2022

1N 5200 V02