BIOLABO
www.biolabo.fr
MANUFACTURER:
BIOLABO SAS,
Les Hautes Rives
02160, Maizy, France

AMYLASE CNPG3

Reagent for quantitative determination of α-amylase activity [EC 3.2.1.1] in human serum and plasma or urines

REF K1523	**R1**	8 x 10 mL
REF K2523	**R1**	8 x 10 mL
I REF K4523	**R1**	4 x 30 mL

TECHNICAL SUPPORT AND ORDERS
Tel: (33) 03 23 25 15 50
support@biolabo.fr
Latest revision: www.biolabo.fr

CE

IVD

Made In France

I: corresponds to significant modifications

I INTENDED USE

This reagent is designated for professional use in laboratory (automated method).
It allows the quantification of α-amylase activity [EC 3.2.1.1] in human serum and plasma or urines.

I GENERALITIES (1) (2)

α-amylase (AMY) is most frequently measured in the diagnostic of acute pancreatitis. In this case, a transient rise in serum amylase activity occurs within 2 to 12 h of the onset and maximal levels are attained 12 to 72 h later. However, elevation of α-amylase activity in serum is also associated with other disorders (abdominal disorders, biliary tract diseases, diabetic ketoacidosis, severe glomerular dysfunction, salivary glands disorders…). The organ source can sometimes be identified by determining whether the major isoenzyme present is type P (pancreatic) or S (salivary). Diagnostic specificity and sensitivity of elevation of α-amylase activity in urine remain disputed. Renal clearance of amylase, as related to the reasonably constant clearance of creatinine, is useful as a diagnostic concept.

PRINCIPLE (4)

Several procedures are available for the assay of α-amylase activity in serum (Amyloclastic methods, saccharogenic methods). Both these methods have poor linearity, sensitivity and precision when compared CNPG3 method. Reaction scheme is as follows:

$$10\ CNPG_3 \xrightarrow{\alpha\text{-amylase}} 9\ CNP + 1\ CNPG_2 + 9\ G_3 + G$$

CNPG3: 2-chloro-4-nitrophényl malto trioside
CNP : Chloro-nitro-phénol
G3: Maltotriose
G: Glucose

The rate of formation of CNP, directly proportional to the α-amylase activity in the specimen, is measured at 405 nm.

REAGENTS

R1 AMY Reagent

Calcium Acetate	6.0	mmol/L
MES Buffer pH 6.0 at 25°C	100	mmol/L
CNPG3	2.25	mmol/L
Potassium thiocyanate	900	mmol/L
NaCl	350	mmol/L
Preservative		

EUH210: Safety data sheet of working reagent is available on request
According to 1272/2008 regulation, this reagent is not classified as dangerous

SAFETY CAUTIONS

- Refer to current Material Safety Data Sheet available on request or on www.biolabo.fr
- Verify the integrity of the contents before use.
- Waste disposal: Respect legislation in force in the country.
- All specimens or reagents of biological origin should be handled as potentially infectious. Respect legislation in force in the country.

I Any serious incident that has occurred in connection with the device is notified to the manufacturer and the competent authority of the Member State in which the user and/or patient is based.

REAGENTS PREPARATION

Ready for use

STABILITY AND STORAGE

Stored away from light, well caped in the original vial at 2-8°C, reagents are stable when stored and used as described:

Unopened:
- Until expiry date stated on the label.

Once opened:
- Reagent is stable at least for 3 months.
- Discard any cloudy reagent or if absorbance is > 0.600 at 405 nm.

SPECIMEN COLLECTION AND HANDLING (1) (2)

Serum

Heparinised plasma.
α-amylase activity is stable in serum/plasma for:
- at least 7 days at room temperature.
- 1 month at 2-8°C.

Urines: Adjust pH to alkaline range before storage.
α-amylase activity is stable in urines for 7 days at 2-8°C.
In case of delay in transporting urines to the laboratory, use a preservative as merthiolate or thimerozal (0.24mM or 0.1 g/L).

LIMITS (3) (5)

For a more comprehensive review of factors affecting this assay refer to the publication of Young D.S.

MATERIAL REQUIRED BUT NOT PROVIDED

1. Basic medical analysis laboratory equipment.
2. Biochemistry Clinical Analyzer Kenza One, Kenza 240TX/ISE or Kenza 450TX/ISE

EXPECTED VALUES (1)

At 37°C	α-amylase (IU/L)	α-amylase (µKat/L)
Serum	22-80	[0.38-1.36]
Urines	24-408 IU/24 h	[0.41-6.94]/24 h

Each laboratory should establish its own normal ranges for the population that it serves.

PERFORMANCES

On Kenza 240TX, 37°C, 405 nm

Linearity Range: between 6 and 2000 IU/L

Detection limit: approx. 3 IU/L

Precision:

Within-run N = 20	*Low level*	*Normal level*	*High level*
Mean (IU/L)	80	157	473
S.D. (IU/L)	2.9	3.7	8
C.V. %	3.7	2.4	1.7

Between run N = 20	*Low level*	*Normal level*	*High level*
Mean (IU/L)	76	152	461
S.D. IU/L	3	4	11
C.V. %	3.6	2.9	2.4

Comparison studies with commercially available reagent:
Realised on human specimens (n=100) between 4.4 and 439 IU/L

y = 1.0109 x – 0.9039 r = 0.9977

Analytical Sensitivity: approx. 0.003 abs/min for 10 IU/L

Interferences:

Turbidity	No interference up to 0.256 abs
Total bilirubin	No interference up to 400 µmol/L
Direct bilirubin	No interference up to 477 µmol/L
Ascorbic acid	No interference up to 2500 mg/dL
Glucose	No interference up to 950 mg/dL
Haemoglobin	No interference up to 360 µmol/L

Other substances may interfere (see § Limits)

On the board stability: 2 months

Calibration Stability: 1 month

Make a new calibration when changing reagent batch, if quality control results are found out of the established range and after maintenance operations.

Performances and stability data on Kenza 450TX/ISE and Kenza One are available on request.

CALIBRATION (6)

- REF 95015 Multicalibrator traceable on *IRMM/IFCC-456*

The calibration frequency depends on proper instrument functions and on the preservation of reagent

QUALITY CONTROL

- REF 95010 EXATROL-N Level I
- REF 95011 EXATROL-P Level II
- External quality control program

It is recommended to control in the following cases:

- At least once a run
- At least once within 24 hours
- When changing vial of reagent
- After maintenance operations on the instrument

If control is out of range, apply following actions:

1. Prepare a fresh control serum and repeat the test
2. If control is still out of range, use a new vial of fresh calibrator
3. If control is still out of range, use a new vial of reagent and reassay

If control is still out of range, please contact BIOLABO technical support or your local Agent.

PROCEDURE

Refer to validated application of the Kenza Analyzer used.

CALCULATION

The analyzer provides directly final result.
Refer to the instruction of use of Kenza analyzer

REFERENCES

(1) *TIETZ N.W. Text book of clinical chemistry, 3rd Ed. C.A. Burtis, E.R. Ashwood, W.B. Saunders (1999) p. 689-698, 1284, 1286.*
(2) *Clinical Guide to Laboratory Test, 4th Ed., N.W. TIETZ (2006) p. 100-107.*
(3) *YOUNG D.S., Effect of Drugs on Clinical laboratory Tests, 4th Ed. (1995) p. 3-43 to 3-47.*
(4) *E.S. WINN-DEEN . H.DAVID, G. SIGLER and R. CHAVEZ, Development of a direct assay for α-amylase, Clin. Chem. 34, (1988), p. 2005-2008.*
(5) *A. Ying Foo, Renze Bais, Clin Chim Acta, (1998) 272 : p.137-147*
(6) *SRM: Standard Reference Material ®*

Manufacturer	Expiry date	In vitro diagnostic	Storage temperature	Dematerialized water	Biological risk
Product Reference	See Insert	Batch number	Store away from light	Sufficient for	Dilute wih