SBio LIPASE KIT

(Turbidimetric U.V. Method)

(For invitro diagnostic use only)

REF	90570025
Pack Size	25 ml

CE

8C 2C Store at 2-8°C	Manufacturer	IVD *In vitro* Diagnostic Medical Device	L1 Lipase Reagent	Turbidimetric U.V. Turbidimetric U.V. Method
Use by (Last day of stated month)	Consult Instructions for use	LOT Batch Number	C Calibrator (for 1ml)	
Date of Manufacture	REF Catalogue Number	EC REP Authorised Representative in the European Community		This way up

INTENDED USE

Lipase kit is used for the determination of Lipase Activity in serum.

PRINCIPLE OF THE TEST

Pancreatic Lipase catalyses the hydrolysis of Triolein, in the presence of colipase, to form monoglycerides and fatty acids. The rate of decrease in turbidity measured at 340nm, is proportional to the lipase activity. The activities of other lipases in the serum are inhibited by the cholic acid salts in the reagent.

$$\text{Triolein} + 2H_20 \xrightarrow{\textit{Lipase}} \text{Monoglyceride} + 2\ \text{Oleic Acid}$$

CLINICAL SIGNIFICANCE

Lipases are enzymes which hydrolyse glycerol esters of long chain fatty acids. The enzyme and its cofactor, colipase is produced in the pancreas, lipase being also secreted in small amounts by the salivary glands as well as by the gastric, pulmonary and intestinal mucosa. Bile acids and colipase form micellar complexes with the lipids and bind lipase on the substrate water interface. Determination of Lipase is used for investigation of pancreatic disorders. In acute pancreatitis the lipase concentrations rise 2-50 fold the upper reference limit within 4-8 hours after beginning of abdominal pain peaking at 24 hours and decreasing within 8-14 days. Elevated Lipase values can also be observed in chronic pancreatitis and obstruction of the pancreatic duct.

PRESENTATION	25 ml
L1 : Lipase Reagent	25 ml
C : Calibrator (for 1ml)	1 No.

COMPOSITION

Tris Buffer 20 mM; pH 8.0; Deoxycholate 20 mmol; Colipase >10 mg; Triolein >5mmol; Non Reactive Stabilizers, Detergent and Preservatives.

STORAGE / STABILITY

Contents are stable at 2-8° C till the expiry mentioned on the labels. Do not freeze.

REAGENT PREPARATION

The Lipase Reagent is ready to use.

Calibrator : Reconstitute the calibrator with 1 ml of D.W. Allow to stand for 10 mins with occasional mixing. The reconstituted control is stable for at least 7 days when stored at 2-8°C and for at least 4 weeks when stored at -20°C. Do not repeatedly thaw and refreeze.

SAMPLE REQUIRED

Serum. Free from Hemolysis.
Lipase is reported to be stable in serum for 5 days at 2-8°C.

SAMPLE WASTE AND DISPOSAL

Do not reuse the reagent containers, bottles, caps or plugs due to the risks of contamination and the potential to compromise reagent performance.
This product requires the handling of human specimens. It is potentially hazardous and are handled in accordance with the OSHA standard on blood borne pathogens.
Appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.
Handle specimens, solid and liquid waste and test components in accordance with local regulations and NCCLS guidelines M29, or other published biohazard safety guidelines.

PROCEDURE

Wavelength / Filter	:	340 nm
Temperature	:	37° C
Light path	:	1 cm

MATERIALS REQUIRED BUT NOT PROVIDED

Photometer analyzer with standard thermostatic cuvette holder, micropipette and appropriate laboratory equipment.

Pipette into clean dry test tubes labelled as Calibrator(C), and Test (T)

Addition Sequence	C (ml)	T (ml)
Lipase Reagent (L1)	1.0	1.0
Calibrator (C)	0.04	-
Sample	-	0.04

Mix well and incubate at 37°C for 4 mins. and read the initial absorbance A_1 for the Calibrator (C) and Test (T). Read another absorbance A_2 of the Calibrator and Test after exactly 5 mins. Calculate the change in absorbance DA for both the Calibrator and Test.

For Calibrator $\Delta AC = A_2C - A_1C$
For Test $\Delta AT = A_2T - A_1T$

Calculations

$$\text{Lipase in U/L} = \frac{\Delta AT}{\Delta AC} \times \text{Conc.of Calibrator}$$

QUALITY CONTROL

The following process is recommended for QC during the assay of Lipase. Define and establish acceptable range for your laboratory.

1. Two levels of control (Normal and Abnormal) are to be run on a daily basis.
2. If QC results fall outside acceptance criteria, re-calibration may be necessary.
3. Review QC results and run acceptance criteria following a change of reagent lot.

SPECIFIC PERFORMANCE CHARACTERISTICS

Linearity:
The procedure is linear upto 700 U/L. If values exceed this limit, dilute the serum with normal saline (NaCl 0.9%) and repeat the assay. Calculate the value using the proper dilution factor.

Method comparison:
Comparative studies were done to compare our reagent with another commercial Lipase Assay. No significant differences were observed. Details of the comparative studies are available on request.

REFERENCE RANGE

Serum : up to 190U/L.

It is recommended that each laboratory establish its own normal range representing its patient population.

NOTE

Reagents such as Cholesterol / Triglycerides / HDL / LDL contain High Concentrations of detergents and hydrolysing enzymes, cross contamination from such reagents should be avoided.
All glassware / tips and cuvettes being used for the test should be throughly cleaned.
Samples having a very high activity show a very low initial absorbance as most of the substrate is consumed prior to the start of measurement. If this is suspected then dilute the sample and repeat the assay.
Do not use the Lipase reagent if the initial absorbance is below 1.000 at 340 nm against D.W.
In rare cases some sera may give an increase in absorbance, the Lipase activity of these samples usually falls within the normal range.
Components from human origin in the calibrator 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. Do not use deteriorated or leaking reagents.

REFERENCES

1. Ziegenhorn J., et al. Clin.Chem.1979; **25**:1067.
2. Teitz NW et al. Clin. Chem.1993; **39**:746-756.
3. Lott,J. A., et al. Clin. Chem. 1986:**32**:1920
4. Tietz Textbook of Clinical Chemistry.3rded.: W.B Saunders Company; 1999.p.689-708.

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EC REP

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