ACCUCARE®

LIPASE

Kinetic chromogenic substrate

Quantitative determination of Lipase in serum/plasma
Only for *In Vitro* Diagnostic use

ORDER INFORMATION

REF	Cont.
LIPSLR 10	1 X 10 mL
LIPSLR 20	1 X 20 mL

CLINICAL SIGNIFICANCE

Lipase is a pancreatic enzyme necessary for the absorption and digestion of nutrients that catalyzes the hydrolysis of glycerol esters of fatty acids. Determination of Lipase is used for the diagnosis of diseases of pancreas such as acute and chronic pancreatitis and obstruction of pancreatic duct.

Method

Enzymatic color 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'methylresourfin)- ester. to 1-2-O-dilauryl-rac-glycerol and Glutaric(6'methylresourfin)- ester which is monitored as increase in the absorbance. The rate of methylresorufin formation measured photometrically is proportional to the catalytic concentration of lipase present in the sample.

REAGENT

Reagent I : Buffer Reagent
Reagent 2 : Substrate Reagent
Lipase calibrator : (Lyophilized) Human Serum.

REAGENT PREPARATION

Reagent 1 & 2: Ready to use
Lipase calibrator : Reconstitute the calibrator with the exact volume of D/W as mentioned on the label , cap and mix gently to dissolve contents. stability ; 7 days at 2-8° or 3 months at -20°c aliquot into small volume and freeze.

REAGENT STORAGE AND STABILITY

When stored between 2-8°C the reagent is stable until the expiration date stated on the bottle and kit box label.
R1 - Ready to use stability after opening 90 days at 2-8 deg c
R2 - Mix gentle before use

WARNING AND PRECAUTIONS

- For in vitro diagnostic use.
- Do not use components beyond the expiration date.
- Do not mix materials from different kit lot numbers.
- Exercise the normal precautions required for handling all laboratory reagents.
- The reagent contains preservative. Do not swallow. Avoid contact with skin and mucous membranes.
- For detailed information refer Material Safety Data Sheet.

WASTE MANAGEMENT

Please refer to local legal requirements.

MATERIALS REQUIRED BUT NOT PROVIDED

- NaCl solution 9 g/L
- General laboratory equipment

SAMPLE COLLECTION AND PRESERVATION

Serum or heparin plasma or EDTA plasma
Stability: 7 days at 20 – 25°C
7 days at 4 – 8°C
1 year at –20°C
Only freeze once! Discard contaminated specimens!

ASSAY PROCEDURE

Operating Instructions

- Check reagent inventories at least daily to ensure that quantities are sufficient for the planned work load.
- Bring all reagents, standard and samples to room temperature 18 - 28°C, prior to analysis.
-

AUTOMATED PARAMETERS	
Wavelength	578 nm
Reaction Temperature	37°C
Measurement	Against D/W
Reaction	Fix time Kinetic
Reaction Direction	Increasing
Sample Volume	20 µl
Reagent Volume	800 + 200 µl
Delay	120 Sec.
Interval	120 Sec.
Low normal	5 IU/L
High Normal	60 IU/L
Linearity	250 IU/L

MANUAL ASSAY PROCEDURE

Pipette into Test Tubes

	Calibrator	SAMPLE
Reagent 1	800 µl	800 µl
Sample	-	20 µl
Calibrator	20 µl	-
Mix Well and Incubate for 2-3 min.		
Reagent 2	200 µl	200 µl

Mix well and incubate at 37°C for 120 Sec. (Delay Time). Measure the absorbance increase for 120 Sec. (Interval Time) and determine the Δ Absorbance for sample (ΔA_{sample})And Calibrator ($\Delta A_{calibrator}$) .

SAMPLE DILUTIONS

- This method is linear upto a concentration of 250 IU/L.
- Dilute samples above this concentration 1:1 with 0.9% saline
- Repeat assay. Multiply the result by 2.

CALCULATION

Results are calculated, usually automatically by the instrument, as follows:

$$\text{LIPASE (IU/L)} = \frac{(\Delta A_{sample})}{(\Delta A_{calibrator})} \times \text{Calibrator Value}$$

CALIBRATORS AND CONTROLS

For the calibration of automated photometric systems the commercially available suitable multi-calibrator is recommended.

The assigned values of the calibrator have been made traceable to the molar extinction coefficient of an available measuring method

It is recommended to run a normal and a pathological control serum which is commercially available to verify the performance of the measured procedure. The value of controls should fall within the established limit.

Each laboratory should establish corrective action in case of deviations in control recovery.

PERFORMANCE CHARACTERISTICS

WITHIN RUN

Sample	Mean Concentration	SD	CV %
Level 1	33.18	1.00	3.01%
Level 2	126.26	3.35	2.65%

Art No.: IFU/BC/LIP
Effective Date: 20/09/2019
Revision No.: 01

RUN TO RUN

Sample	Mean Concentration	SD	CV %
Level 1	33.39	1.06	3.17%
Level 2	127.03	2.70	2.12%

LINEARITY

The method is linear upto a concentration of 250 IU/L. Dilute samples above this concentration 1:1 with 0.9% saline solution and repeat assay. Multiply the result by 2.

Limit of detection: The limit of detection for Lipase is 5 IU/L.

METHOD COMPARISON

A comparison of Accucare Lipase with a commercially available assay (x) using 20 samples gave following results: $R^2 = 0.9900$

REFERENCE VALUES

Serum/plasma	< 60 IU/L

The reference values are to be considered as indicative only. Every laboratory should establish its own normal range.

LIMITATION OF THE PROCEDURE

- For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

INTERFERENCE

- Hemoglobin: No interference found upto 400 mg/dL.
- Bilirubin: No interference found upto 50mg /dL.
- Ascorbic Acid: No interference found upto 50 mg/dL.
- These characteristics have been obtained using an automatic analyzer. Results may vary if a different instrument or a manual procedure is used.

BIBLIOGRAPHY

1. Lorentz K. Lipase. In: Thomas L, editor. Clinical laboratory diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 95-7.
2. Moss DW, Henderson AR. Digestive enzymes of pancreatic origin. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999. p. 689–708.
3. Tietz N, Shuey DF. Lipase in serum – the elusive enzyme: an overview. Clin Chem 1993; 39: 746-56.

GLOSSARY OF SYMBOL

	Consult Instruction for Use	LOT	Lot Number
REF	Catalog Number		Date of Manufacturing
	Store between		Use By or Expiration Date
	Manufacturer	IVD	For *in vitro* Diagnostic use only
	Keep away from sunlight	CONT	Content of the kit

LAB-CARE DIAGNOSTICS (INDIA) PVT. LTD.
C1 Type, Shed No.: 3225, Chemical Zone,
GIDC Sarigam – 396155, Dist. Valsad, Gujarat, India.
Tel.: +91 22 2554 2109 /1558
Email: accucare@labcarediagnostics.com;
Website: www.labcarediagnostics.com