DIAGNOSTIC KIT FOR DETERMINATION OF LIPASE ACTIVITY

OS – LIPASE

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-dilauryl-racglycerol and an unstable intermediate, glutaric acid-(6-methyl resorufin) 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.

REAGENTS

Package

1-Reagent 2 x 26 ml 2-Reagent 2 x 14 ml

The reagents when stored at 2-8°C are stable up to expiry date printed on the package. The reagents are stable for 12 weeks on board the analyser at 2-10°C. Protect from light and avoid contamination!

Concentrations in the test

1-Reagent

TAPS [N-Tris(hydroxymethyl)methyl-3-100 mM aminopropanesulfonic acid] sodium hydroxide 40 mM sodium deoxycholate 34 mM 2-Reagent tartaric acid 9.5 mM sodium hydroxide 19 mM colipase 460 IU/ml 2-propanol 0.65 M DGGMR [1,2-o-dilauryl-rac-glycero-3-glutaric acid-0.4 mM (6'-methylresorufin)-ester]

Warnings and notes

- Product 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 (< 0.1%) as a preservative.
 Avoid contact with skin and mucous membranes.

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!

PROCEDURE

These reagents may be used in automatic analysers Olympus AU400/AU640.

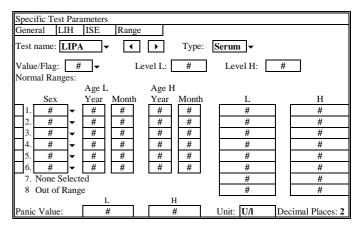
1-Reagent and 2-Reagent are ready to use.

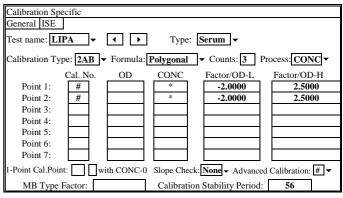
For reagent blank 0.9% NaCl is recommended.

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APPLICATION

Reagent ID: 030 Specific Test Parameters Range General **→** Test name: LIPA Type: Serum ▼ Operation: Yes uL Dilution 10 Sample: Volume μL Pre-Dilution Rate: 1 Reagents: R1 Volume μL Dilution μL Min OD R2 Volume 65 μL Dilution 0 L -2.0000 H 2.5000 Reagent OD Limit: Wavelength: Pri. **570** ▼ First L -2.0000 First H 2.5000 Method: RATE Last L -2.0000 Last H 2.5000 Reaction Slope: Dynamic Range: L 10.70 H 520 Measuring Point 1: First 13 Last Measuring Point 2: First Last Correlation Factor: Linearity: A 1.000 В 0.000 No-Lag-Time On-board Stability Period:





- # User defined
- * Calibrator value

REFERENCE VALUES 4

TEST ESTED (TESTED				
	Normal range	13 – 60 U/l	$0.22 - 1.00 \mu kat/l$	

It is recommended for each laboratory to establish its own reference ranges for local population.

QUALITY CONTROL

For internal quality control it is recommended to use the CORMAY SERUM HN (Cat. No 5-172) and CORMAY SERUM HP (Cat. No 5-173) with each batch of samples.

For the calibration of automatic analysers systems the CORMAY MULTICALIBRATOR LEVEL 1 (Cat. No 5-174; 5-176) and LEVEL 2 (Cat. No 5-175; 5-177) is recommended.

The calibration curve should be prepared every 8 weeks, with change of reagent lot number or as required e.g. quality control findings outside the specified range.

PERFORMANCE CHARACTERISTICS

These metrological characteristics have been obtained using the automatic analyser Olympus AU400. Results may vary if a different instrument is used.

• **Sensitivity:** 10.7 U/l (0.18 µkatal/l).

• **Linearity:** up to 520 U/l (8.67 μkat/l).

For higher activity dilute sample with 0.9% NaCl and repeat the assay. Multiply the result by the dilution factor.

Specificity / Interferences

Haemoglobin up to 0.16~g/dl, ascorbate up to 62~mg/l, bilirubin up to 15~mg/dl and triglycerides up to 750~mg/dl do not interfere with the test.

Precision

Repeatability (run to run)	Mean	SD	CV
n = 20	[U/l]	[U/l]	[%]
level 1	33.86	0.26	0.77
level 2	91.44	0.46	0.50

Reproducibility (day to day)	Mean	SD	CV
n = 80	[U/l]	[U/l]	[%]
level 1	38.69	0.57	1.46
level 2	95.29	1.24	1.30

Method comparison

A comparison between lipase activity at Olympus AU400 (y) and at Cobas Integra 400 (x) using 25 samples gave following results: y = 0.8595 x + 6.8263 U/l;

y = 0.8595 x + 6.8263 U/13R = 0.9967

(R – correlation coefficient)

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.
- Steinberg WM, Goldstein SS, Davies ND et al. Diagnostic assays in acute pancreatitis. (Review). Ann Intern Med 1985; 102:576-580
- Leybold A, Junge W. Importance of colipase for the measurement of serum lipase activity. Adv clin Enzymol 1986;4:60-67.
- Alan H. B. Wu, Tietz Clinical Guide to Laboratory Tests, W.B. Saunders Company, 4th edition, 676 (2006).

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MANUFACTURER

PZ CORMAY S.A.

22 Wiosenna Street, 05-092 Łomianki, POLAND tel.: +48 (0) 22 751 79 10 fax: +48 (0) 22 751 79 14 http://www.cormay.pl