

## α-Amylase CC\* FS\*\*

### Order Information

**Cat. No.**  
1 0501 99 10 964

**Kit size**  
900 (R1: 6 x 150, R2: 6 x 150)

### Intended Use

Diagnostic reagent for quantitative in vitro determination of α-amylases in human serum, heparin plasma or urine on automated BioMajesty® JCA-BM6010/C.

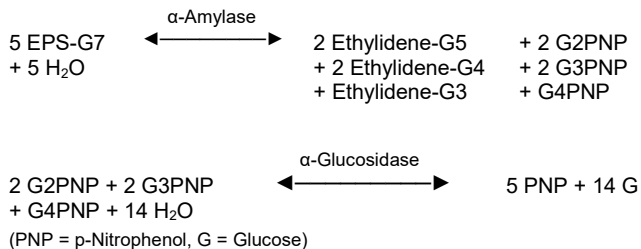
### Summary

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

<b>R1:</b>	Good's buffer	pH 7.15	0.1 mol/L
	NaCl		62.5 mmol/L
	MgCl <sub>2</sub>		12.5 mmol/L
	α-Glucosidase		≥ 2 kU/L
<b>R2:</b>	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 from light.

### Warnings and Precautions

- 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 and biological material. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
- Saliva and skin contain α-Amylases, consequently never pipette the reagents by mouth and avoid skin contact with these reagents.
- In very rare cases, samples of patients with gammopathy might give falsified results [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.
- 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 Level 1 and Level 2 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.

### with serum/plasma

Measuring range up to 2000 U/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***	6 U/L
Onboard stability	13 weeks
Calibration stability	13 weeks

Interfering substance	Interferences ≤ 10% up to	Analyte concentration [U/L]
Ascorbic acid	30 mg/dL	36.0
	60 mg/dL	207
Bilirubin (conjugated)	60 mg/dL	36.0
	60 mg/dL	201
Bilirubin (unconjugated)	60 mg/dL	36.0
	60 mg/dL	203
Hemoglobin	120 mg/dL	50.0
	500 mg/dL	222
Lipemia (triglycerides)	1200 mg/dL	36.0
	1700 mg/dL	192

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

Precision (Serum/Plasma)			
Within run (n=20)	Sample 1	Sample 2	Sample 3
Mean [U/L]	36.9	74.9	1473
CV [%]	1.86	1.11	0.517
Total Precision CLSI (n=80)	Sample 1	Sample 2	Sample 3
Mean [U/L]	35.6	101	1471
CV [%]	1.79	1.31	1.08

Method comparison (Serum/Plasma; n=100)	
Test x	Competitor α-Amylase
Test y	DiaSys α-Amylase CC FS
Slope	0.973
Intercept	-3.17 U/L
Coefficient of correlation	0.999

### with urine

Measuring range from 22 up to 4000 U/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***	12 U/L

Interfering substance	Interferences ≤ 10% up to	Analyte concentration [U/L]
Ascorbic acid	250 mg/dL	233
	250 mg/dL	889
Bilirubin (conjugated)	60 mg/dL	234
	60 mg/dL	891
Boric Acid	250 mg/dL	267
	250 mg/dL	946
Glucose	2000 mg/dL	258
	2000 mg/dL	947
Hemoglobin	250 mg/dL	252
	400 mg/dL	894
Protein	300 mg/dL	261
	300 mg/dL	1010
Sodium-Oxalate	60 mg/dL	260
	60 mg/dL	1025
Urobilinogen	40 mg/dL	233
	40 mg/dL	888

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

Precision (Urine)			
Within run (n=20)	Sample 1	Sample 2	Sample 3
Mean [U/L]	70.9	477	2084
CV [%]	1.17	2.22	0.836
Total Precision CLSI (n=80)	Sample 1	Sample 2	Sample 3
Mean [U/L]	78.5	480	2078
CV [%]	3.43	0.892	0.921

Method comparison (Urine; n=100)	
Test x	Competitor α-Amylase
Test y	DiaSys α-Amylase CC FS
Slope	0.986
Intercept	-1.50 U/L
Coefficient of correlation	0.999

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

### Conversion Factor

$\alpha\text{-Amylase [U/L]} \times 0.0167 = \alpha\text{-Amylase } [\mu\text{kat/L}]$

### Reference Range [9]

	Women	Men
<b>Serum/Plasma</b>	< 100 U/L < 1.67 $\mu\text{kat/L}$	< 100 U/L < 1.67 $\mu\text{kat/L}$
<b>Urine</b>	< 447 U/L < 7.45 $\mu\text{kat/L}$	< 491 U/L < 8.18 $\mu\text{kat/L}$

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.  $\alpha$ -Amylase. In: Thomas L, editor. Clinical laboratory diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 46-51.
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. 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.
4. Schumann G, Aoki R, Ferrero CA et al. IFCC primary reference procedures for the measurement of catalytic activity concentrations of enzymes at 37°C. Clin Chem Lab Med 2006; 44(9): 1146-1155.
5. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007; 45(9): 1240-1243.
6. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 16-7, 50-1.
7. 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.
8. Young DS. Effects on Clinical Laboratory Tests - Drugs Disease, Herbs & Natural Products, <https://clinf.wiley.com/aaccweb/aacc/>, accessed in September 2021. Published by AACC Press and John Wiley and Sons, Inc.
9. 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.



DiaSys Diagnostic Systems GmbH  
Alte Strasse 9 65558 Holzheim  
Germany  
[www.diasys-diagnostics.com](http://www.diasys-diagnostics.com)

\* Complete Color

\*\* Fluid Stable

## $\alpha$ -Amylase CC FS

Chemistry code 10 050

### Application for serum, plasma and urine samples

This application was set up and evaluated by DiaSys. It is based on the standard equipment at that time and does not apply to any equipment modifications undertaken by unqualified personnel.

Analytical Conditions	
R1 volume	80
R2e volume	0
R2 volume	20
R1 diluent vol	0
R2e diluent vol	0
R2 diluent vol	0
Sample vol (S)	1.5
Sample vol (U)	1.5
Reagent 1 mix	weak
Reagent 2e mix	weak
Reagent 2 mix	weak
Reaction time	10

Sub-analy. Conditions	
Name	AMY
Digits	2
M-wave L.	410
S-wave.L	694
Analy.mthd.	RRA
Calc.mthd.	STD
Qualit. judge	No

Analysis Test Condition Setting (M)		
Sample Type	Serum	Urine
Reac. sample vol.	1.5	1.5
Diluent method	No dil	With dil
Undil. sample vol.	0	25
Diluent volume	0	25
Diluent position	0	0

# entered by user

Endpoint method	
Re.absorb (u)	9.999
Re. Absorb (d)	-9.999

Calculation Method Setting	
M-DET.P.l	21
M-DET.P.m	32
M-DET.P.n	41
S-DET.P.p	0
S-DET.P.r	0
Check D.P.l.	21
Limit value	0.003
Variance	10
Reac.type	Inc

Reaction Rate Method	
Cycle	2
Factor	2
E2 corre	Do
Blank (u)	9.999
Blank (d)	-9.999
Sample (u)	1.5
Sample (d)	-9.999

Standards Setting	
FV	#
BLK H	9.999
BLK L	-9.999
STD H	9.999
STD L	-9.999