Cat. No 9-426

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-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
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.

APPLICATION
Reagent ID: **030**

Specific Test Parameters — General | LIH | ISE | Range

Test name: **LIPA** Type: **Serum** Operation: **Yes**

Sample: Volume	2	µL	Dilution	10	µL	Pre-Dilution Rate:	1	
Reagents: R1 Volume	135	µL	Dilution	0	µL	Min OD	Max OD	
R2 Volume	65	µL	Dilution	0	µL	L -2.0000	H 2.5000	
						Reagent OD Limit:		
Wavelength: Pri.	570		Sec.	700		First L -2.0000	First H 2.5000	
Method:	RATE					Last L -2.0000	Last H 2.5000	
Reaction Slope:	+					Dynamic Range:		
Measuring Point 1: First	13		Last	19		L 10.70	H 520	
Measuring Point 2: First			Last			Correlation Factor:		
Linearity:	15	%				A 1.000	B 0.000	
No-Lag-Time:						On-board Stability Period:	84	

Specific Test Parameters — General | LIH | ISE | Range

Test name: **LIPA** Type: **Serum**

Value/Flag: # Level L: # Level H: #

Normal Ranges:

	Sex	Age L Year	Age L Month	Age H Year	Age H Month	L	H
1.	#	#	#	#	#	#	#
2.	#	#	#	#	#	#	#
3.	#	#	#	#	#	#	#
4.	#	#	#	#	#	#	#
5.	#	#	#	#	#	#	#
6.	#	#	#	#	#	#	#
7. None Selected						#	#
8 Out of Range						#	#

Panic Value: L # H # Unit: **U/l** Decimal Places: **2**

Calibration Specific — General | ISE

Test name: **LIPA** Type: **Serum**

Calibration Type: **2AB** Formula: **Polygonal** Counts: **3** Process: **CONC**

	Cal. No.	OD	CONC	Factor/OD-L	Factor/OD-H
Point 1:	#		*	-2.0000	2.5000
Point 2:	#		*	-2.0000	2.5000
Point 3:					
Point 4:					
Point 5:					
Point 6:					
Point 7:					

1-Point Cal.Point: with CONC-0 Slope Check: **None** Advanced Calibration: #

MB Type Factor: Calibration Stability Period: **56**

\# User defined
* Calibrator value

REFERENCE VALUES [4]

Normal range	13 – 60 U/l	0.22 – 1.00 µkat/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) n = 20	Mean [U/l]	SD [U/l]	CV [%]
level 1	33.86	0.26	0.77
level 2	91.44	0.46	0.50

Reproducibility (day to day) n = 80	Mean [U/l]	SD [U/l]	CV [%]
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;
R = 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.
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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