respons®920

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®920.

Summary

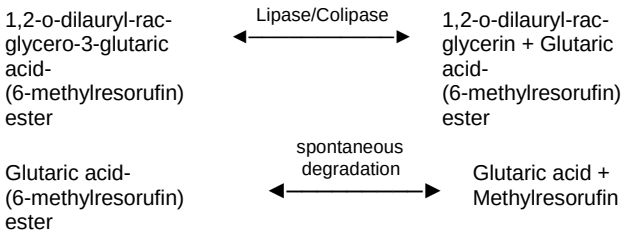
Lipases are enzymes which hydrolyze glycerol esters of long fatty acids. The enzyme and its cofactor colipase are produced in the pancreas, lipase being also secreted in small amounts by the salivary glands as well as by gastric, pulmonary and intestinal mucosa. Bile acids and colipase form micellar 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. To avoid carryover interference, please take care of efficient washing especially after use of interfering reagents. Please refer to the DiaSys respons®920 Carryover Pair Table. Carryover pairs and automated washing steps with the recommended cleaning solution can be specified in the system software. Please refer to the user manual.
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

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	9 weeks

Interfering substance	Interferences ≤ 10% up to	Analyte concentration [U/L]
Ascorbic acid	60 mg/dL	41.7
	60 mg/dL	129
Bilirubin (conjugated)	60 mg/dL	51.7
	60 mg/dL	152
Bilirubin (unconjugated)	70 mg/dL	48.3
	70 mg/dL	150
Hemoglobin	600 mg/dL	49.6
	600 mg/dL	129
Lipemia (triglycerides)	2000 mg/dL	57.5
	2000 mg/dL	106
N-acetylcysteine (NAC)	2000 mg/L	57.2
	2000 mg/L	147

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]	31.9	63.1	286
CV [%]	1.87	0.691	1.10
Total Precision CLSI (n=80)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	31.0	60.6	285
CV [%]	2.74	1.89	1.59

Method comparison (n=107)	
Test x	Competitor Lipase (cobas c 311)
Test y	DiaSys Lipase DC FS (respons®920)
Slope	0.975
Intercept	–0.047 U/L
Coefficient of correlation	0.998

*** 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

Lipase DC FS

Application for serum and plasma

Test Details		Test Volumes		Reference Ranges	
Test : LPS				Auto Rerun	☐
Report Name : Lipase				Online Calibration	☐
Unit : U/L	Decimal Places : 1			Cuvette Wash	☐
Wavelength-Primary : 578	Secondary : 700			Total Reagents : 2	
Assay Type : RATE - A	Curve Type : Linear			Reagent R1 : LPS R1	
M1 Start : 0	M1 End : 0			Reagent R2 : LPS R2	
M2 Start : 22	M2 End : 25				
Sample Replicates : 1	Standard Replicates : 3			Consumables/Calibrators:	
Control Replicates : 1	Control Interval : 0			Blank/Level 0 : *	
Reaction Direction : Increasing	React. Abs. Limit : 1.50			Calibrator 1 : *	
Prozone Limit % : 0	Prozone Check : Lower				
Linearity Limit % : 0	Delta Abs./Min. : 0.00				
Technical Minimum : 3.00	Technical Maximum : 300.00				
Y = aX + b a= : 1.00	b= : 0.00				

Enter calibrator value.

Test Details		Test Volumes		Reference Ranges
Test : LPS				
Sample Type : Serum				

Sample Volumes

Normal :	4.00 µL	Dilution Ratio :	1 X
Increase :	8.00 µL	Dilution Ratio :	1 X
Decrease :	2.00 µL	Dilution Ratio :	1 X
Standard Volume :	4.00 µL		

Reagent Volumes and Stirrer Speed

RGT-1 Volume :	160 µL	R1 Stirrer Speed :	Medium
RGT-2 Volume :	40 µL	R2 Stirrer Speed :	High

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other

Test Details		Test Volumes		Reference Ranges
Test : LPS				
Sample Type : Serum				
Reference Range : DEFAULT				
Category : Male				

Reference Range

	Lower Limit (U/L)	Upper Limit (U/L)
Normal :	0.00	60.00
Panic :	0.00	0.00

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other