LIPASE

Colorimetric Method

R1: 2 x 50 ml + R2: 2 x 30 ml **CL43-160S**

INTENDED USE

Kit for quantitative determination of Lipase in serum and plasma.

CLINICAL MEANING

Lipase is an enzyme synthesized mostly in the pancreas and is normally present in small quantities in the serum. The increase in serum lipase levels is linked in most cases to pancreatic inflammation; it is in fact more specific than the increase in the activity of the enzyme amylase even if high lipase values can be found in the course of intestinal infarction, cholecystitis, peritonitis. In acute pancreatitis, lipase levels rise a little later than those of amylase (the peak is 24-48 hours after the onset of pancreatitis) and remain elevated for longer, even for more than 7 days. For these reasons it is of important help in the case of a non-immediate diagnosis of acute pancreatitis.

PRINCIPLE

At alkaline pH the lipase substrate 1,2 Ōdilauryl-rac-glycero-3-glutaric acid-(6-methylresofurin)-esther is cleaved by the catalytic action of pancreatic lipase to form 1,2-O-dilauryl-rac-glycerol and unstable compound glutaric acid-(6-methylresofurin)-esther- In that alkaline solution, this compound degrades to glutaric acid and methyl-resorufin. The color intensity of the red dye formed is directly proportional to the lipase activity. This activity can be measured at 578 nm.

SAMPLE

Serum or heparinized plasma. Use sample free from hemolysis. Do not use plasma with EDTA.

STABILITY: 15 days at 2-8°C, 24 hours at room temperature (<25 °C).

REAGENTS

Only for in Vitro diagnostic use. Liquid reagents ready to use.

Package Content:	**CL43-160S**
REAGENT 1 Good Buffer ph 8.0, colipase, sodium deoxycholate	**CL43-160SR1** **2 x 50 ml**
REAGENT 2 Tartrate Buffer ph 4.0, substrate, taurodeoxy-cholate.	**CL43-160SR2** **2 x 30 ml**

STABILITY: stored at 2-8°C, reagents are stable up to the expiration date. Do not freeze.

WARNING: handle the standard with same precautions used for patient samples.

NECESSARY ITEMS – NOT PROVIDED

Usual laboratory equipment: UV/VIS Spectrophotometer with temperature control; automatic micropipettes; Optical glass cuvettes or, alternatively, disposable ones in optical polystyrene; Saline solution.

MANUAL ASSAY PROCEDURE

Wavelength:	578 nm
Optical path:	1 cm
Reading:	against blank reagent
Temperature:	37°C
Method:	kinetic
Reaction time:	2 minutes
Linearity:	up to 300 U/L
Ratio Sample/R1/R2:	1/100/60

It is recommended to wash the cuvettes thoroughly to avoid contamination.
Bring the reagents to the chosen temperature for the analysis.

Pipette in cuvettes labeled as it follows: B/R: Blank Reagent, S: Sample, Std: standard

	B/R	S	Std
Distilled water	10 µl	-	-
Sample	-	10 µl	-
Standard	-	-	10 µl
Reagent 1	1000 µl	1000 µl	1000 µl

Mix and incubate for 5 minute a 37°C. Add:

Reagent 2	600 µl	600 µl	600 µl

Mix and incubate for 60 seconds.
Read Absorbance (Abs1) for Sample (S), Standard (Std) and Blank Reagent (B/R).
Read again after 90 secondis (Abs2).
Determine ΔAbs = Abs2-Abs1 for each Campione, Standard and Blank Reagent.
Reaction volumes can be proportionally varied without any change in calculation.

CALCULATION

$$\text{Lipase (U/L)} = \frac{(\Delta\text{Abs S} - \Delta\text{A B/R})}{(\Delta\text{A Std} - \Delta\text{A B/R})} \times \text{conc. Standard (U/L)}$$

REFERENCE VALUES

Serum or plasma: ≤ 38 U/L.

Each laboratory should define its own reference values for this method.

QUALITY CONTROL – CALIBRATION

All Clinical Chemistry laboratories should implement a quality control program. Control serums of human origin are available for this purpose on request:
PRE-NORM serums with normal values
PRE-PATH serums with pathological values
If the method requires it, a multi-parameter calibrator of human origin is available (**CALIBRATOR CLINICAL CHEMISTRY** REF 7532).

ERFORMANCE CHARACTERISTICS

Sensitivity
The sensitivity of the method is 6,9 U/L.
Linearity
The method is linear up to 300.
For higher values, dilute the samples 1:5 with saline solution and multiply the result by 5.
Precision

Within-run CV %	3,01 %

Run-to-run CV %	3,65 %

Interferences
Hemolysis interferes with the assay.
Concentration of hemoglobin higher than 125 mg/dl, of bilirubin higher than 20 mg/dl and triglycerides than 625 mg/dl can interfere with the assay.

Correlation against a reference method
The correlation of method (Y) with reference method (X) highlighted the following equation:

Y =0,9342X + 0,1617 r = 0,9948

DISPOSAL

The product must be used for professional analysis only. The product must be disposed of according to national/international laws.

WARNINGS AND PRECAUTIONS

The reagents may contain non-reactive components and various preservatives. Contact with the skin and ingestion should be avoided. Use the normal precautions expected with correct behavior in laboratory.

REFERENCES

1. Rick. W., (1969), Zeittschrift Clin. Chem. Biochem., 7, 530-536
2. Ziegenhorn, J. et al., (1979), Clin. Chem., 25, 1067.

MANUFACTURER

FAR
Via Fermi, 12 - 37026 Pescantina - VERONA - ITALY
tel +39 045 6700870
website http://www.fardiag.com
e-mail: order@fardiag.com
e-mail: fardiag@fardiag.com

KEY SYMBOLS

IVD	In Vitro diagnostic medical device
LOT	batch number
REF	catalog number
	temperature limits
	use by
	caution
	consult accompanying documents

Issue 02 - Sep 2022 RR