

Lipase DC* FS**

Diagnostic reagent for quantitative in vitro determination of lipase in serum or plasma on Sysmex BX-Series

Order Information

Cat. No.	Kit size	Number of tests
1 4321 99 10 972	R1 3 x 11.8 mL	BX-3010 3 x 90 tests BX-4000 3 x 61 tests
	R2 3 x 5.1 mL	BX-3010 3 x 90 tests BX-4000 3 x 61 tests

Method

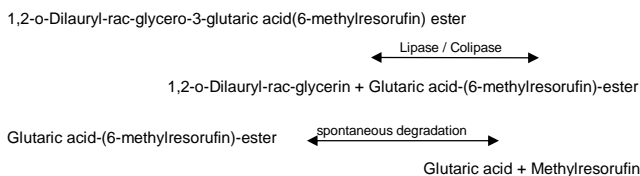
Enzymatic color test

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. This combination of lipase and bile acids is 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. [7,8,9]

Principle

Lipase catalyzes 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 (pork)		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 Instructions and Reagent Stability

The reagents are stable up to the end of the indicated month of expiry, if stored at 2 – 8°C, protected from light and contamination is avoided. Do not freeze the reagent!

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

- Reagent 2: Warning. H319 Causes serious eye irritation. P280 Wear protective gloves/protective clothing/eye protection/face 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.
- Reagent 1 contains sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
- Reagent 1 contains animal material. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practices.

- Many other clinical reagents contain lipase or high concentrations of detergents. Avoid contamination and carry over! For lipase determination thoroughly cleaned cuvettes only must be used. Special care should be taken in combination with triglycerides, HDL and LDL reagents. The contamination pairs should be programmed in the Contamination Set window of the analyzer.
- In very rare cases, samples of patients with gammopathy might give falsified results [11].
- 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.
- For professional use only!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

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

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. Only freeze once!

Calibrators and Controls

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

Measuring range up to 300 U/L (5 µkat/L) lipase (in case of higher activities re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function)	
Limit of detection***	1 U/L (0.017 µkat/L) lipase
On-board stability	6 weeks
Calibration stability	6 weeks

*** lowest measurable activity which can be distinguished from zero mean + 3 SD (n=20) of an analyte free specimen

Interfering substance	Interferences < 10%	Analyte concentration
Ascorbate	up to 30 mg/dL	33.2 U/L (0.553 µkat/L)
Hemoglobin	up to 500 mg/dL	32.9 U/L (0.548 µkat/L)
Bilirubin, conjugated	up to 60 mg/dL	32.4 U/L (0.540 µkat/L)
Bilirubin, unconjugated	up to 60 mg/dL	57.4 U/L (0.957 µkat/L)
Lipemia (triglycerides)	up to 2000 mg/dL	55.1 U/L (0.918 µkat/L)

For further information on interfering substances refer to Young DS [10].

Precision BX-4000			
Within run (n=20)	Sample 1	Sample 2	Sample 3
Mean [U/L]	47.8	86.6	231
Mean [μ kat/L]	0.797	1.45	3.86
Coefficient of variation [%]	1.08	0.880	1.22
Between run (n=20)	Sample 1	Sample 2	Sample 3
Mean [U/L]	42.3	75.8	156
Mean [μ kat/L]	0.705	1.27	2.61
Coefficient of variation [%]	1.43	2.37	2.64

Method comparison (n=113)	
Test x	DiaSys Lipase DC FS (BioMajesty 6010C)
Test y	DiaSys Lipase DC FS (BX-4000)
Slope	1.01
Intercept	0.219 U/L (-0.004 μ kat/L)
Coefficient of correlation	0.999

Conversion factor

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

Reference Range [2]

≤ 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

- Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 36-7.
- 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.
- Lorentz K. Lipase. In: Thomas L, editor. Clinical laboratory diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 95-7.
- 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.
- Tietz N, Shuey DF. Lipase in serum – the elusive enzyme: an overview. Clin Chem 1993; 39: 746-56.
- Lott J, Patel ST, Sawhney AK, Kazmierczak SC, Love JE. Assays of serum lipase: analytical and clinical considerations. Clin Chem 1986; 32: 1290-1302.
- Leybold A, Junge W. Importance of colipase for the measurement of serum lipase activity. Adv Clin Enzymol 1986; 4: 60-7.
- Borgström B. The action of bile salts and other detergents on pancreatic lipase and the interaction with colipase. Biochimica et Biophysica Acta 1977; 488: 381-91.
- 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.
- 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.
- Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: Mechanism, detection and prevention. Clin Chem Lab Med 2007; 45(9): 1240–1243.

Manufacturer



DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany

Chemistry Parameters 1		Sysmex BX-3010 Chemistry Analyzer Analytical Parameters					
Method No.	<input type="text" value="*"/>	Method Name	<input type="text" value="LIP"/>	Reagent Name	Reagent (µL)	Water (µL)	
Print Name	<input type="text" value="Lipase"/>	MethodColor		R1	<input type="text" value="LIP"/>	<input type="text" value="100"/>	
Sample Type	<input type="text" value="Serum"/>			R2	<input type="text" value="LIP"/>	<input type="text" value="25"/>	
Unit	<input type="text" value="U/L"/>			Diluent	<input type="text" value="Disable"/>		
Assay Type	<input type="text" value="Rate"/>			Sample Ppt. Wash	<input type="text" value="Disable"/>		
Measuring points		Start	End	Stirring Speed R1	<input type="text" value="Middle"/>	R2 <input type="text" value="Middle"/>	
		1	<input type="text" value="33"/> - <input type="text" value="39"/>				
		2	<input type="text" value="Disable"/> - <input type="text" value=""/>				
Wave Length	Prim. <input type="text" value="570"/>	Sec. <input type="text" value="800"/>					
				Normal Range			
				No.	Normal Range Name	Min	Max
				1	Male-G1	*	*
				2	Male-G2	*	*
				3	Male-G3	*	*
				4	Female-G1	*	*
Normal	Sample Volume (µL)	Diluted Sample (µL)	Diluent (µL)	Technical Range			
	Low <input type="text" value="0.0"/> < Normal <input type="text" value="2.5"/> < High <input type="text" value="0.0"/>			(Conc)	<input type="text" value="1"/> - <input type="text" value="300"/>		
<input type="checkbox"/> Diluent				(mAbs/10)	<input type="text" value="*"/> - <input type="text" value="*"/>		
	Rerun (High/Prozone)			Previous Result Comparison (%)	<input type="text" value="*"/> - <input type="text" value="*"/>	%	
<input type="checkbox"/> Diluent	<input type="text" value="0.0"/> < <input type="text" value="2.5"/> < <input type="text" value="0.0"/>			Abnormal Range	<input type="text" value="*"/> - <input type="text" value="*"/>		
	Rerun (Low)			Panic Range	<input type="text" value="*"/> - <input type="text" value="*"/>		
<input type="checkbox"/> Diluent	<input type="text" value="0.0"/> < <input type="text" value="2.5"/> < <input type="text" value="0.0"/>			Decimal Point	<input type="text" value="0"/>	Profile SI <input type="text" value="Disable"/>	

*Entered by user

Chemistry Parameters 2		Sysmex BX-3010 Chemistry Analyzer Analytical Parameters	
Method No.	<input type="text" value="*"/>	Method Name	<input type="text" value="LIP"/>
		Sample	<input type="text" value="Serum"/>
Limit Checks		Blank measurement	
<input checked="" type="checkbox"/> Duplicate Limit	<input type="text" value="50"/> mAbs/10	Blank measurement:	<input type="text" value="Disable reagent blank and C1 blank"/>
<input checked="" type="checkbox"/> Sensitivity Limit	<input type="text" value="500"/> mAbs/10	Measurement of Reagent Blank during Run:	<input type="text" value="None"/>
<input checked="" type="checkbox"/> Linearity Limit	<input type="text" value="10"/> %	Reagent blank measurement at calibration:	<input type="text" value="Reagent blank (No sample)"/>
	<input type="text" value="200"/> (mAbs/10)/min	The number of measurement:	<input type="text" value="Duplicate"/>
<input type="checkbox"/> Prozone Limit	<input type="text" value="Higher"/> %	Reagent blank limit checks:	
	<input type="text" value=""/>	<input checked="" type="checkbox"/> Duplicate Limit	<input type="text" value="10"/> mAbs/10
SL1-S <input type="text" value=""/>	-	SL1-F <input type="text" value=""/>	
SL2-S <input type="text" value=""/>	-	SL2-F <input type="text" value=""/>	
Sensitivity	<input type="text" value=""/> mAbs/10	Instrument Factor	
<input checked="" type="checkbox"/> Absorbance Limit		a	<input type="text" value="1.00"/>
Abs. in reaction	<input type="text" value="Increase"/>	b	<input type="text" value="0.00"/>
Limit	<input type="text" value="15400"/> mAbs/10		

Calibration Registration

**Sysmex BX-3010 Chemistry Analyzer
Analytical Parameters**

Method No.

Method Name

Sample Type

Replication

Check Interval

Test without calibration

Calibration Type

Reagent Lot

Calibrator Name

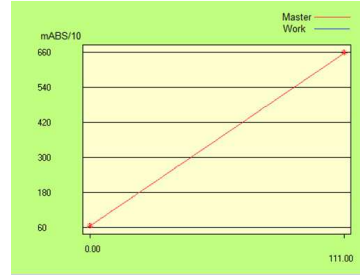
	Conc.	WORK	MASTER	Calibr. Lot No.	<input type="checkbox"/> All
C1	<input type="text" value="0"/>	Automatic entry	Automatic entry	*	
C2	*	Automatic entry	Automatic entry	*	
C3	*				
C4	*				
C5	*				
C6	*				
C7	*				

K C1 Blank
 Reagent Blank for C1

Reagent Lot No.

(R1)
 (R2)

Last



The calibration curve is lot dependent

Reagent blank mAbs/10 Last

Blank mAbs/10 Last

Calibration Curve Conc.

Absorbance mAbs/10

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Lipase DC FS

Chemistry Code 100 58

Chemistry Parameters		Sysmex BX-4000 Chemistry Analyzer Analytical Parameters																							
Method	* <input type="text"/>	Name	<input type="text" value="LIP"/>	Reagent Name	<input type="text"/>																				
Print Name	<input type="text" value="Lipase"/>	R1	<input type="text" value="LIP"/>	Reagent (µL)	<input type="text" value="152"/>																				
Sample	<input type="text" value="Serum"/>	R2	<input checked="" type="checkbox"/> Enable <input type="text" value="LIP"/>	Reagent (µL)	<input type="text" value="38"/>																				
Unit	<input type="text" value="U/L"/>	Diluent	<input type="checkbox"/> Enable <input type="text"/>	Water (µL)	<input type="text"/>																				
Assay Type	<input type="text" value="Rate"/>	Measuring points	Start	End	Decimal Points																				
		1	<input type="text" value="54"/>	-	<input type="text" value="67"/>																				
		<input type="checkbox"/> Enable 2	<input type="text"/>	-	<input type="text"/>																				
Wave Length	Prim. <input type="text" value="340"/>	Sec	<input type="checkbox"/> Disable <input type="text" value="415"/>	Normal Range																					
				<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th>No.</th> <th>Normal Range Name</th> <th>Min</th> <th>Max</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Male-G1</td> <td>*</td> <td>*</td> </tr> <tr> <td>2</td> <td>Male-G2</td> <td>*</td> <td>*</td> </tr> <tr> <td>3</td> <td>Male-G3</td> <td>*</td> <td>*</td> </tr> <tr> <td>4</td> <td>Female-G1</td> <td>*</td> <td>*</td> </tr> </tbody> </table>		No.	Normal Range Name	Min	Max	1	Male-G1	*	*	2	Male-G2	*	*	3	Male-G3	*	*	4	Female-G1	*	*
No.	Normal Range Name	Min	Max																						
1	Male-G1	*	*																						
2	Male-G2	*	*																						
3	Male-G3	*	*																						
4	Female-G1	*	*																						
Normal Dilution	<input type="checkbox"/> <input type="text" value="3.8"/>	Sampling	<input type="text"/>	Sample (µL)	<input type="text"/>																				
Rerun (High/Prozone)	<input type="checkbox"/> <input type="text" value="3.8"/>	Diluent (µL)	<input type="text"/>	Technical Range (Conc)	<input type="text" value="1"/> - <input type="text" value="300"/>																				
Rerun (Low)	<input type="checkbox"/> <input type="text" value="3.8"/>			(mAbs/10)	<input type="text"/> - <input type="text"/>																				
Dilution	<input type="checkbox"/> <input type="text" value="3.8"/>	SPT Wash	<input type="checkbox"/> Enable	Reagent Name	<input type="text"/>																				
		Stirring Speed	R1	<input type="text" value="Middle"/>	R2 <input type="text" value="Middle"/>																				

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Chemistry Parameters		Sysmex BX-4000 Chemistry Analyzer Analytical Parameters			
Method No.	* <input type="text"/>	Name	<input type="text" value="LIP"/>	Sample	<input type="text" value="Serum"/>
Limit Checks	<input checked="" type="checkbox"/> Duplicate Limit	<input type="text" value="50"/>	mAbs/10	Blank measurement	Blank measurement:
	<input checked="" type="checkbox"/> Sensitivity Limit	<input type="text" value="500"/>	mAbs/10		<input type="text" value="Disable reagent blank and S1 blank"/>
	<input checked="" type="checkbox"/> Linearity Limit	<input type="text" value="10"/>	%	Measurement of Reagent Blank during Run:	<input type="text" value="None"/>
	<input type="checkbox"/> Prozone Limit	<input type="text"/>	%	Reagent blank measurement at calibration:	<input type="text" value="Reagent blank (No sample)"/>
		SL1-S	<input type="text"/>	The number of measurement:	<input type="text" value="Duplicate"/>
			-	Reagent blank limit checks:	<input checked="" type="checkbox"/> Duplicate Limit
		SL1-F	<input type="text"/>		<input type="text" value="10"/>
		SL2-S	<input type="text"/>		mAbs/10
			-	Instrument Factor	a <input type="text" value="1.00"/>
		SL2-F	<input type="text"/>		b <input type="text" value="0.00"/>
		Sensitivity	<input type="text"/>		
		mAbs/10			
<input checked="" type="checkbox"/> Absorbance Limit	Reaction	<input type="text" value="Increase"/>	Limit	<input type="text" value="15400"/>	mAbs/10

Registration Calibration		Sysmex BX-4000 Chemistry Analyzer Analytical Parameters																																							
<p>Method <input type="text" value="*"/> Name <input type="text" value="LIP"/></p> <p>Sample <input type="text" value="Serum"/></p> <p>Sampling <input type="text" value="Duplicate"/></p> <p>Check Interval <input type="text" value="42"/> days</p> <p>Auto <input type="text" value="Change Lot"/> <input type="text" value="Full Calibration"/></p> <p>Auto Interval <input type="text"/> hours</p> <p>Type <input type="text" value="Linear"/> Lot <input type="text" value="New"/></p> <p>Material Name <input type="text" value="TruCal U"/></p> <table border="1" style="width:100%; border-collapse: collapse; margin-top: 10px;"> <thead> <tr> <th style="width:5%;"></th> <th style="width:20%;">Conc.</th> <th style="width:20%;">WORK</th> <th style="width:20%;">MASTER</th> <th style="width:35%;">Lot No. (S) <input type="checkbox"/> All</th> </tr> </thead> <tbody> <tr><td>S1</td><td><input type="text" value="0"/></td><td><small>Automatic entry</small></td><td><small>Automatic entry</small></td><td></td></tr> <tr><td>S2</td><td><input type="text" value="*"/></td><td><small>Automatic entry</small></td><td><small>Automatic entry</small></td><td></td></tr> <tr><td>S3</td><td><input type="text" value="*"/></td><td></td><td></td><td></td></tr> <tr><td>S4</td><td><input type="text" value="*"/></td><td></td><td></td><td></td></tr> <tr><td>S5</td><td><input type="text" value="*"/></td><td></td><td></td><td></td></tr> <tr><td>S6</td><td><input type="text" value="*"/></td><td></td><td></td><td></td></tr> <tr><td>S7</td><td><input type="text" value="*"/></td><td></td><td></td><td></td></tr> </tbody> </table> <p>K <input type="text" value="Automatic entry"/> <input type="checkbox"/> S1 Blank <input type="checkbox"/> Reagent Blank for S1</p>		Conc.	WORK	MASTER	Lot No. (S) <input type="checkbox"/> All	S1	<input type="text" value="0"/>	<small>Automatic entry</small>	<small>Automatic entry</small>		S2	<input type="text" value="*"/>	<small>Automatic entry</small>	<small>Automatic entry</small>		S3	<input type="text" value="*"/>				S4	<input type="text" value="*"/>				S5	<input type="text" value="*"/>				S6	<input type="text" value="*"/>				S7	<input type="text" value="*"/>				<p>R Lot No. R1 <input type="text" value="*"/> Last <input type="text"/></p> <p>R2 <input type="text" value="*"/></p> <div style="text-align: center; margin: 10px 0;"> </div> <p>The calibration curve is lot dependent</p> <p>Reagent blank <input type="text"/> mAbs/10 Last <input type="text"/></p> <p>Blank <input type="text" value="Automatic entry"/> mAbs/10 Last <input type="text"/></p> <p>Type <input type="text"/> Conc. <input type="text"/></p> <p>Absorbance <input type="text"/> mAbs/10 <input type="button" value="Recalculation"/></p>
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