respons®910

Lipase DC* FS**

Order Information

Cat. No.	Kit size
1 4321 99 10 921	Σ 480 (4 x 120)

Intended Use

Diagnostic reagent for quantitative in vitro determination of lipase in human serum or heparin plasma on automated DiaSys respons®910.

Summary

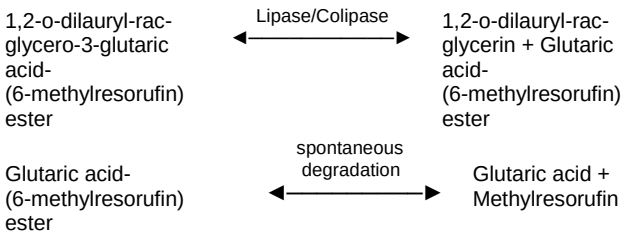
Lipases are enzymes which hydrolyze glycerol esters of long fatty acids. The enzyme and its cofactor colipase are produced in the pancreas, lipase being also secreted in small amounts by the salivary glands as well as by gastric, pulmonary and intestinal mucosa. Bile acids and colipase form micellar 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. In very rare cases, samples of patients with gammopathy might give falsified results [8].
5. 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.
6. 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

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	6 weeks
Calibration stability	2 weeks

Interfering substance	Interferences ≤ 10% up to	Analyte concentration [U/L]
Ascorbic acid	60 mg/dL	41.6
	60 mg/dL	129
Bilirubin (conjugated)	60 mg/dL	52.5
	60 mg/dL	146
Bilirubin (unconjugated)	70 mg/dL	52.5
	70 mg/dL	153
Hemoglobin	600 mg/dL	48.4
	600 mg/dL	145
Lipemia (triglycerides)	2000 mg/dL	41.7
	2000 mg/dL	100
N-acetylcysteine (NAC)	2000 mg/L	64.2
	2000 mg/L	156
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]	35.1	65.6	290
CV [%]	2.27	2.11	2.37
Total Precision CLSI (n=80)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	32.5	62.4	289
CV [%]	4.36	3.88	3.39

Method comparison (n=107)	
Test x	Competitor Lipase (cobas c 311)
Test y	DiaSys Lipase DC FS (respons®910)
Slope	0.975
Intercept	–0.321 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

1. Lorentz K. Lipase. In: Thomas L, editor. Clinical laboratory diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 95-7.
2. Moss DW, Henderson AR. Digestive enzymes of pancreatic origin. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999. p. 689–708.
3. Tietz N, Shuey DF. Lipase in serum – the elusive enzyme: an overview. Clin Chem 1993; 39: 746-56.
4. Lott J, Patel ST, Sawhney AK, Kazmierczak SC, Love JE. Assays of serum lipase: analytical and clinical considerations. Clin Chem 1986; 32: 1290–1302.
5. Leybold A, Junge W. Importance of colipase for the measurement of serum lipase activity. Adv Clin Enzymol 1986;4: 60-7.
6. Borgström B. The action of bile salts and other detergents on pancreatic lipase and the interaction with colipase. Biochimica et Biophysika Acta 1977; 488: 381-91.
7. Gargouri Y, Julien R, Bois A, Verger R, Sarda L. Studies on the detergent inhibition of pancreatic lipase activity. J of Lipid Research 1983; 24: 1336-42.
8. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: Mechanism, detection and prevention. Clin Chem Lab Med 2007; 45(9): 1240–1243.
9. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 36-7.
10. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press 2000.
11. Young DS. Effects on Clinical Laboratory Tests - Drugs Disease, Herbs & Natural Products, https://clinfx.wiley.com/aaccweb/aacc/, accessed in August 2021. Published by AACC Press and John Wiley and Sons, Inc.
12. Junge W, Abicht K, Goldman J. Evaluation of the colorimetric liquid assay for pancreatic lipase on Hitachi analyzers in 7 clinical centres in Europe. Clin Chem Lab Med 1999; 37, Special suppl: 469.

IVD CE

DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim
Germany
www.diasys-diagnostics.com

* Direct Color

** Fluid Stable

respons®910

Lipase DC FS

Application for serum and 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.

Identification	
This method is usable for analysis:	Yes
Twin reaction:	No
Name:	LPS
Shortcut:	
Reagent barcode reference:	046
Host reference:	

Technic	
Type:	Linear kinetic
First reagent:[µL]	160
Blank reagent	Yes
Sensitive to light	
Second reagent:[µL]	40
Blank reagent	No
Sensitive to light	
Main wavelength:[nm]	570
Secondary wavelength:[nm]	700
Polychromatic factor:	1.000
1 st reading time [min:sec]	6:12
Last reading time [min:sec]	7:12
Reaction way:	Increasing
Linear Kinetics Substrate depletion: Absorbance li	0.6000
Linearity: Maximum deviation [%]	100
Fixed Time Kinetics Substrate depletion: Absorbance limit	
Endpoint Stability: Largest remaining slope	
Prozone Limit [%]	

Reagents	
Decimals	
Units	

Sample	
Diluent	DIL A (NaCl)
Hemolysis:	
Agent [µL]	0 (no hemolysis)
Cleaner	
Sample [µL]	0
Technical limits	
Concentration technical limits-Lower	4
Concentration technical limits-Upper	300
SERUM	
Normal volume [µL]	4
Normal dilution (factor)	1
Below normal volume [µL]	8
Below normal dilution (factor)	1
Above normal volume [µL]	4
Above normal dilution (factor)	6
URIN	
Normal volume [µL]	4
Normal dilution (factor)	1
Below normal volume [µL]	8
Below normal dilution (factor)	1
Above normal volume [µL]	4
Above normal dilution (factor)	6
PLASMA	
Normal volume [µL]	4
Normal dilution (factor)	1
Below normal volume [µL]	8
Below normal dilution (factor)	1
Above normal volume [µL]	4
Above normal dilution (factor)	6
CSF	
Normal volume [µL]	4
Normal dilution (factor)	1
Below normal volume[µL]	8
Below normal dilution (factor)	1
Above normal volume [µL]	4
Above normal dilution (factor)	6
Whole blood	
Normal volume [µL]	4
Normal dilution (factor)	1
Below normal volume[µL]	8
Below normal dilution (factor)	1
Above normal volume [µL]	4
Above normal dilution (factor)	6

Results	
Decimals	1
Units	U/L
Correlation factor-Offset	0.000
Correlation factor-Slope	1.000

Range	
Gender	All
Age	
SERUM	>= <=60
URINE	
PLASMA	>= <=60
CSF	
Whole blood	
Gender	
Age	
SERUM	
URINE	
PLASMA	
CSF	
Whole blood	

Contaminants
Please refer to r910 Carryover Pair Table

Calibrators details	
Calibrator list	**Concentration**
Cal. 1/Blank	0
Cal. 2	*
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
	Max delta abs.
Cal. 1	0.1000
Cal. 2	0.1000
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
Drift limit [%]	0.8

Calculations	
Model	X
Degree	1

* Enter calibrator value