respons®910

Lipase DC* FS**

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

Order Information

Cat. No. 1 4321 99 10 921
4 twin containers for 120 tests each

Method

Enzymatic color test
A synthetically produced lipase substrate (1,2-o-dilauryl-rac-glycero-3-glutaric acid-(6-methylresorufin) ester) in a micro-emulsion 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 so there are no 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.

Principle

Lipase catalyzes the reaction:

1,2-o-Dilauryl-rac-glycero-3-glutaric acid(6-methylresorufin) ester

Lipase / Colipase ⟷

1,2-o-Dilauryl-rac-glycerin + Glutaric acid-(6-methylresorufin)-ester

Glutaric acid-(6-methylresorufin)-ester ⟷ (spontaneous degradation)

Glutaric acid + Methylresorufin

The increase in absorbance is measured photometrically.

Reagents

Components and Concentrations

R1:	Goods buffer	pH 8.0	50 mmol/L
	Taurodesoxycholate		4.3 mmol/L
	Desoxycholate		8.0 mmol/L
	Calcium chloride		15 mmol/L
	Colipase		2.2 mg/L
	Detergent, preservative		
R2:	Tartrate buffer	pH 4.0	7.5 mmol/L
	Taurodesoxycholate		17.2 mmol/L
	Color substrate		0.65 mmol/L
	Coemulgator, stabilizer, preservative		

Storage Instructions and Reagent Stability

The reagents are stable up to the end of the indicated month of expiry, if stored at 2 – 8 °C and contamination is avoided. Do not freeze the reagents and protect them from direct sunlight. DiaSys respons containers provide protection from light.

Warnings and Precautions

1. In very rare cases, samples of patients with gammopathy might give falsified results.
2. 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.

Waste Management

Please refer to local legal requirements.

Reagent Preparation

The reagents are ready to use. The bottles are placed directly into the reagent rotor. Do not shake!

Specimen

Serum or heparin plasma

Stability [1]:

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

Discard contaminated specimens. Freeze only once.

Calibrators and Controls

For calibration, DiaSys TruCal U calibrator is recommended. The assigned values of the calibrator have been made traceable to the molar extinctioncoefficient of an available measuring method. For internal quality control DiaSys TruLab N and P controls should be assayed. 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

Measuring range up to 300 U/L lipase (in case of higher activities re-measure samples after manual dilution or use rerun function)	
Limit of detection***	4 U/L lipase
On-board stability	6 weeks
Calibration stability	7 days

Interfering substance	**Interferences < 10%**	**Lipase [U/L]**
Ascorbate	up to 30 mg/dL	127
Hemoglobin	up to 550 mg/dL	54.8
	up to 550 mg/dL	115
Bilirubin, conjugated	up to 60 mg/dL	54.7
	up to 60 mg/dL	132
Bilirubin, unconjugated	up to 70 mg/dL	54.6
	up to 70 mg/dL	131
Lipemia (triglycerides)	up to 2000 mg/dL	51.2
	up to 2000 mg/dL	89.4
For further information on interfering substances refer to Young DS [2].		

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	46.3	60.5	96.5
Coefficient of variation [%]	2.17	1.99	2.23
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	43.0	49.1	94.2
Coefficient of variation [%]	4.56	4.97	2.20

Method comparison (n=110)	
Test x	DiaSys Lipase DC FS (Hitachi 917)
Test y	DiaSys Lipase DC FS (respons®910)
Slope	1.007
Intercept	1.86 U/L
Coefficient of correlation	0.998

*** according to NCCLS document EP17-A, vol. 24, no. 34

Conversion factor

Lipase [U/L] x 0,0167= Lipase [µkat/L]

Reference Range [3]

≤ 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.

* direct color
** fluid stable

Literature

1. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 36-7.
2. 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.
3. 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.
4. Lorentz K. Lipase. In: Thomas L, editor. Clinical laboratory diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 95-7.
5. 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.
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7. Lott J, Patel ST, Sawhney AK, Kazmierczak SC, Love JE. Assays of serum lipase: analytical and clinical considerations. Clin Chem 1986; 32: 1290-1302.
8. Leybold A, Junge W. Importance of colipase for the measurement of serum lipase activity. Adv Clin Enzymol 1986; 4: 60-7.
9. 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.
10. 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.

Manufacturer

IVD CE

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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
Name:	LPS
Shortcut:	
Reagent barcode reference:	046
Host reference:	

Technic	
Type:	Linear Kinetic
First reagent:[µL]	160
Blanc correction	Yes
Second reagent:[µL]	40
Blanc correction	Yes
Main wavelength:[nm]	570
Secondary wavelength:[nm]	700
Polychromatic factor:	1.000
1 st reading time [min:sec]	7:00
Last reading time [min:sec]	8:24
Reaction way:	Increasing
Linear Kinetics Substrate deplation: absorbance limit	0.6
Linearity: Maximum deviation [%]	100
Fixed Time Kinetics Substrate deplation: absorbance limit	
Endpoint Stability: largest remaining slope	
Prozone Limit [%]	

Sample	
Diluent	NaCl
Concentration technical limits-Lower	4
Concentration technical limits-Upper	300
SERUM	
Normal volume [µL]	4
Normal dilution (factor)	3
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

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

Range	
Genre	All
Age	
SERUM	>= <=60
URINE	
PLASMA	>= <=60
CSF	
Genre	
Age	
SERUM	
URINE	
PLASMA	
CSF	

Contaminants	
Contaminant 1	CHOL/TRIG
Wash with	CLN A
Cycle	1
Volume [µL]	250
Contaminant 2	HDL/LDL
Wash with	CLN A
Cycle	1
Volume [µL]	250

Calibrators details	
Calibrator list	**Concentration**
Cal. 1	0
Cal. 2	*
Cal. 3	*
Cal. 4	*
Cal. 5	*
Cal. 6	*
	Max delta abs.
Cal. 1	0.015
Cal. 2	0.010
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
Drift limit [%]	0.8
Calculations	
Model	X degree
Degree	1

* Enter calibrator value