α-AMYLASE - DIRECT

COD 12550 5 x 20 mL
Only for *in vitro* use in the clinical laboratory

Automated Systems

BioSystems

α-AMYLASE - DIRECT
DIRECT SUBSTRATE

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 A25 and A15 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 dextrans, maltose and some glucose molecules. α-Amylase is produced mainly by the exocrine pancreas (P-type) and the salivary glands (S-type) but it is also found in other tissues.

Assays of 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)[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

α-Amylase catalyzes the hydrolysis of 2-chloro-4-nitrophenyl-malto-trioside (CNP-G3) to 2-chloro-4-nitrophenol (CNP). The catalytic concentration is determined from the rate of 2-chloro-4-nitrophenol formation, measured at 405 nm[3-5].

$$\text{CNP} - \text{G3} \xrightarrow{\alpha\text{-amylase}} \text{CNP} + \text{maltotriose}$$

CONTENTS AND COMPOSITION

A. Reagent: 5 x 20 mL. MES 50 mmol/L, calcium chloride 5 mmol/L, sodium chloride 300 mmol/L, sodium thiocyanate 450 mmol/L, CNP-G3 2.25 mmol/L, pH 6.1.

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 (BioSystems cod. 18011) or Biochemistry Calibrator Human (BioSystems cod. 18044).

REAGENT PREPARATION

The Reagent is provided ready to use.

SAMPLES

Serum, plasma or urine collected by standard procedures.

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

α-Amylase in urine is stable for 30 days 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. 18005, cod. 18009 and cod. 18042) and II (cod. 18007, cod. 18010 and 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

Reaction temperature	Serum, plasma U/L	Serum, plasma µkat/L	Urine U/L	Urine µkat/L
25ºC	12-45	0.21-0.75	< 180	< 3.00
30ºC	17-60	0.28-1.00	< 240	< 4.00
37ºC[6,7]	22-80	0.37-1.33	< 321	< 5.35

Values at 25ºC and 30ºC are obtained from those at 37ºC by using a conversion factor.

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

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METROLOGICAL CHARACTERISTICS

The metrological characteristics described below have been obtained using an A25 analyzer. Results are similar with A15.

- Detection limit: 10.9 U/L = 0.18 µkat/L.
- Linearity limit: 1300 U/L = 21.6 µkat/L.
- Precision:

Mean concentration	Repeatability (CV)	Within-laboratory (CV)
130 U/L = 2.17 µkat/L	1.6 %	2.6 %
635 U/L = 10.59 µkat/L	0.9 %	2.3 %

- 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 250 mg/dL) and lipemia (triglycerides up to 1000 mg/dL) do not interfere. Other drugs and substances may interfere[7].

BIBLIOGRAPHY

1. Friedman and Young. Effects of disease on clinical laboratory tests, 4th ed. AACC Press, 2001.
2. Lorentz K, Gütschow B, Renner F. Evaluation of a direct alpha-amylase assay using 2-chloro-4-nitrophenyl-alpha-D-maltotrioside. *Clin Chem Lab Med* 1999; 37: 1053-1062.
3. Gella FJ, Gubern G, Vidal R, Canalias F. Determination of total and pancreatic α-amylase in human serum with 2-chloro-4-nitrophenyl-α-D-maltotrioside as substrate. *Clin Chim Acta* 1997; 259: 147-160.
4. Gubern G, Balsells D, Ferragut R, Galán A, Gella FJ, et al. Procedimiento recomendado para la determinación en rutina de la concentración catalítica de α-amilasa en suero sanguíneo humano. *Quim Clin* 1996; 15: 51-52.
5. Balsells D, Gella FJ, Gubern G, Canalias F. Reference values for α-amylase in human serum and urine using 2-chloro-4-nitrophenyl-α-D-maltotrioside as substrate. *Clin Chim Acta* 1998; 274: 213-217.
6. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 4th ed. Burtis CA, Ashwood ER, Bruns DE. WB Saunders Co, 2005.
7. 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.

	A25	A15
GENERAL		
Name	**AMYLASE DIRECT**	**AMYLASE DIRECT**
Sample type	SER /URI	SER / URI
Analysis mode	kinetic mon.	kinetic mon.
Units	U/L	U/L
Turbidimetry test	no	no
Decimals	0	0
Type of reaction	increasing	increasing
PROCEDURE		
Reading mode	monoch.	monoch.
Main filter	405	405
Reference filter	-	-
Sample	6	6
Vol. R1	300	300
Vol. R2	-	-
Washing	1.2	1.2
Reading 1 (cycle)	5	4
Reading 2 (cycle)	14	10
Reagent 2 (cycle)	-	-
Predilution factor	- / 2	- / 2
CALIBRATION AND BLANK		
Calibration type	multiple	multiple
Number of calibrators	-	-
Calibration curve	-	-
OPTIONS		
Blank absorbance limit	0.500	0.500
Kinetic blank limit	-	-
Linearity limit	1300 / 2600	1300 / 2600
Substrate depletion	-	-

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