GENESIS

Instructions For Use

lipase (Kinetic Method (5+1))

Cat no.	size
1210 101	1*60
1210 102	2*60

INTENDED USE

Lipase reagent is intended for in-vitro quantitative determination of Lipase in human serum and heparinized or plasma.

DIAGNOSTIC CHARACTERISTICS

Lipase (LPS) is a pancreatic enzyme necessary for the absorption and digestion of nutrients that catalyzes the hydrolysis of glycerol esters of fatty acids. Determination of LPS is used for diagnosis of diseases of pancreas such as acute and chronic pancreatitis and obstruction of the pancreatic duct. Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

PRINCIPLE OF THE METHOD

The method for the determination of lipase is based on the cleavage of specific chromogenic lipase substrate 1,2-Odilaurylrac-
glycero-3-glutaric acid-(6'methyl-resorufin)-ester
emulsified in stabilized micro-particles. In the presence of specific activators of pancreatic lipase as colipase, calcium ions and bile acids, the substrate is con-verted to 1,2-O-dilauryl-rac-glycerol and
glutaric acid-6'-methylresorufinester which decomposes spontaneously to glutaric acid and methyl resorufin. The increase of
absorbance at 580 nm, due to methyl resorufin formation, is proportional to the activity of lipase in the sample.

COMPOSITION

Reagent (R1)	TRIS pH 8,3	40 mmol/L
	Colipase	> 1 mg/L
	Desoxycholate	1.8 mmol/L
	Taurodesoxycholate	7.2 mmol/L
Reagent (R2)	Tartrate pH 4,0	15 mmol/L
	Lipase Substrate	≥ 0.7 mmol/L
	Calcium chloride (CaCl2)	0.1 mmol/L
(Caibrator)	Standard. Lyophilised human serum The LPS activity (U/L methylresorufin at 37ºC) is indicated on the label of the vial.	

STORAGE AND STABILITY.

Store at 2-8ºC.

Reagent are stable until the expiry date shown on the Vial label when stored tightly closed and if contaminations are prevented during their use.

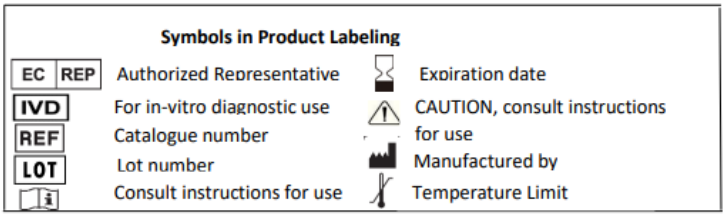
REAGENT PREPARATION

- Reagents **R1** and **R2** are ready to use. **R2** Swirl the vial gently before performing the assay.

Calibrator. Reconstitute the contents of one vial with **3.0 mL** of distilled water, swirling gently until complete dissolution. Stable 7 days at 2-8°C. Aliquoted into small volumes and frozen is stable for
3 months at -20°C.

ADDITIONAL EQUIPMENT

− Analyzer, spectrophotometer able to read at 580 nm.



SPECIMEN

Fresh serum and heparinized plasma. Stable 7 days at 2-8°C or frozen at -20°C for a longer period of time.

PRECAUTTIONS

For in vitro diagnostic use only.

PROCEDURE

1. Assay conditions:

Wavelength: …… 580 nm
Cuvette: ……..1 cm light path
Constant temperature ……37ºC
Reaction……..kinetic
Delay time……60 sec
Read time……120 sec

2. Adjust the instrument to zero with distilled water.
3. Pipette into a cuvette:

	Blank	Standard/Sample
R 1 (mL)	1.0	1.0
R 2 (µL)	200	200
Calibrator	-----	10 µl
Distilled water (µL)	10 µl	-----
Standard / Sample (µL)	-----	10 µl

4. Mix, incubate at 37ºC for 1 minute.
5. Read initial absorbance (A) of the sample, start the stopwatch and read absorbances at 1 minute intervals thereafter for 2 minutes.
6. Calculate the difference between absorbances and the average absorbance differences per minute (△A/min).

CALCULATIONS

(ΔA/min) Sample - (ΔA /min) Blank = (ΔA /min) of sample
(ΔA/min) Standard - (ΔA/min) Blank= (ΔA/min) of Standard

$$\frac{\triangle A/\text{min Sample}}{\triangle A/\text{min)Calibrator}} \times \text{calibrator activity} = \text{U/L of lipase in the sample}$$

Conversion factor: LPS [U/L] x 0,01667= LPS [µkal/L]

REFERENCE VALUES

≤ 38 U/L (U/L methyl resorufin at 37ºC). These values are for orientation purpose; each laboratory should establish its own reference range.

QUALITY CONTROL

It is recommended to use the Control Serum level I And II to verify the performance of the measurement procedure.
Each laboratory should establish its own internal Quality Control.

METROLOGICAL CHARACTERISTICS

Measuring range:

- detection limit of 5 U/L
- linearity limit of 250 U/L.

Precision:

	Intra-assay (n=20)		Inter-assay (n=20)	
Mean (U/L)	36.91	70.27	37.18	70.08
SD	0.92	1.29	0.5	1.04
CV (%)	2.5	1.84	1.34	1.49

Sensitivity: 1 U/L= 0,00059792 (A)

Accuracy: Results obtained using genesis reagents (y) did not show systematic differences when compared with other commercial reagents (x).

The results obtained using 101 samples were the following:

Correlation coefficient $(r)^2$:0.99732.

Regression equation: y= 0.50054x + 3.9443.

INTERFERENCES

No interference lower than:

- Triglycerides 300 mg/dL - Hemoglobin 150 mg/dL
- Bilirubin 20 mg/dL
- drugs and other interfering substances with lipase determination may be interfere.

BIBLIOGRAPHY

1. McNeely M. Lipase. Kaplan A et al. Clin Chem The C.V. Mosby Co. St Louis. Toronto. Princeton 1984; 1130-1134, 892.
2. Neumann U et al. Comptes Rend. 4 colloque de Pont-a-Musson, Masson 627-634 (1979)
3. Junge W et al. J.Clin.Chem.Clin.Biochem., 21 445-451 (1983).
4. Neumann U et al. Methods of Enzymatics Analysis, 3rd ed. Vol.4, 26-34 (1984) 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. 8. Tietz N W et al. Clinical Guide to Laboratory Tests, 3rd ed AACC 1995.

GENESIS LAB FOR DIAGNOSTIC REAGENTS
1st industrial area, Obour City, Cairo, Egypt
(+202) 44891632 Fax : (+202) 44891632
www.genesis-egy.com
info@genesis-egy.com

IFU-LIP-12
Rev. (2) 17/09/2023

ISO 13485:2016 Medical Devices

CE

EC REP CMC Medical device, C/ Horacio Lengo n18 C.P 29006, Málaga-Spain