Cat. No 4-556

DIAGNOSTIC KIT FOR DETERMINATION OF LIPASE ACTIVITY

HC – 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	4 x 88 ml
2-Reagent	4 x 49 ml

The reagents when stored at 2-8°C are stable up to expiry date printed on the package. The reagents are stable for 11 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-aminopropanesulfonic acid]	100 mM
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-(6'-methylresorufin)-ester]	0.4 mM

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 2-8ºC or 24 hours at 20-25ºC.
Nevertheless it is recommended to perform the assay with freshly collected samples!

PROCEDURE

The reagents are ready to use.
These reagents may be used in automatic analyser Hitachi 911/912.
Application should be entered using handheld barcode scanner and attached barcodes sheet, according to procedure described below:

1. Delete previous version of application and calibrators assigned to it and restart the analyser.
2. Enter codes of calibrators according to the attached list.
3. Enter barcoded application and assign proper values to calibrators.
4. To activate entered application go to the tab UTILITY | APPLICATION | RANGE and change value of field DATA MODE from INACTIVE to ON BOARD. Confirm the change using UPDATE button.
5. Put reagents on board the analyser – they will be assigned to relevant tests automatically. Perform also measurement of level of reagents inside the bottles.
6. After calibration analyser is ready to use.

REFERENCE VALUES [4]

Normal range	13 – 60 U/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) is recommended. Calibrator and 0.9% NaCl should be used for calibration.
The calibration curve should be prepared every 11 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 analysers Hitachi 912. Results may vary if a different instrument is used.

- **Sensitivity:** 7.46 U/l (0.13 µkatal/l).
- **Linearity:** up to 900 U/l (15.03 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) n = 20	Mean [U/l]	SD [U/l]	CV [%]
level 1	32.95	0.38	1.15
level 2	93.21	0.56	0.60

Reproducibility (day to day) n = 80	Mean [U/l]	SD [U/l]	CV [%]
level 1	37.81	1.25	3.30
level 2	92.80	3.39	3.66

- **Method comparison**

A comparison between lipase activity at Hitachi 912 (y) and at Cobas Integra 400 (x) using 43 samples gave following results:
y = 1.0596 x - 6.4628 U/l;
R = 0.9978 (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.
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 lipase activity. Adv clin Enzymol 1986;4:60-67.
4. 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

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