α-AMYLASE-PANCREATIC

COD 21799 2 x 60 mL + 2 x 15 mL
Only for *in vitro* use in the clinical laboratory

BioSystems

α-AMYLASE-PANCREATIC
IMMUNOINHIBITION

INTENDED USE

Reagent for the measurement of α-amylase concentration in human serum, plasma or urine. The obtained values are useful as an aid in the diagnosis and treatment of acute and chronic pancreatitis.

This reagent is for use in the BioSystems BA analyzers or in other analyzer with similar performance characteristics.

CLINICAL SIGNIFICANCE

α-Amylase catalyzes the hydrolysis of α-1,4-linkages of carbohydrates constituted of α-D-glucose units. The result is the formation of dextrins, maltose and some glucose molecules. α-Amylase is produced mainly by the exocrine pancreas (P-type; P-AMY) and the salivary glands (S-type; S-AMY) but it is also found in other tissues. The enzyme present in normal serum and urine is predominantly of pancreatic and salivary gland origin.

Assays of α-amylase activity in serum and urine are largely of use in the diagnosis of pancreatic diseases such as acute or chronic pancreatitis. Hyperamylasemia can also be due to renal insufficiency, acute pain of the abdomen, tumors of the lungs and the ovaries, salivary glands lesions, macroamylasemia, diabetic ketoacidosis, biliary tract disease, cerebral trauma, chronic alcoholism and drugs (opiates). The lack of specificity of total α-amylase measurements has led to the interest in the direct measurement of pancreatic α-amylase instead of total enzyme activity for the differential diagnosis of patients with acute abdominal pain[1,2].

Clinical diagnosis should not be made on the findings of a single test result, but should integrate both clinical and laboratory data.

PRINCIPLE OF THE METHOD

Amylase catalyzes the hydrolysis of 4-nitrophenyl-maltoheptaoside-ethylidene to smaller oligosacharides which are hydrolyzed by α-glucosidase liberating 4-nitrophenol. The catalytic concentration is determined from the rate of 4-nitrophenol formation, measured at 405 nm[3,4]. Specific antibodies inhibits the salivary isoenzyme and thus allow the measurement of pancreatic α-amylase[5,6].

CONTENTS AND COMPOSITION

A. Reagent: 2 x 60 mL. HEPES 50 mmol/L, calcium chloride 0.075 mmol/L, sodium chloride 90 mmol/L, magnesium chloride 13 mmol/L, α-glucosidase > 4 U/mL, pH 7.1, monoclonal antibodies (mouse) 50 mg/L.

B. Reagent: 2 x 15 mL. HEPES 50 mmol/L, 4-Nitrophenyl-maltoheptaoside-ethylidene 18 mmol/L, pH 7.1.

STORAGE AND STABILITY

Store at 2-8 ºC.

Components are stable once opened until the expiry date marked in the label if they are stored well closed and care is taken to prevent contamination during their use.

On board stability: Reagents open and kept in the refrigerated compartment of the analyzer are stable 2 months.

Indications of deterioration: Absorbance of the blank over the limit indicated in "Test Parameters".

ADDITIONAL MATERIALS REQUIRED (NOT PROVIDED)

Biochemistry Calibrator Human (BioSystems cod. 18044).

REAGENT PREPARATION

Reagents are provided ready to use.

SAMPLES

Serum, plasma or urine collected by standard procedures.

Pancreatic α-Amylase in serum or plasma is stable for 30 days at 2-8ºC. Use heparin or EDTA as anticoagulant.

Pancreatic α-Amylase in urine is stable for 1 month at 2-8ºC if pH is adjusted to approximately 7 before storage. Centrifuge or filter before testing.

CALIBRATION

A reagent blank should be done every day and a calibration at least every 2 months, after reagent lot change or as required by quality control procedures.

QUALITY CONTROL

It is recommended to use the Biochemistry Control Serum level I (cod. 18042), level II (cod. 18043) and the Biochemistry Control Urine (cod. 18054 and cod. 18066) to verify the accuracy of the measurement procedure. Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if control results are not within the acceptable limits.

REFERENCE VALUES

Serum, plasma[7]		Urine[7]	
U/L	µkat/L	U/L	µkat/L
13-53	0.22-0.88	7-356	0.12-5.92

These ranges are given for orientation only; each laboratory should establish its own reference ranges.

METROLOGICAL CHARACTERISTICS

The metrological characteristics described below have been obtained using a BA400 analyzer and following the guidelines of the Clinical & Laboratory Standards Institute (CLSI).

- Detection limit: 4.30 U/L = 0.072 µkat/L.
- Linearity limit: 1300 U/L = 21.6 µkat/L
- Precision:

Serum. Mean concentration	Repeatability (CV)	Within-laboratory (CV)
66 U/L = 1.10 µkat/L	1.5 %	1.7 %
149 U/L = 2.47 µkat/L	1.4 %	1.4 %

Urine. Mean concentration	Repeatability (CV)	Within-laboratory (CV)
62 U/L = 1.03 µkat/L	2.1 %	2.5 %
124 U/L = 2.06 µkat/L	1.3 %	1.9 %

- Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagents. Details of the comparison experiments are available on request.

LIMITATIONS OF THE PROCEDURE

- Interferences: bilirubin (up to 20 mg/dL), hemolysis (hemoglobin up to 1000 mg/dL) and lipemia (triglycerides up to 3000 mg/dL) do not interfere. Other drugs and substances may interfere[8].

BIBLIOGRAPHY

1 Friedman and Young. Effects of disease on clinical laboratory tests, 4th ed. AACC Press, 2001.

2 Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 4th edition. Burtis CA, Ashwood ER. WB Saunders Co., 2005.

3. IFCC primary reference procedures for the measurement of catalytic activity concentrations of enzymes at 37˚C. Part 8. Reference procedure for the measurement of catalytic concentration of α-amylase. *Clin Chem Lab Med* 2006; 44: 1146-1155.

4. Lorentz K. Routine α-amylase assay using protected 4-nitrophenyl-1,4-α-D-maltoheptaoside and a novel α-glucosidase. *Clin Chem* 2000;46:644-649.

5. Gerber M, Naujooks H, Lenz H, Wulff K. A monoclonal antibody that specifically inhibits human salivary α-amylase. *Clin Chem.* 1987;33:1158–62.4.

6. Steen G, Blijenberg BG, Leijnse B. Experiences with a new assay for pancreas specific alpha-amylase. *Ann Biol Clin* 1990;48(2):91-97.

7. Junge W, Werner W, Wilke B et al. Development and evaluation of assays for the determination of total and pancreatic amylase at 37ºC according to the principle recommended by the IFCC. *Clin Biochem* 2001;34:607-615.

8. Young DS. Effects of drugs on clinical laboratory tests, 5th ed. AACC Press, 2000.

TEST PARAMETERS

These reagents may be used in several automatic analyzers. Specific instructions for application in many of them are available on request.

R1: use Reagent A, R2: use Reagent B.

	BA200	**BA400**
GENERAL		
Name	**AMYLASE PANCREAT**	**AMYLASE PANCREAT**
Short name	P-AMY	P-AMY
Sample type	serum / plasma / urine	serum / plasma / urine
Analysis mode	kinetic bireagent	kinetic bireagent
Unit	U/L	U/L
Decimals	1	1
Reaction type	increasing	increasing
PROCEDURE		
Reading mode	monochromatic	monochromatic
Main filter	405	405
Reference filter	-	-
Sample	9	9
Vol. R1	240	240
Vol. R2	60	60
Reading 1 (cycle)	21	43
Reading 2 (cycle)	31	63
Predilution factor	- / - / 2	- / - / 2
CALIBRATION AND BLANK		
Blank type	distilled water	distilled water
Calibration mode	experimental calibrator	experimental calibrator
Number of calibrators	1	1
Calibration curve	-	-
OPTIONS		
Blank absorbance limit	0.300	0.300
Kinetic blank limit	-	-
Linearity limit	1300 / 1300 / 2600	1300 / 1300 / 2600
Substrate depletion	-	-

BioSystems S.A. Costa Brava, 30. 08030 Barcelona (Spain)
www.biosystems.global