α-Amylase CC* FS**

Order Information

Cat. No.	Kit size			
1 0501 99 10 021	R1 5 x 20 mL	+	R2	1 x 25 mL
1 0501 99 10 026	R1 5 x 80 mL	+	R2	1 x 100 mL
1 0501 99 10 023	R1 1 x 800 mL	+	R2	1 x 200 mL
1 0501 99 10 704	R1 8 x 50 mL	+	R2	8 x 12.5 mL
1 0501 99 10 930	R1 4 x 20 mL	+	R2	2 x 10 mL

Intended Use

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

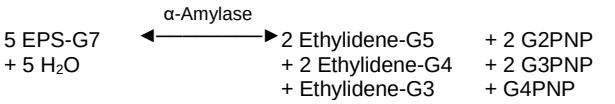
Summary

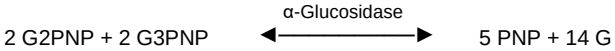
α-Amylases are hydrolytic enzymes which break down starch into maltose. In the human body, α-amylases originate from various organs: pancreatic amylase is produced by the pancreas and released into the intestinal tract; salivary amylase is synthesized in the salivary glands and secreted into saliva. 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]





(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 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 from light.

Warnings and Precautions

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

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.

Assay Procedure

Basic settings for BioMajesty® JCA-BM6010/C

Wavelength	410/694 nm
Temperature	37°C
Measurement	Kinetic
Sample/Calibrator	1.5 µL
Reagent 1	80 µL
Reagent 2	20 µL
Addition reagent 2	Cycle 19 (286 s)
Absorbance 1	–
Absorbance 2	Cycle 32/41 (464 s/586 s)
Calibration	Linear

Calculation

With calibrator

$$\text{α-Amylase [U/L]} = \frac{\Delta A/\text{min. Sample}}{\Delta A/\text{min. Cal}} \times \text{Conc. Cal [U/L]}$$

Conversion Factor

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

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

Data evaluated on BioMajesty® JCA-BM6010/C

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

with serum/plasma

Measuring range up to 2000 U/L. When values exceed this range, samples should be diluted 1 + 9 with NaCl solution (9 g/L) and the result multiplied by 10.	
Limit of detection***	6 U/L

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. When values exceed this range, samples should be diluted 1 + 9 with NaCl solution (9 g/L) and the result multiplied by 10.	
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

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

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