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

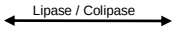
Method

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

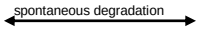
Lipase catalyzes the reaction:

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



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

Glutaric acid-(6-methylresorufin)-ester



Glutaric acid + Methylresorufin

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

1. 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.
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 practices.
4. 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.
5. In very rare cases, samples of patients with gammopathy might give falsified results [11].
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

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].		

* direct color
** fluid stable

Precision BX-4000			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	47.8	86.6	231
Mean [µkat/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 [µkat/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 µkat/L)
Coefficient of correlation	0.999

Conversion factor

Lipase [U/L] x 0.0167= Lipase [µkat/L]

Reference Range [2]

≤ 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. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 36-7.
2. 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.
3. Lorentz K. Lipase. In: Thomas L, editor. Clinical laboratory diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 95-7.
4. 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.
5. Tietz N, Shuey DF. Lipase in serum – the elusive enzyme: an overview. Clin Chem 1993; 39: 746-56.
6. Lott J, Patel ST, Sawhney AK, Kazmierczak SC, Love JE. Assays of serum lipase: analytical and clinical considerations. Clin Chem 1986; 32: 1290-1302.
7. Leybold A, Junge W. Importance of colipase for the measurement of serum lipase activity. Adv Clin Enzymol 1986; 4: 60-7.
8. 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.
9. 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.
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. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: Mechanism, detection and prevention. Clin Chem Lab Med 2007; 45(9): 1240–1243.

Manufacturer

IVD CE DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany

Lipase DC FS

Chemistry Code 100 58

Chemistry Parameters 1

Sysmex BX-3010 Chemistry Analyzer
Analytical Parameters

Method No.	*	Method Name	LIP	Reagent Name	Reagent (µL)	Water (µL)
Print Name	Lipase	MethodColor		R1 LIP	100	
Sample Type	Serum			R2 LIP	25	
Unit	U/L			Diluent	Disable	
Assay Type	Rate			Sample Ppt. Wash	Disable	

Measuring points

	Start	End
1	33	39
2	Disable	

Stirring Speed R1: Middle R2: Middle

Wave Length: Prim. 570 Sec. 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) Low	Normal	High	Diluted Sample (µL)	Diluent (µL)
☐ Diluent	0.0 <	2.5 <	0.0		
Rerun (High/Prozone)					
☐ Diluent	0.0 <	2.5 <	0.0		
Rerun (Low)					
☐ Diluent	0.0 <	2.5 <	0.0		

Technical Range
(Conc) 1 – 300
(mAbs/10) * – *

Previous Result Comparison (%): * – * %

Abnormal Range (Conc): * – *

Panic Range (Conc): * – *

Decimal Point: 0 Profile SI: Disable

***Entered by user**

Chemistry Parameters 2

Sysmex BX-3010 Chemistry Analyzer
Analytical Parameters

Method No. * Method Name LIP Sample Serum

Limit Checks

- ✓ Duplicate Limit: 50 mAbs/10
- ✓ Sensitivity Limit: 500 mAbs/10
- ✓ Linearity Limit: 10 %
  200 (mAbs/10)/min
- ☐ Prozone Limit: Higher %

SL1-S – SL1-F
SL2-S – SL2-F
Sensitivity: mAbs/10

- ✓ Absorbance Limit
  Abs. in reaction: Increase
  Limit: 15400 mAbs/10

Blank measurement

Blank measurement:
Disable reagent blank and C1 blank

Measurement of Reagent Blank during Run:
None

Reagent blank measurement at calibration:
Reagent blank (No sample)

The number of measurement:
Duplicate

Reagent blank limit checks:
- ✓ Duplicate Limit: 10 mAbs/10

Instrument Factor

a 1.00 b 0.00

Lipase DC FS

Chemistry Code 100 58

Calibration Registration

Sysmex BX-3010 Chemistry Analyzer
Analytical Parameters

Method No. *

Method Name LIP

Sample Type Serum

Replication Duplicate

Check Interval 42

Test without calibration

Disable

Calibration Type Linear

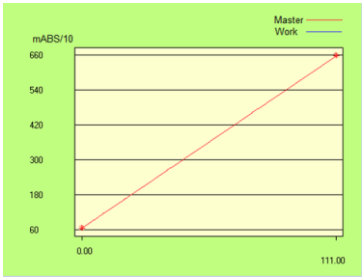
Reagent Lot New Add

Calibrator Name TruCal U

	Conc.	WORK	MASTER	Calibr. Lot No.	☐ All
C1	0	Automatic entry	Automatic entry	*	
C2	*	Automatic entry	Automatic entry	*	
C3	*				
C4	*				
C5	*				
C6	*				
C7	*				

K Automatic entry ☐ C1 Blank
☐ Reagent Blank for C1

Reagent Lot No.
(R1) *
(R2) *
Last



The calibration curve is lot dependent

Reagent blank mAbs/10 Last

Blank Automatic entry mAbs/10 Last

Calibration Curve Conc.

Absorbance mAbs/10 Recalculation

***Entered by user**

Lipase DC FS

Chemistry Code 100 58

Chemistry Parameters

Sysmex BX-4000 Chemistry Analyzer
Analytical Parameters

Method	*	Name	LIP		Reagent Name	Reagent (µL)	Water (µL)
Print Name	Lipase			R1	LIP	152	
Sample	Serum			R2 ✓ Enable	LIP	38	
Unit	U/L						
Assay Type	Rate			Diluent ☐ Enable			

Measuring points

		Start		End
	1	48	–	57
☐ Enable	2		–	

Decimal Points: 0

Wave Length
Prim. 570 Sec ☐ Disable 800

Normal Range

No.	Normal Range Name	Min	Max
1	Male-G1	*	*
2	Male-G2	*	*
3	Male-G3	*	*
4	Female-G1	*	*

	Normal	Sampling	Sample (µL)	Diluent (µL)
☐	Dilution	3.8		
	Rerun (High/Prozone)			
☐	Dilution	3.8		
	Rerun (Low)			
☐	Dilution	3.8		

Technical Range
(Conc) 1 – 300
(mAbs/10) –

SPT Wash ☐ Enable — Reagent Name

Stirring Speed R1 Middle R2 Middle

***Entered by user**

Chemistry Parameters

Sysmex BX-4000 Chemistry Analyzer
Analytical Parameters

Method No. * Name LIP Sample Serum

Limit Checks

✓ Duplicate Limit	50	mAbs/10	
✓ Sensitivity Limit	500	mAbs/10	
✓ Linearity Limit	10	% 200	(mAbs/10)/min
☐ Prozone Limit		% Upper	
SL1-S		– SL1-F	
SL2-S		– SL2-F	
Sensitivity		mAbs/10	
✓ Absorbance Limit			
Reaction	Increase		
Limit	15400	mAbs/10	

Blank measurement

Blank measurement:
Disable reagent blank and S1 blank

Measurement of Reagent Blank during Run:
None

Reagent blank measurement at calibration:
Reagent blank (No sample)

The number of measurement:
Duplicate

Reagent blank limit checks:
✓ Duplicate Limit 10 mAbs/10

Instrument Factor
a 1.00 b 0.00

Lipase DC FS

Chemistry Code 100 58

Registration Calibration

Sysmex BX-4000 Chemistry Analyzer
Analytical Parameters

Method: * Name: LIP

Sample: Serum

Sampling: Duplicate

Check Interval: 42 days

Auto: Change Lot Full Calibration

Auto Interval: hours

Type: Linear Lot: New

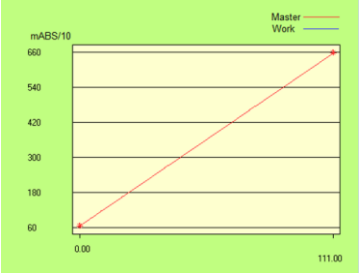
Material Name: TruCal U

	Conc.	WORK	MASTER	Lot No. (S) ☐ All
S1	0	Automatic entry	Automatic entry	
S2	*	Automatic entry	Automatic entry	
S3	*			
S4	*			
S5	*			
S6	*			
S7	*			

K: Automatic entry ☐ S1 Blank ☐ Reagent Blank for S1

***Entered by user**

R Lot No. R1: * R2: * Last:



The calibration curve is lot dependent

Reagent blank: mAbs/10 Last:

Blank: Automatic entry mAbs/10 Last:

Type: Conc.:

Absorbance: mAbs/10 Recalculation