

α-Amylase CC* FS**

Order Information

Cat. No.	Kit size	Instrument	Σ
1 0501 99 10 972	R1 3 x 14.6 mL	BX-3010	225 (3 x 75)
		BX-4000	231 (3 x 77)
	R2 3 x 5.6 mL	BX-3010	225 (3 x 75)
		BX-4000	231 (3 x 77)

Intended Use

Diagnostic reagent for quantitative in vitro determination of α-amylases in human serum, heparin plasma or urine on automated Sysmex BX-Series.

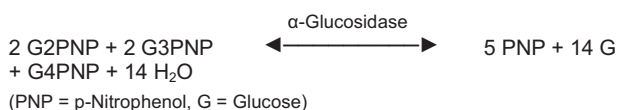
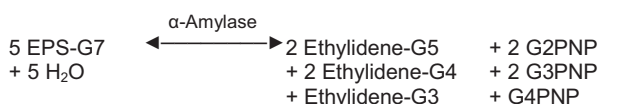
Summary

α-Amylases are hydrolytic enzymes which break down starch into maltose. In the human body, α-amylases originate from various organs: pancreatic amylase is produced by the pancreas and released into the intestinal tract; salivary amylase is synthesized in the salivary glands and secreted into saliva. Amylases present in blood are eliminated through the kidney and excreted into urine. Therefore, elevation of amylase activity in serum is reflected in a rise of urinary amylase activity. Measurement of α-amylases in serum and urine is mainly used to diagnose pancreatic disorders as well as for detecting the development of complications. In acute pancreatitis the blood amylase activity increases within few hours after onset of abdominal pain, peaks after approx. 12 h and returns to values within the reference range at the latest after 5 days. The specificity of α-amylases for pancreatic disorders is not very high as elevated levels are measured also in various non-pancreatic diseases, e.g. parotitis and renal insufficiency. Therefore, for confirmation of an acute pancreatitis, lipase should be measured in addition. [1,2]

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. The increase in absorbance represents the total (pancreatic and salivary) amylase activity in the sample. [3,4]



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 kU/L
R2: Good's buffer	pH 7.15	0.1 mol/L	
		EPS-G7	8.5 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. Protect the reagents from light.

Warnings and Precautions

1. Saliva and skin contain α-amylases, consequently never pipette the reagents by mouth and avoid skin contact with these reagents.
2. In very rare cases, samples of patients with gammopathy might give falsified results [5].
3. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
4. Reagent 1 contains animal material. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
5. 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.
6. For professional use only.

Waste Management

Refer to local legal requirements.

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, heparin plasma or urine

Stability in serum/plasma [6]:

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

Stability in urine [6]:

2 days	at	20 – 25°C
10 days	at	4 – 8°C
3 weeks	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 against the original IFCC [International Federation of Clinical Chemistry and Laboratory Medicine] formulation from 1998. Use DiaSys TruLab N and P or TruLab Urine for internal quality control. 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
TruLab Urine Level 1	5 9170 99 10 062	20 x 5 mL
	5 9170 99 10 061	6 x 5 mL
TruLab Urine Level 2	5 9180 99 10 062	20 x 5 mL
	5 9180 99 10 061	6 x 5 mL

Performance Characteristics

Exemplary data mentioned below may slightly differ in case of deviating measurement conditions.

Measuring range up to 2000 U/L (33.4 µkat/L). In case of higher activities re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.	
Limit of detection***	1.0 U/L (0.017 µkat/L)
Onboard stability	6 weeks
Calibration stability	6 weeks

Interfering substance	Interferences ≤ 10% up to	Analyte concentration
Ascorbic acid	30 mg/dL	67.2 U/L (1.12 µkat/L)
Bilirubin (conjugated)	60 mg/dL	68.0 U/L (1.13 µkat/L)
Bilirubin (unconjugated)	60 mg/dL	68.4 U/L (1.14 µkat/L)
Hemoglobin	500 mg/dL	66.3 U/L (1.11 µkat/L)
Lipemia (triglycerides)	1600 mg/dL	61.4 U/L (1.03 µkat/L)

For further information on interfering substances refer to Young DS [7,8].

Precision (Serum) BX-3010			
Within run (n=20)	Sample 1	Sample 2	Sample 3
Mean [U/L]	71.5	225	301
Mean [µkat/L]	1.19	3.74	5.02
CV [%]	1.55	1.09	0.689
Between day (n=20)	Sample 1	Sample 2	Sample 3
Mean [U/L]	72.9	218	544
Mean [µkat/L]	1.21	3.63	9.09
CV [%]	2.27	2.21	0.943

Precision (Urine) BX-3010			
Within run (n=20)	Sample 1	Sample 2	Sample 3
Mean [U/L]	45.3	208	501
Mean [µkat/L]	0.755	3.48	8.37
CV [%]	2.05	0.841	0.829
Between day (n=20)	Sample 1	Sample 2	Sample 3
Mean [U/L]	45.1	207	285
Mean [µkat/L]	0.753	3.45	4.77
CV [%]	2.38	1.10	1.09

Method comparison (n=141)	
Test x	DiaSys α-Amylase CC FS (BioMajesty 6010C)
Test y	DiaSys α-Amylase CC FS (BX-3010)
Slope	1.00
Intercept	-1.15 U/L (-0.019 µkat/L)
Coefficient of correlation	0.999

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

Conversion Factor

α-Amylase [U/L] x 0.0167 = α-Amylase [µkat/L]

Reference Range [9]

	Women	Men
Serum/Plasma	< 100 U/L < 1.67 µkat/L	< 100 U/L < 1.67 µkat/L
Urine	< 447 U/L < 7.45 µkat/L	< 491 U/L < 8.18 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

- Lorentz K. α-Amylase. In: Thomas L, editor. Clinical laboratory diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 46-51.
- 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.
- Kruse-Jarres JD, Kaiser C, Hafkenscheid 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.
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- Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240-1243.
- Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 16-7, 50-1.
- 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.
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- 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.



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* Complete Color

** Fluid Stable

Application for serum, plasma and urine samples

Chemistry Parameters 1				Sysmex BX-3010 Chemistry Analyzer Analytical Parameters																							
Method No.	<input type="text" value="*"/>	Method Name	<input type="text" value="AMY"/>	Reagent Name	Reagent (μL)	Water (μL)																					
Print Name	<input type="text" value="Amylase"/>	MethodColor		R1	<input type="text" value="Amylase"/>	<input type="text" value="100"/>																					
Sample Type	<input type="text" value="*"/>			R2	<input type="text" value="Amylase"/>	<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	*	*
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	(Conc)	<input type="text" value="1.0"/>	- <input type="text" value="2000"/>																				
	Low <input type="text" value="0.0"/>	Normal <input type="text" value="1.9"/>	High <input type="text" value="0.0"/>		(mAbs/10)	*	- *																				
<input type="checkbox"/> Diluent	<input type="text" value="0.0"/>	< <input type="text" value="1.9"/>	< <input type="text" value="0.0"/>		Previous Result Comparison (%)	<input type="text" value="*"/>	<input type="text" value="*"/> %																				
<input type="checkbox"/> Rerun (High/Prozone)	<input type="text" value="0.0"/>	< <input type="text" value="1.9"/>	< <input type="text" value="0.0"/>		Abnormal Range	(Conc) <input type="text" value="*"/>	- <input type="text" value="*"/>																				
<input type="checkbox"/> Diluent	<input type="text" value="0.0"/>	< <input type="text" value="1.9"/>	< <input type="text" value="0.0"/>		Panic Range	(Conc) <input type="text" value="*"/>	- <input type="text" value="*"/>																				
<input type="checkbox"/> Rerun (Low)	<input type="text" value="0.0"/>	< <input type="text" value="1.9"/>	< <input type="text" value="0.0"/>		Decimal Point	<input type="text" value="0"/>	Profile SI <input type="text" value="Disable"/>																				

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Chemistry Parameters 2				Sysmex BX-3010 Chemistry Analyzer Analytical Parameters			
Method No.	<input type="text" value="*"/>	Method Name	<input type="text" value="AMY"/>	Sample	<input type="text" value="*"/>		
Limit Checks	<input checked="" type="checkbox"/> Duplicate Limit <input type="text" value="30"/> mAbs/10 <input checked="" type="checkbox"/> Sensitivity Limit <input type="text" value="220"/> mAbs/10 <input checked="" type="checkbox"/> Linearity Limit <input type="text" value="10"/> % <input type="text" value="375"/> (mAbs/10)/min <input type="checkbox"/> Prozone Limit <input type="text" value="Higher"/> % <input type="text"/> 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 Abs. in reaction <input type="text" value="Increase"/> Limit <input type="text" value="20300"/> mAbs/10						
Blank measurement				Blank measurement: <input type="text" value="Disable reagent blank and C1 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="10"/> mAbs/10			
Instrument Factor				a <input type="text" value="1.00"/> b <input type="text" value="0.00"/>			

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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) Last
 (R2)



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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Application for serum, plasma and urine samples

Chemistry Parameters		Sysmex BX-4000 Chemistry Analyzer Analytical Parameters				
Method	<input type="text" value="*"/>	Name	<input type="text" value="AMY"/>	Reagent Name	Reagent (μL)	Water (μL)
Print Name	<input type="text" value="Amylase"/>	R1	<input type="text" value="AMY"/>	<input type="text" value="150"/>	<input type="text" value=""/>	<input type="text" value=""/>
Sample	<input type="text" value="*"/>	R2	<input checked="" type="checkbox"/> Enable	<input type="text" value="AMY"/>	<input type="text" value="38"/>	<input type="text" value=""/>
Unit	<input type="text" value="U/L"/>	Diluent		<input type="checkbox"/> Enable	<input type="text" value=""/>	<input type="text" value=""/>
Assay Type	<input type="text" value="Rate"/>					
Measuring points	Start	End	Decimal Points	<input type="text" value="0"/>		
	1	<input type="text" value="54"/>	-	<input type="text" value="67"/>		
<input type="checkbox"/> Enable	2	<input type="text" value=""/>	-	<input type="text" value=""/>		
Wave Length	Prim. <input type="text" value="415"/>	Sec	<input type="checkbox"/> Disable	<input type="text" value="700"/>		
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)	Technical Range		
<input type="checkbox"/> Dilution	<input type="text" value="2.8"/>	<input type="text" value=""/>	<input type="text" value=""/>	(Conc)	<input type="text" value="1.0"/>	- <input type="text" value="2000"/>
	Rerun (High/Prozone)			(mAbs/10)	<input type="text" value=""/>	- <input type="text" value=""/>
<input type="checkbox"/> Dilution	<input type="text" value="2.8"/>	<input type="text" value=""/>	<input type="text" value=""/>			
	Rerun (Low)					
<input type="checkbox"/> Dilution	<input type="text" value="2.8"/>	<input type="text" value=""/>	<input type="text" value=""/>			
SPT Wash	<input type="checkbox"/> Enable	Reagent Name	<input type="text" value=""/>			
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="AMY"/>	Sample	<input type="text" value="*"/>
Limit Checks					
<input checked="" type="checkbox"/> Duplicate Limit	<input type="text" value="30"/>	mAbs/10			
<input checked="" type="checkbox"/> Sensitivity Limit	<input type="text" value="220"/>	mAbs/10			
<input checked="" type="checkbox"/> Linearity Limit	<input type="text" value="10"/>	%	<input type="text" value="375"/>	(mAbs/10)/min	
<input type="checkbox"/> Prozone Limit	<input type="text" value=""/>	%	<input type="text" value="Upper"/>		
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			
<input checked="" type="checkbox"/> Absorbance Limit	Reaction	<input type="text" value="Increase"/>			
	Limit	<input type="text" value="20300"/>	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="10"/>	mAbs/10			
Instrument Factor					
a	<input type="text" value="1.00"/>	b	<input type="text" value="0.00"/>		

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Registration Calibration

**Sysmex BX-4000 Chemistry Analyzer
Analytical Parameters**

Method Name

Sample

Sampling

Check Interval days

Auto

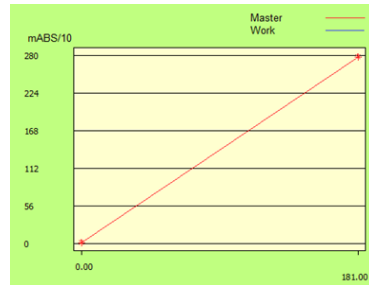
Auto Interval hours

Type Lot

Material Name

R Lot No. R1
R2

Last



The calibration curve is lot dependent

	Conc.	WORK	MASTER	Lot No. (S) <input type="checkbox"/> All
S1	0	Automatic entry	Automatic entry	
S2	*	Automatic entry	Automatic entry	
S3	*			
S4	*			
S5	*			
S6	*			
S7	*			

K S1 Blank Reagent Blank for S1

*Entered by user

Reagent blank mAbs/10 Last

Blank mAbs/10 Last

Type Conc.

Absorbance mAbs/10