Pancreatic amylase CC* FS**

Diagnostic reagent for quantitative in vitro determination of pancreatic amylase in serum, plasma or urine on BioMajesty JCA-BM6010/C

Order Information

Cat. No. 1 0551 99 10 964
R1: 6 x 150 tests
R2: 6 x 150 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

$$5\ \text{EPS-G7} + 5\ H_2O \xrightarrow{\alpha\text{-Amylase}} 2\ \text{Ethylidene-G5} + 2\ \text{G2PNP} + 2\ \text{Ethylidene-G4} + 2\ \text{G3PNP} + \text{Ethylidene-G3} + \text{G4PNP}$$

$$2\ \text{G2PNP} + 2\ \text{G3PNP} + \text{G4PNP} + 14\ H_2O \xrightarrow{\alpha\text{-Glucosidase}} 5\ \text{PNP} + 14\ \text{G}$$

(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

1. 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.
2. The reagents contain 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 laboratory practice.
4. In very rare cases, samples of patients with gammopathy might give falsified results [11].
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

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, urine

Stability [6]:

in serum/plasma	7 days	at	20 – 25°C
	7 days	at	4 – 8°C
	1 year	at	–20°C
in urine	2 days	at	20 – 25°C
	10 days	at	4 – 8°C
	3 weeks	at	–20°C

Discard contaminated specimens. Freeze only once.

Pancreatic α-amylase is unstable in acid urine. Assay immediately or adjust pH to alkaline range before storage [9].

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 1740 U/L (29 µkat/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**	2 U/L (0.03 µkat/L) P-amylase
On-board stability	6 weeks
Calibration stability	6 weeks

Interferences < 10% by
Ascorbate up to 30 mg/dL
Bilirubin (conjugated and unconjugated) up to 54 mg/dL
Lipemia (triglycerides) up to 2000 mg/dL
Hemoglobin up to 600 mg/dL
For further information on interfering substances refer to Young DS [10].

Precision (Serum/plasma)			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	26.3	115	252
Mean [µkat/L]	0.44	1.91	4.20
Coefficient of variation [%]	0.90	0.64	0.61
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	44.9	142	247
Mean [µkat/L]	0.75	2.37	4.13
Coefficient of variation [%]	1.40	0.86	0.59

Method comparison (Serum/plasma; n=135)	
Test x	DiaSys P-amylase CC FS (Hitachi 917)
Test y	DiaSys P-amylase CC FS (BM JCA-BM6010/C)
Slope	1.01
Intercept	0.96 U/L (0.016 µkat/L)
Coefficient of correlation	0.9995

Precision (Urine)			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	43.6	124	80.6
Mean [µkat/L]	0.73	2.07	1.35
Coefficient of variation [%]	0.81	1.53	0.37
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	43.9	125	81.1
Mean [µkat/L]	0.73	2.09	1.36
Coefficient of variation [%]	1.41	1.95	1.58

Method comparison (Urine; n=100)	
Test x	DiaSys P-amylase CC FS (Hitachi 917)
Test y	DiaSys P-amylase CC FS (BM JCA-BM6010/C)
Slope	1.03
Intercept	–2.99 U/L (-0.05 µkat/L)
Coefficient of correlation	0.9988

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

Conversion factor

Pancreatic amylase [U/L] x 0.0167= Pancreatic amylase [µkat/L]

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Reference Range [7]

	Women	Men
Serum/plasma	< 53 U/L (< 0.88 µkat/L)	< 53 U/L (< 0.88 µkat/L)
Urine	< 319 U/L (< 5.3 µkat/L)	< 356 U/L (< 5.9 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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Manufacturer

IVD CE

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P-Amylase CC FS

Chemistry code 10 055

Application for serum, plasma, 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)	2
Sample vol (U)	1
Reagent 1 mix	weak
Reagent 2e mix	weak
Reagent 2 mix	weak
Reaction time	10

Sub-analy. Conditions	
Name	PAMY
Digits	1
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.	2	1
Diluent method	No dil	No dil
Undil. sample vol.	0	0
Diluent volume	0	0
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.I	21
M-DET.P.m	32
M-DET.P.n	42
S-DET.P.p	0
S-DET.P.r	0
Check D.P.I.	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)	1.6
Sample (d)	-9.999

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