NEO CHEM
LIPASE
(Colorimetric method)

KIT NAME	KIT SIZE
NEO CHEM - LIPASE	2 x 12 ml

NEOGENIX
DIAGNOSTICS PVT LTD

INTRODUCTION
Lipase is a digestive enzyme released into the intestine from the pancreas where it breaks down triglycerides into fatty acids and glycerol prior to absorption. Lipase measurements are used in the diagnosis and treatment of diseases of the pancreas such as acute pancreatitis, obstruction of the pancreatic duct and pancreatic tumours.

METHOD PRINCIPLE
The colorimetric method is based on a lipase specific degradation of a chromogenic substrate. The specific lipase substrate-DGGMR [1,2-o-dilauryl-racglycero-3-glutaric acid-(6'-methylresorufin) ester] is cleaved by the catalytic action of lipase to form 1,2-o-dilaurylracglycerol and an unstable intermediate, glutaric acid-(6-methylresorufin) ester. This decomposes spontaneously in alkaline solution to form glutaric acid and methylresorufin. The lipase activity in the specimen is proportional to the production of methylresorufin in the reaction and can be determined photometrically.

KIT CONTENTS

Reagent Name	Pack Size
R1 Lipase Reagent	2 x 10 ml
R2 Lipase Reagent	2 x 2 ml
R3 Calibrator	0.5 ml

The calibrator value is mentioned on the vial label.

WORKING REAGENT PREPARATION AND STABILITY
The reagents are ready to use.The reagents when stored at 2-8°C are stable up to expiry date printed on the package. The reagents are stable for 7days on board the analyser at approximately 10°C.

Working Reagent (WR): Assay can be performed with use of separate R1 and R2 or with use of working reagent. For Working reagent preparation mix gently 5 parts of R1 and 1 part of R2 reagent. Since R2 is coloured in nature, do not store working reagent for prolonged usage. Always use freshly prepared working reagent for better absorbance.

CONCENTRATIONS IN THE TEST

BICIN Buffer, pH 8.0	50 mmol/L
Colipase ≥ 1 mg/L Sodium deoxycholate 1.6 mmol/L	
Calcium Chloride 10 mmol/L Tartarate Buffer, pH 4.0	10 mmol/L
Taurodeoxycholate	8.8 mmol/L
DGGMR [1,2-o-dilauryl-rac-glycero-3-glutaric acid-(6'-methylresorufin)-ester]	0.27 mmol/L

WARNINGS AND NOTES
- Products for in vitro diagnostic use only.
- The reagents must be used only for the purpose intended by suitably qualified laboratory personnel, under appropriate laboratory conditions.
- Products contain sodium azide (<1 g/l) as a preservative. Avoid contact with skin and mucous membranes.

ADDITIONAL EQUIPMENT
- Automatic analyzer or photometer able to read at 578 nm
- Thermostat at 37°C
- General laboratory equipment

SPECIMEN
Serum, heparinized plasma free from hemolysis.
Sample may be stored for up to 5 days at 2-8°C or 24 hours at 20-25°C. Nevertheless it is recommended to perform the assay with freshly collected samples.
Serum, heparinized or EDTA plasma.

PROCEDURE
These reagents may be used both for manual assay (Sample Start and Reagent Start method) and in several automatic analyzers. Programme Sheets are available on request.

Wavelength	578 nm
Temperature	37°C
Cuvette	1 cm

Pipette into the cuvette:

Reagent	Calibrator(C)	Test (T)
R1 Lipase Reagent	1000 µl	1000 µl
R2 Lipase Reagent	200 µl	200 µl
Mix well and bring to assay temperature, then add		
R3 Calibrator	10 µl	
Sample		10 µl

Mix well and after exactly 60 secs read the absorbance A1 of the Test (T) and Calibrator (C) against air or water. In next 60 secs repeat absorbancereading A2 and calculate ΔA (A2-A1) for test and calibrator.

CALCULATION
Lipase activity [U/L] = ΔA (T) / ΔA (C) x Calibrator concentration

REFERENCE VALUES
5 - 60 U/L
It is recommended for each laboratory to establish its own reference ranges for local population.

QUALITY CONTROL
To ensure adequate quality control, each run should include assayed normal and abnormal controls. If commercial controls are not available it is recommended that known value samples be aliquoted, frozen and used as controls.

PERFORMANCE CHARACTERISTICS
Sensitivity / Limit of Quantitation: 5 U/L.

Linearity: up to 250 U/L. If the sample activity exceeds 250 U/L, dilute sample with 0.9% NaCl and repeat the assay. Multiply the result by the dilution factor.

Specificity / Interferences:
Haemoglobin up to 2.5 g/dl, bilirubin up to 20 mg/dl, triglycerides up to 500 mg/dl, ascorbate up to 62 mg/l do not interfere with the test.

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

1. Tietz NW et al. Lipase in serum-the elusive enzyme: An overview. Clin Chem 1993;39:746-756.
2. Steinberg WM, Goldstein SS,Davies ND et al. Diagnostic assays in acute pancreatitis. (Review). Ann Intern Med 1985; 102:576-580.
3. Leybold A, Junge W. Importance of colipase for the measurement of serum

SYSTEM PARAMETERS

Method	Fixed Time (2-point)
Wavelength	578 nm
Zero Setting Temperature	Distilled Water
Setting Incubation	37° C
Temperature Incubation	37° C
Time	----
Delay Time	60 secs
Read Time	60 secs
No. of Reading	2
Interval Time	----
Sample Volume	0.01 ml (10 ul)
Reagent Volume	1.2 ml (1200 ul)
Calibrator Concentration	Refer Calibrator vial
Units	U/L
Factor	----
Reaction Slope	Increasing
Linearity	250 U/L