BioMajesty®

Lipase DC* FS**

Order Information

Cat. No. | **Kit size**

1 4321 9910 962 | Σ 1890 (R1: 6 x 315, R2: 6 x 315)

Intended Use

Diagnostic reagent for quantitative in vitro determination of lipase in human serum or heparin plasma on automated BioMajesty® JCA-BM6010/C.

Summary

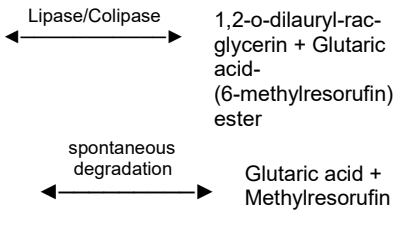
Lipases are enzymes which hydrolyze glycerol esters of long fatty acids. The enzyme and its cofactor colipase are produced in the pancreas, lipase being also secreted in small amounts by the salivary glands as well as by gastric, pulmonary and intestinal mucosa. Bile acids and colipase form micellar 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, lipase concentrations rise to 2 – 50 fold the upper reference limit within 4 – 8 hours after the beginning of abdominal pain peaking at 24 hours and decrease within 8 to 14 days. Elevated lipase values may also be observed in chronic pancreatitis and obstruction of the pancreatic duct. [1,2,3,4]

Method

Enzymatic color test

A synthetically produced lipase substrate (1,2-o-dilauryl-rac-glycero-3-glutaric acid-(6-methylresorufin) ester) is added to a micro-emulsion which is specifically split by lipase in the presence of colipase and bile acids. The combination of lipase and bile acids make this specific and reliable for pancreatic lipase without any reaction due to lipolytic enzymes or esterases. The reagent composition has been thoroughly optimized to avoid serum matrix effects. The generated methylresorufin ester is spontaneously degraded to methylresorufin. The absorbance by this red dye is directly proportional to the lipase activity in the sample. [5,6,7]

Lipase catalyses the reaction:



The increase in absorbance is measured photometrically.

Reagents

Components and Concentrations

R1:	Good's buffer	pH 8.0	50 mmol/L
	Taurodesoxycholate		4.3 mmol/L
	Desoxycholate		8.0 mmol/L
	Calcium chloride		15 mmol//L
	Colipase (porcine)		2.2 mg/L
R2:	Tartrate buffer	pH 4.0	7.5 mmol/L
	Taurodesoxycholate		17.2 mmol/L
	Color substrate		≤ 0.65 mmol/L

Storage and Stability

Reagents are stable up to the date of expiry indicated on the kit, if stored at 2 – 8°C and contamination is avoided. Do not freeze and protect from light.

Note: A slight apparent red precipitate may occur in reagent 2, which does not affect the performance of the test. Please do not resuspend before use.

Warnings and Precautions

1. ⚠ Reagent 2: Warning. H319 Causes serious eye irritation. P280 Wear protective gloves/protective clothing/eye protection. P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313 If eye irritation persists: Get medical advice/attention.
2. Reagent 1 contains sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
3. Reagent 1 contains animal material. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
4. Many other clinical reagents contain lipase or high detergent concentrations. Avoid contamination and carry over! Only use thoroughly cleaned cuvettes for lipase determination. Take special care in combination with triglycerides, HDL and LDL reagents. The contamination pairs should be programmed in the "Contamination Set" analyzer window.
5. In very rare cases, samples of patients with gammopathy might give falsified results [8].
6. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
7. For professional use only.

Waste Management

Refer to local legal requirements.

Reagent Preparation

The reagents are ready to use. The bottles are placed directly into the reagent rotor.

Materials Required

General laboratory equipment

Specimen

Human serum or heparin plasma

Stability [9]:

7 days	at	20 – 25°C
7 days	at	4 – 8°C
1 year	at	–20°C

Only freeze once. Discard contaminated specimens.

Calibrators and Controls

DiaSys TruCal U is recommended for calibration. Calibrator values have been made traceable to the molar extinction coefficient of an available measuring method. Use DiaSys TruLab N and P for internal quality control. Use of human based controls is strictly recommended. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruCal U	5 9100 99 10 063	20 x 3 mL
	5 9100 99 10 064	6 x 3 mL
TruLab N	5 9000 99 10 062	20 x 5 mL
	5 9000 99 10 061	6 x 5 mL
TruLab P	5 9050 99 10 062	20 x 5 mL
	5 9050 99 10 061	6 x 5 mL

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Performance Characteristics

Exemplary data mentioned below may slightly differ in case of deviating measurement conditions.

Measuring range up to 300 U/L. In case of higher activities re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.	
Limit of detection***	5 U/L
Onboard stability	12 weeks
Calibration stability	12 weeks

Interfering substance	**Interferences ≤ 10% up to**	**Analyte concentration [U/L]**
Ascorbic acid	60 mg/dL	38.7
	60 mg/dL	112
Bilirubin (conjugated)	60 mg/dL	40.1
	60 mg/dL	110
Bilirubin (unconjugated)	70 mg/dL	39.2
	70 mg/dL	110
Hemoglobin	600 mg/dL	40.7
	600 mg/dL	116
Lipemia (triglycerides)	2000 mg/dL	42.3
	2000 mg/dL	129
N-acetylcysteine (NAC)	2000 mg/L	39.2
	2000 mg/L	107
For further information on interfering substances refer to Young DS [10,11].		

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	30.9	60.9	286
CV [%]	1.26	0.611	0.263
Total Precision CLSI (n=80)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	30.2	59.9	284
CV [%]	2.01	1.20	1.10

Method comparison (n=107)	
Test x	Competitor Lipase (cobas c 311)
Test y	DiaSys Lipase DC FS (BioMajesty® JCA-BM6010C)
Slope	0.982
Intercept	–0.168 U/L
Coefficient of correlation	0.999

*** according to CLSI document EP17-A2, Vol. 32, No. 8

Conversion Factor
Lipase [U/L] x 0.0167 = Lipase [µkat/L]

Reference Range [12]

≤ 60 U/L ≤ 1.00 µkat/L

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Literature

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IVD CE

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* Direct Color

** Fluid Stable

BioMajesty

Lipase DC FS

Chemistry code 10 432

Application for serum, plasma samples

This application was set up and evaluated by DiaSys. It is based on the standard equipment at that time and does not apply to any equipment modifications undertaken by unqualified personnel.

Analytical Conditions	
R1 volume	80
R2e volume	0
R2 volume	20
R1 diluent vol	0
R2e diluent vol	0
R2 diluent vol	0
Sample vol (S)	2
Sample vol (U)	2
Reagent 1 mix	weak
Reagent 2e mix	weak
Reagent 2 mix	weak
Reaction time	10

Sub-analy. Conditions	
Name	LPS
Digits	2
M-wave L.	571
S-wave.L	805
Analy.mthd.	RRA
Calc.mthd.	STD
Qualit. judge	No

Analysis Test Condition Setting (M)		
Sample Type	**Serum**	**Urine**
Reac. sample vol.	2	2
Diluent method	No dil	No dil
Undil. sample vol.	0	0
Diluent volume	0	0
Diluent position	0	0

entered by user

Endpoint method	
Re.absorb (u)	9.999
Re. Absorb (d)	-9.999

Calculation Method Setting	
M-DET.P.I	21
M-DET.P.m	25
M-DET.P.n	30
S-DET.P.p	0
S-DET.P.r	0
Check D.P.I.	21
Limit value	0,003
Variance	10
Reac.type	Inc

Reaction Rate Method	
Cycle	2
Factor	2
E2 corre	Do
Blank (u)	9.999
Blank (d)	-9.999
Sample (u)	0.9
Sample (d)	-9.999

Standards Setting	
FV	#
BLK H	9.999
BLK L	-9.999
STD H	9.999
STD L	-9.999