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LIPASE

STABLE LIQUID REAGENT

CE

Cat. No.:: 49361
120 ml
(1x100ml+1x20ml)

Reagent kit for the quantitative determination of lipase activity in serum or plasma, enzymatic, colorimetric method.

Only pancreatic lipase is of interest in medical diagnosis. Lipase hidrolyzes glycerol esters of long chain fatty acids. Lipase measurement is used for diagnosis of diseases of pancreas such as acute and chronic pancreatitis and obstruction of the pancreatic dust. Clinical diagnosis should not be made on the findings of a single test result, but should integrate both clinical and laboratory data.

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

$$Lipase \rightarrow 1\text{-}2\text{-}O\text{-}dilauryl\text{-}rac\text{-}glycerol + Glutaric\text{-}6'\text{-}methylresorufin\text{-}ester$$

$$Glutaric\text{-}6'\text{-}methylresorufin\text{-}ester \xrightarrow{OH^-} Glutaric-acid + Methylresorufin$$

Reference values
<38 U/l (0,63 µkat/l)

It is recommended that each laboratory should assign its own normal range.

Reagents
1. Reagent (R1)

TRIS buffer, pH=8,3	40 mmol/l
Colipase	>1 mg/l
Desoxycholate	1,8 mmol/l
Taurodesoxycholate	7,2 mmol/l

2. Reagent (R2)

Tartrate	15 mmol/l
$CaCl_2$	>1 mmol/l
pH=4,0	

3. Calibrator

Samples
Serum or plasma with sodium citrate, EDTA or heparin. Avoid repeated frozen and unfrozen.

PROCEDURE

The reagents are ready to use
Calibrator: dissolve the contents with 1 ml of distilled water. Cap the vial and mix gently to dissolve the content

Assay conditions

Wavelength:	580 nm (560-600 nm)
Temperature:	37 °C
Cuvette:	1 cm light path
Read against:	distilled water or air
Method:	kinetic (increasing)

• **Two-reagent procedure**

Reagent 1	1000 µl
Sample	10 µl

Mix and wait 30 seconds

Reagent 2	200 µl

Mix and after a 60-second incubation read the change of optical density (ΔA) during 2 minutes. Determine the change of optical density per minute (ΔA/min).

Calibration: (37°C, methylresorufin method)
S1: Distilled water
S2: Lipase Calibrator

Calibration frequency
Two-point calibration is recommended:
- after reagent lot change,
- as required following quality control procedures.

Calculation using calibration

$$\frac{\Delta A_{sample}}{\Delta A_{standard}} xC_{standard} = C_{sample}$$

A = Absorbance, C = Concentration

Quality control
A quality control program is recommended for all clinical laboratories. The analysis of control material in both the normal and abnormal ranges with each assay is recommended for monitoring the performance of the procedure. Each laboratory should establish corrective measures to be taken if values fall outside the limits.

PERFORMANCES DATA

Linearity
The method is linear up to 250 U/l (4,17 µkat/l)

Sensitivity
It is recommended that each laboratory establishes its own range of sensitivity as this is limited by the sensitivity of the spectrophotometer used. The detection limit is 5 U/l (0,083 µkat/l)

Precision

	Reproducibility	
Sample	Average activity (U/l)	CV%
Sample I.	119	3,3
Sample II.	215	2,8

	Repeatability	
Sample	Average activity (U/l)	CV%
Sample I.	119	4,5
Sample II.	215	5,0

Correlation
Comparative studies were done to compare our reagent with another commercial lipase assay on 101 human samples.
The results from these studies are detailed below.
Correlation coefficient: r=0,99732
Linear regression: y (U/l)= 0.500x+3.94
(x= other commercial reagent, y= own reagent).

Specificity
Triglycerides at 300 mg/dl interfere on the determination reducing the activity of enzyme of 6%. No interference were observed with haemoglobin until 150 mg/dl and bilirubin 20 mg/dl. Other drugs and substances may interfere.

Note

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 on the reagents performance; however, it is recommended to resuspend the reagent with a slight rotation.

Do not use reagents after the expiry date stated on each reagent container label. Do not use products, test solutions and reagents described above for any purpose other than described herein.

For *in vitro* diagnostic use only.

The following symbols are used on labels

IVD For in vitro diagnostic use

Use by (last day of the month)

Temperature limitation

LOT Batch Code

REF Code

Bibliography

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