respons®910

Pancreatic amylase CC* FS**

Diagnostic reagent for quantitative in vitro determination of pancreatic amylase in serum or plasma on DiaSys respons®910

Order Information

Cat. No. 1 0551 99 10 921
4 twin containers for 120 tests each

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

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

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

(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. DiaSys respons containers provide protection from light. Do not freeze the reagents!

Warnings and Precautions

1. The remaining activity of salivary α-amylase is 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 [10].
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 rotor.

Specimen

Serum, heparin plasma or EDTA plasma

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

Discard contaminated specimens. Freeze only once.

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 2000 U/L Pancreatic 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 Pancreatic amylase
On-board stability	6 weeks
Calibration stability	6 weeks

Interfering substance	Interferences < 10%	P- amylase [U/L]
Ascorbate	up to 30 mg/dL	80.8
Hemoglobin	up to 200 mg/dL	54.8
	up to 200 mg/dL	175
Bilirubin, conjugated	up to 45 mg/dL	54.7
	up to 45 mg/dL	180
Bilirubin, unconjugated	up to 50 mg/dL	55.1
	up to 50 mg/dL	188
Lipemia (triglycerides)	up to 2000 mg/dL	51.7
	up to 1200 mg/dL	241
For further information on interfering substances refer to Young DS [7].		

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	31.9	143	295
Coefficient of variation [%]	1.80	2.43	1.95
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	25.2	102	133
Coefficient of variation [%]	3.44	2.31	1.99

Method comparison (n=137)	
Test x	DiaSys Pancreatic amylase CC FS (Hitachi 917)
Test y	DiaSys Pancreatic amylase CC FS (respons®910)
Slope	0.959
Intercept	0.349 U/L
Coefficient of correlation	0.99998

*** according to NCCLS document EP17-A, vol. 24, no. 34

Conversion factor

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

Reference Range [8]

	Women	Men
Serum/plasma	< 53 U/L	< 53 U/L
	< 0.88 µkat/L	< 0.88 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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IVD CE

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respons®910

Pancreatic Amylase CC FS

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:	PAMY
Shortcut:	
Reagent barcode reference:	016
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	1.2000
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	2
Concentration technical limits-Upper	2000
SERUM	
Normal volume [µL]	4
Normal dilution (factor)	1
Below normal volume [µL]	8
Below normal dilution (factor)	1
Above normal volume [µL]	4
Above normal dilution (factor)	6
URIN	
Normal volume [µL]	4
Normal dilution (factor)	1
Below normal volume [µL]	8
Below normal dilution (factor)	1
Above normal volume [µL]	4
Above normal dilution (factor)	6
PLASMA	
Normal volume [µL]	4
Normal dilution (factor)	1
Below normal volume [µL]	8
Below normal dilution (factor)	1
Above normal volume [µL]	4
Above normal dilution (factor)	6
CSF	
Normal volume [µL]	4
Normal dilution (factor)	1
Below normal volume[µL]	8
Below normal dilution (factor)	1
Above normal volume [µL]	4
Above normal dilution (factor)	6
Whole blood	
Normal volume [µL]	4
Normal dilution (factor)	1
Below normal volume[µL]	8
Below normal dilution (factor)	1
Above normal volume [µL]	4
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	>= <=53.0
URINE	>= <=319
PLASMA	>= <=53.0
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	0.002
Cal. 2	0.005
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
Drift limit [%]	0.8

Calculations	
Model	X
Degree	1

* Enter calibrator value