

Lipase DC* FS**

Order Information

Cat. No.

1 4321 99 10 921

Kit size



480 (4 x 120)

Intended Use

Diagnostic reagent for quantitative in vitro determination of lipase activity in human serum or heparin plasma on automated respons[®]940.

Summary

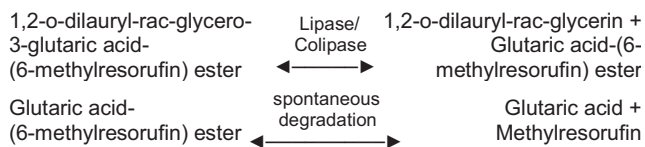
Lipases are enzymes which hydrolyze glycerol esters of long-chain fatty acids [1]. The enzyme and its cofactor colipase are produced in the pancreas [1,2], lipase being also secreted in small amounts by the salivary glands as well as by gastric, pulmonary and intestinal mucosa [2]. Bile acids and colipase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

Method

Enzymatic color test

A synthetically produced lipase substrate (1,2-o-dilauryl-rac-glycerol-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. [4-6]

Lipase catalyses the reaction:



The increase in absorbance is measured photometrically.

One unit of lipase is the amount of enzyme that converts 1.0 μmol of 1,2-o-dilauryl-racglycerol-3-glutaric acid-(6-methylresorufin) ester to 1,2-o-dilauryl-racglycerin + glutaric acid-(6-methylresorufin) ester per minute at the enzyme specific conditions.

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.

The open-vial stability of the reagent is 18 months until expiry date.

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. Components contained in Lipase DC FS are classified according to EC regulation 1272/2008 (CLP) as follows:



⚠ 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 material of biological origin. 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 [7].
5. In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
6. Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.
7. Please refer to the safety data sheets (SDS) 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.
8. For professional use only.

Waste Management

Refer to local legal requirements for chemical disposal regulations as stated in the relevant SDS to determine the safe disposal.

Warning: Handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

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

Only use suitable tubes or collection containers for specimen collection and preparation.

When using primary tubes, follow the manufacturer's instructions.

Stability [8]:

7 days	at	20 – 25°C
3 weeks	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. All target values of the controls are traceable to DiaSys reagent/calibrator system. Use of human based controls is strictly recommended. Quality control must be performed after calibration. Control intervals and limits have to be adapted to the individual requirements of each laboratory. Results must be within the defined ranges. Follow the relevant legal requirements and guidelines. 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 from 3.3 U/L up to 430 U/L. Linearity < 10 U/L is given with ± 3 U/L, between 10 U/L to 30 U/L within $\pm 10\%$, at > 30 U/L within $\pm 5\%$.
In case of higher activities re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.

Limit of detection***	3 U/L
Limit of quantitation***	3 U/L
Onboard stability	16 weeks
Calibration stability	16 weeks

Interference by	Interferences $\leq 10\%$ up to	Analyte concentration [U/L]
Ascorbic acid	36 mg/dL	51.2
	36 mg/dL	137
Bilirubin (conjugated)	73 mg/dL	53.9
	73 mg/dL	145
Bilirubin (unconjugated)	72 mg/dL	52.2
	72 mg/dL	141
Hemolysis	360 mg/dL	51.4
	1000 mg/dL	109
Lipemia (triglycerides)	2400 mg/dL	50.2
	2400 mg/dL	134

For further information on interfering substances, refer to the literature [9,10].

Precision			
Repeatability (n=20)	Sample 1	Sample 2	Sample 3
Mean [U/L]	36.5	58.1	231
CV [%]	0.783	1.54	0.471
Within-laboratory (n=80)	Sample 1	Sample 2	Sample 3
Mean [U/L]	45.8	62.7	214
CV [%]	1.67	1.31	0.954
Reproducibility (n=75, no. of instruments=3)	Sample 1	Sample 2	Sample 3
Mean [U/L]	37.8	59.0	199
CV [%]	1.95	1.50	1.07

Method comparison (n=155)	
Test x	Competitor Lipase (cobas c 501)
Test y	DiaSys Lipase DC FS (respons [®] 940)
Slope	0.977
Intercept	0.407 U/L
Coefficient of correlation	0.997

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

Conversion Factor

Lipase [U/L] x 0.0167 = Lipase [μ kat/L]

Reference Range [11]

≤ 60 U/L ≤ 1.00 μ kat/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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Additions and/or changes in the document are highlighted in grey. Deletions are communicated via customer info by stating the edition no. of the package insert/instruction for use.



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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	<input type="checkbox"/>
Report Name	: Lipase DC			Online Calibration	<input type="checkbox"/>
Unit	: U/L	Decimal Places	: 1	Cuvette Wash	<input type="checkbox"/>
Wavelength-Primary	: 570	Secondary	: 700	Special Diluent	<input type="checkbox"/>
Assay Type	: RATE-A	Curve Type	: Linear	Warn after	: 20
M1 Start	: 0	M1 End	: 0	Reagents Used	: 2
M2 Start	: 44	M2 End	: 50	Reagent R1	LPS R1
Sample Replicates	: 1	Standard Replicates	: 2	Reagent R2	LPS R2
Control Replicates	: 1	Control Interval	: 0	Consumables/Calibrators:	
Reaction Direction	: Increasing	React. Abs. Limit	: 1.4000	Blank /Level 0	0
Prozone Limit %	: 0	Prozone Check	: Lower	Calibrator 1	*
Linearity Limit %	: 0	Delta Abs./Min.	: 0.0000	Calibrator 2	
Technical Minimum	: 3.3000	Technical Maximum	: 430.0000	Calibrator 3	
Y = aX + b a=	: 1.0000	b=	: 0.0000	Calibrator 4	
Reagent Abs Min	: 0.0000	Reagent Abs Max	: 0.0000	Calibrator 5	

Test Details		Test Volumes		Reference Ranges	
Test	: LPS				
Sample Type	: Serum				
Sample Volumes				Sample Types	
Normal	: 4.00 μ L	Dilution Ratio	: 1 X	<input checked="" type="checkbox"/> Serum <input type="checkbox"/> Urine <input type="checkbox"/> CSF <input checked="" type="checkbox"/> Plasma <input type="checkbox"/> Whole Blood <input type="checkbox"/> Other	
Increase	: 8.00 μ L	Dilution Ratio	: 1 X		
Decrease	: 2.00 μ L	Dilution Ratio	: 1 X		
Standard Volume	: 4.00 μ L				
Reagent Volumes and Stirrer Speed					
RGT-1 Volume	: 160.00 μ L	R1 Stirrer Speed	: Medium		
RGT-2 Volume	: 40.00 μ L	R2 Stirrer Speed	: High		

Test Details		Test Volumes		Reference Ranges	
Test	: LPS				
Sample Type	: Serum				
Reference Range	: DEFAULT				
Category	: Male				
Reference Range				Sample Types	
	Lower Limit (U/L)	Upper Limit (U/L)			
Normal	: #	: #	<input checked="" type="checkbox"/> Serum <input type="checkbox"/> Urine <input type="checkbox"/> CSF <input checked="" type="checkbox"/> Plasma <input type="checkbox"/> Whole Blood <input type="checkbox"/> Other		
Panic	: #	: #			

* Enter calibrator value
Editable by user