

Pancreatic amylase CC* FS**

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

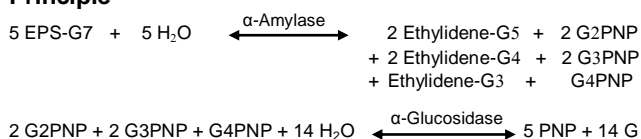
Order information

Cat. No.	Kit size	Number of tests
1 0551 99 10 972	R1 3 x 10.1 mL	BX-3010 3 x 75 tests BX-4000 3 x 52 tests
	R2 3 x 4.5 mL	BX-3010 3 x 75 tests BX-4000 3 x 52 tests

Method

Enzymatic photometric test, in which the substrate 4,6-ethylidene-(G7)-p-nitrophenyl-(G1)- α -D-maltoheptaoside (EPS-G7) is cleaved by α -amylases into various fragments. These are further hydrolyzed in a second step by α -glucosidase producing glucose and p-nitrophenol [1,2]. As the salivary isoenzyme is inhibited selectively by a combination of two monoclonal antibodies during the preincubation phase, the increase in absorbance represents the pancreatic amylase activity in the sample [3-5].

Principle



(PNP = p-Nitrophenol, G = Glucose)

Reagents

Components and Concentrations

R1:	Good's buffer	pH 7.15	0.1 mol/L
	NaCl		62.5 mmol/L
	MgCl ₂		12.5 mmol/L
	α -Glucosidase		≥ 2.5 kU/L
	Monoclonal antibodies against salivary amylase (mouse)		≥ 31 mg/L
R2:	Good's buffer	pH 7.15	0.1 mol/L
	EPS-G7		8.5 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 reagents!

Warnings and Precautions

- The remaining activity of salivary α -amylase can be up to 3%. Very rarely extremely high activities of salivary α -amylase may lead to increased readings of pancreatic α -amylase. However, saliva and skin do contain α -amylase, therefore avoid contact with the reagents.
- The reagents contain 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 laboratory practice.
- In very rare cases, samples of patients with gammopathy might give falsified results.
- 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, heparin plasma or EDTA plasma

Stability [6]:

in serum/plasma	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 the DiaSys TruCal U calibrator is recommended. This method is traceable to the molar extinction coefficient). 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 2000 U/L (33.3 μ kat/L) P-amylase (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 μ kat/L) P-amylase
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	23.6 U/L (0.393 μ kat/L)
Hemoglobin	up to 60 mg/dL	117 U/L (1.95 μ kat/L)
Bilirubin, conjugated	up to 20 mg/dL	71.0 U/L (1.18 μ kat/L)
Bilirubin, unconjugated	up to 35 mg/dL	71.1 U/L (1.18 μ kat/L)
Lipemia (triglycerides)	up to 2000 mg/dL	69.1 U/L (1.15 μ kat/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]	25.5	85.8	138
Mean [μ kat/L]	0.425	1.43	2.30
Coefficient of variation [%]	0.883	0.643	0.757
Between run (n=20)	Sample 1	Sample 2	Sample 3
Mean [U/L]	26.7	82.5	139
Mean [μ kat/L]	0.444	1.37	2.31
Coefficient of variation [%]	1.38	1.05	0.709

Method comparison (n=111)	
Test x	P-amylase CC FS (BioMajesty 6010C)
Test y	P-amylase CC FS (BX-4000)
Slope	0.994
Intercept	-0.779 U/L (-0.013 μ kat/L)
Coefficient of correlation	0.99996

Conversion factor

Pancreatic amylase [U/L] x 0.0167 = Pancreatic amylase [μ kat/L]

Reference Range [7]

	Women	Men
Serum/plasma	< 53 U/L (< 0.88 μ kat/L)	< 53 U/L (< 0.88 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

1. Lorentz K. α -Amylase. In: Thomas L, editor. Clinical laboratory diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 192-202.
2. 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. 689-98.
3. Gerber M, Naujoks K, Lenz H, Wulff K. A monoclonal antibody that specifically inhibits human salivary alpha-amylase. Clin Chem 1987; 33: 1158-62.
4. Kruse-Jarres JD, Kaiser C, Hafkenschied JC, Hohenwallner W, Stein W., Bohner J et al. Evaluation of a new alpha-amylase assay using 4,6-ethylidene-(G7)-1-4-nitrophenyl-(G1)-alpha,D-maltoheptaoside as substrate. J Clin Chem Biochem 1989; 27: 103-13.
5. Tietz NW, Burlina A, Gerhardt W, Junge W, Maffetherimer P, Mural T et al. Multicenter evaluation of a specific pancreatic isoamylase assay based on a double monoclonal-antibody technique. Clin Chem 1988; 34: 2096-102.
6. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001. p. 16-17, 50-51
7. Junge W, Wortmann W, Wilke B, Waldenstroem J et al. Development and evaluation of assays for determination of total and pancreatic amylase at 37 °C according to the principle recommended by the IFCC. Clin Biochem 2001; 34: 607-15.
8. Junge W, Troge B, Klein G, Poppe W, Gerber M. Evaluation of a new assay for pancreatic amylase: Performance characteristics and estimation of reference interval. Clin Biochem 1989; 22: 109-14.
9. Tietz NW, ed. Clinical Guide to Laboratory Tests. 3rd ed. Philadelphia. Pa: WB Saunders Company; 1995: 46-51.
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: Mechanisms, detection and prevention. Clin Chem Lab Med 2007; 45(11): 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"/>	Method Name	<input type="text" value="PAMY"/>	Reagent Name	Reagent (µL)	Water (µL)																				
Print Name	<input type="text" value="P-Amylase"/>	MethodColor		R1	<input type="text" value="PAMY"/>	<input type="text" value="100"/>																				
Sample Type	<input type="text" value="Serum"/>			R2	<input type="text" value="PAMY"/>	<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="37"/>	- <input type="text" value="45"/>																							
		2 <input type="text" value="Disable"/>	- <input type="text"/>																							
Wave Length	Prim. <input type="text" value="415"/>	Sec. <input type="text" value="700"/>		<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	*	*
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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="2000"/>																						
<input type="checkbox"/> Diluent				(mAbs/10) <input type="text" value="*"/> - <input type="text" value="*"/>																						
<input type="checkbox"/> 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 (Conc) <input type="text" value="*"/> - <input type="text" value="*"/>																						
<input type="checkbox"/> Rerun (Low)				Panic Range (Conc) <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"/>	Method Name	<input type="text" value="PAMY"/>	Sample	<input type="text" value="Serum"/>	
Limit Checks				Blank measurement		
<input checked="" type="checkbox"/> Duplicate Limit	<input type="text" value="20"/>	mAbs/10		Blank measurement: <input type="text" value="Disable reagent blank and C1 blank"/>		
<input checked="" type="checkbox"/> Sensitivity Limit	<input type="text" value="280"/>	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="480"/>	(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"/>			<input checked="" type="checkbox"/> Duplicate Limit <input type="text" value="20"/> mAbs/10		
	SL1-S <input type="text"/>	-	SL1-F <input type="text"/>	Instrument Factor		
	SL2-S <input type="text"/>	-	SL2-F <input type="text"/>	a <input type="text" value="1.00"/> b <input type="text" value="0.00"/>		
	Sensitivity <input type="text"/>	mAbs/10				
<input checked="" type="checkbox"/> Absorbance Limit						
	Abs. in reaction <input type="text" value="Increase"/>					
	Limit <input type="text" value="26000"/>	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

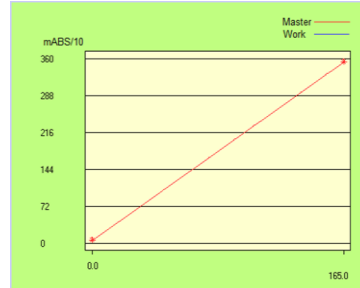
Reagent Lot

Calibrator Name

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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) Last
(R2)



The calibration curve is lot dependent

Reagent blank mAbs/10 Last

Blank mAbs/10 Last

Calibration Curve Conc.

Absorbance mAbs/10

*Entered by user

Pancreatic amylase CC FS

Chemistry Code 100 64

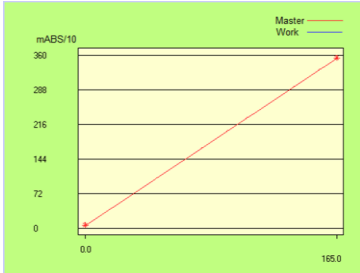
Chemistry Parameters		Sysmex BX-4000 Chemistry Analyzer Analytical Parameters																								
Method	<input type="text" value="*"/>	Name	<input type="text" value="PAMY"/>	Reagent Name	Reagent (μL)	Water (μL)																				
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Sample	<input type="text" value="Serum"/>	R2	<input checked="" type="checkbox"/> Enable	<input type="text" value="PAMY"/>	<input type="text" value="38"/>	<input type="text"/>																				
Unit	<input type="text" value="U/L"/>	Diluent <input type="checkbox"/> Enable		<input type="text"/>	<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="text" value="0"/>																				
<input type="checkbox"/> Enable		2	<input type="text"/>	-	<input type="text"/>																					
Wave Length	Prim. <input type="text" value="415"/>	Sec	<input type="checkbox"/> Disable	<input type="text" value="700"/>	Normal Range																					
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2	Male-G2	*	*																							
3	Male-G3	*	*																							
4	Female-G1	*	*																							
<input type="checkbox"/> Dilution	Normal Sampling <input type="text" value="3.8"/>	Sample (μL)	<input type="text"/>	Diluent (μL)	<input type="text"/>	Technical Range																				
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<input type="checkbox"/> Dilution	<input type="text" value="3.8"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>																					
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<input type="checkbox"/> Dilution	<input type="text" value="3.8"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>																					
		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" value="*"/>	Name	<input type="text" value="PAMY"/>	Sample	<input type="text" value="Serum"/>
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	<input checked="" type="checkbox"/> Sensitivity Limit	<input type="text" value="280"/>	mAbs/10		
	<input checked="" type="checkbox"/> Linearity Limit	<input type="text" value="10"/>	%	<input type="text" value="480"/>	(mAbs/10)/min
	<input type="checkbox"/> Prozone Limit	<input type="text"/>	%	<input type="text" value="Upper"/>	
	SL1-S	<input type="text"/>	-	SL1-F	<input type="text"/>
	SL2-S	<input type="text"/>	-	SL2-F	<input type="text"/>
	Sensitivity	<input type="text"/>	mAbs/10		
<input checked="" type="checkbox"/> Absorbance Limit	Reaction	<input type="text" value="Increase"/>			
	Limit	<input type="text" value="26000"/>	mAbs/10		
Blank measurement		Blank measurement:			
		<input type="text" value="Disable reagent blank and S1 blank"/>			
		Measurement of Reagent Blank during Run:			
		<input type="text" value="None"/>			
		Reagent blank measurement at calibration:			
		<input type="text" value="Reagent blank (No sample)"/>			
		The number of measurement:			
		<input type="text" value="Duplicate"/>			
		Reagent blank limit checks:			
<input checked="" type="checkbox"/>	Duplicate Limit	<input type="text" value="20"/>	mAbs/10		
Instrument Factor		a	<input type="text" value="1.00"/>	b	<input type="text" value="0.00"/>

Pancreatic amylase CC FS

Chemistry Code 100 64

Registration Calibration		Sysmex BX-4000 Chemistry Analyzer Analytical Parameters																																															
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	Conc.	WORK	MASTER	Lot No. (S)	<input type="checkbox"/> All																																												
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