respons®910

α-Amylase CC* FS**

Order Information

Cat. No.	Kit size
1 0501 99 10 921	Σ 480 (4 x 120)

Intended Use

Diagnostic reagent for quantitative in vitro determination of α-amylases in human serum or heparin plasma on automated respons®910.

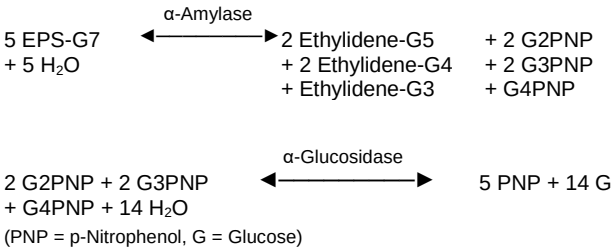
Summary

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. The bottles are placed directly into the reagent rotor.

Materials Required

General laboratory equipment

Specimen

Human serum or heparin plasma

Stability [6]:		
7 days	at	20 – 25°C
7 days	at	4 – 8°C
1 year	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 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

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Performance Characteristics

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

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***	3 U/L
Onboard stability	4 weeks
Calibration stability	2 weeks

Interfering substance	**Interferences ≤ 10% up to**	**Analyte concentration [U/L]**
Ascorbic acid	30 mg/dL	96.3
Bilirubin (conjugated)	70 mg/dL	86.3
	70 mg/dL	194
Bilirubin (unconjugated)	70 mg/dL	84.3
	70 mg/dL	192
Hemoglobin	550 mg/dL	63.6
	550 mg/dL	229
Lipemia (triglycerides)	1000 mg/dL	82.4
	1000 mg/dL	150
For further information on interfering substances refer to Young DS [7,8].		

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	77.3	526	914
CV [%]	1.64	1.80	1.26
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	73.1	475	933
CV [%]	2.63	2.12	2.21

Method comparison (n=118)	
Test x	DiaSys α-Amylase CC FS (Hitachi 917)
Test y	DiaSys α-Amylase CC FS (respons®910)
Slope	0.967
Intercept	0.766 U/L
Coefficient of correlation	0.999

*** according to CLSI document EP17-A, Vol. 24, No. 34

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

Reference Range [9]

	Women	Men
Serum/Plasma	< 100 U/L	< 100 U/L
	< 1.67 µkat/L	< 1.67 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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* Complete Color

** Fluid Stable

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Application for serum and plasma 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.

Identification	
This method is usable for analysis:	Yes
Twin reaction:	No
Name:	AMY
Shortcut:	
Reagent barcode reference:	015
Host reference:	

Technic	
Type:	Linear kinetic
First reagent:[µL]	160
Blank reagent	Yes
Sensitive to light	
Second reagent:[µL]	40
Blank reagent	Yes
Sensitive to light	
Main wavelength:[nm]	405
Secondary wavelength:[nm]	700
Polychromatic factor:	1.000
1 st reading time [min:sec]	07:48
Last reading time [min:sec]	10:00
Reaction way:	Increasing
Linear Kinetics Substrate depletion: Absorbance li	1.0000
Linearity: Maximum deviation [%]	100
Fixed Time Kinetics Substrate depletion: Absorbance limit	
Endpoint Stability: Largest remaining slope	
Prozone Limit [%]	

Reagents	
Decimals	
Units	

Sample	
Diluent	DIL A (NaCl)
Hemolysis:	
Agent [µL]	0 (no hemolysis)
Cleaner	
Sample [µL]	0
Technical limits	
Concentration technical limits-Lower	3
Concentration technical limits-Upper	2000
SERUM	
Normal volume [µL]	3
Normal dilution (factor)	1
Below normal volume [µL]	6
Below normal dilution (factor)	1
Above normal volume [µL]	3
Above normal dilution (factor)	6
URIN	
Normal volume [µL]	3
Normal dilution (factor)	1
Below normal volume [µL]	6
Below normal dilution (factor)	1
Above normal volume [µL]	3
Above normal dilution (factor)	6
PLASMA	
Normal volume [µL]	3
Normal dilution (factor)	1
Below normal volume [µL]	6
Below normal dilution (factor)	1
Above normal volume [µL]	3
Above normal dilution (factor)	6
CSF	
Normal volume [µL]	3
Normal dilution (factor)	1
Below normal volume[µL]	6
Below normal dilution (factor)	1
Above normal volume [µL]	3
Above normal dilution (factor)	6
Whole blood	
Normal volume [µL]	3
Normal dilution (factor)	1
Below normal volume[µL]	6
Below normal dilution (factor)	1
Above normal volume [µL]	3
Above normal dilution (factor)	6

Results	
Decimals	1
Units	U/L
Correlation factor-Offset	0.000
Correlation factor-Slope	1.000

Range	
Gender	All
Age	
SERUM	>= <=100
URINE	
PLASMA	>= <=100
CSF	
Whole blood	
Gender	
Age	
SERUM	
URINE	
PLASMA	
CSF	
Whole blood	

Contaminants
Please refer to r910 Carryover Pair Table

Calibrators details	
Calibrator list	**Concentration**
Cal. 1/Blank	0
Cal. 2	*
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
	Max delta abs.
Cal. 1	0.001
Cal. 2	0.003
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
Drift limit [%]	0.8

Calculations	
Model	X
Degree	1

* Enter calibrator value