Lipase-LQ

Kinetic colorimetric. Liquid

Quantitative determination of lipase

CE IVD

PACKAGING

Ref.: 101-0410	Cont.: 4 x 10 / 1 x 8 mL

Store at 2 - 8º C

CLINICAL SIGNIFICANCE

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[1,7,8]. Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

PRINCIPLE OF THE METHOD

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. The sequence of reactions involved in the enzymatic direct lipase determination is the following:

1-2-O-dilauryl-rac-glycero-3-glutaric-(6' -methylresorufin)-ester $\xrightarrow{\text{Lipase}}$ 1-2-O-dilauryl-rac-glycerol + Glutaric-6'-methylresorufin-ester (no stable) $\xrightarrow{OH^-}$ Glutaric acid + Methylresorufin

The rate of methylresorufin formation, measured photometrically, is proportional to the catalytic concentration of lipase present in the sample.

REAGENTS

R 1 Buffer	TRIS pH 8.3	40 mmol/L
	Colipase	≥ 1 mg/L
	Desoxycholate	1.8 mmol/L
	Taurodesoxycholate	7.2 mmol/L
R 2 (micro-emulsion)	Tartrate pH 4,0	15 mmol/L
	Lipase	≥ 0.7 mmol/L
	Calcium chloride ($CaCl_2$)	0.1 mmol/L
LIPASE CAL	Standard. Lyophilised human serum The LPS activity (U/L methylresorufin at 37º C) is indicate on the label of the vial.	

PRECAUTIONS

LIPASE CAL Components from human origin have been tested and found to be negative for the presence of HBsAg, HCV, and antibody to HIV (1/2). However handle cautiously as potentially infectious.

PREPARATION

- **R1 – R2** Ready to use. Stability after opening 90 days at 2 - 8º C.
- **R2** Mix gently before use [(Nota 1)].
- **LIPASE CAL**: Dissolve with 1 mL of distilled water. Cap and mix gently to dissolve contents. Stability: 7 days at 2 - 8º C or 3 months at –20º C.

STORAGE AND STABILITY

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2 - 8º C, protected from light and contaminations prevented during their use. Do not use reagents over the expiration date.

Signs of reagent deterioration:

- Presence of particles and turbidity.
- Blank absorbance (A) at 580 nm ≥ 1.4
- R 2 is a turbid orange-colored micro-emulsion, discard if turning to red.

ADDITIONAL EQUIPMENT

- Spectrophotometer or colorimeter measuring at 580 nm.
- Thermostatic bath at 37º C (± 0.1º C)
- Matched cuvettes 1.0 cm light path.
- General laboratory equipment

SAMPLES

Serum or plasma with sodium citrate, EDTA or heparin[1].
Avoid repeated frozen and unfrozen. Stability: 2 days at 2 - 8º C.

PROCEDURE

Notes: CHRONOLAB SYSTEMS has instruction sheets for several automatic analyzers. Instructions for many of them are available on request.
In some storage conditions (i.e. storage at a temperature lower that the one indicate) a precipitate may appear in the vial that will not influence that the reagent performance; however, it is recommended to resuspend the product with a slight rotation.
In order to avoid contamination it is recommended to use disposable material.

1. Assay conditions:
   Wavelength: . . . . . 580 nm
   Cuvette: . . . . . 1 cm light path
   Constant temperature . . . . . 37º C
2. Adjust the instrument to zero with distilled water.
3. Pipette into a cuvette [(note 2)]:

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

4. Mix, incubate at 37º C 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 (ΔA/min).

CALCULATIONS

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

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

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

Units: One international unit (IU) is the amount of enzyme that transforms 1 µmol of substrate per minute, in standard conditions. The concentration is expressed in units per litre of sample (U/L).
Conversion factor: LPS [U/L] x 0.01667= LPS [µkal/L]

QUALITY CONTROL

Control sera are recommended to monitor the performance of assay procedures:
Contro-N (Ref. 101-0083, 101-0252) and Contro-P (Ref. 101-0084, 101-0253).
If control values are found outside the defined range, check the instrument, reagents and technique for problems.
Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

REFERENCE VALUES[1]

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

PERFORMANCE CHARACTERISTICS

Measuring range: From *detection limit* of 5 U/L to *linearity limit* of 250 U/L.

Precision:

	Intra-assay (n=20)		Inter-assay (n=20)	
Mean (U/L)	40.2	59.35	38.5	58.9
SD	0.410	0.875	1.10	1.25
CV (%)	1.02	1.47	2.86	2.13

Sensitivity: 1 U/L= 0.00059792 (A)

Accuracy: Results obtained using CHRONOLAB 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): 0.99732.
Regression equation: y= 0.50054x + 3.9443.
The results of the performance characteristics depend on the analyzer used.

INTERFERENCES

Triglycerides at 300 mg/dL interfere on determination reducing the activity of enzyme of 6%. Hemoglobin concentration lower than 150 mg/dL and Bilirubin lower than 20 mg/dL do not interfere. A list of drugs and other interfering substances with lipase determination has been reported.

BIBLIOGRAPHY

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