AMYLASE
CNPG3 Method (IFCC)

DIATEK

CLINICAL SIGNIFICANCE :

The determination of amylase activity in serum and urine is most commonly performed for the diagnosis of acute pancreatitis. In acute pancreatitis, amylase levels are elevated for longer periods of time in urine than in serum. Therefore, determining the ratio of the amylase and creatinine clearances is important in following the course of the pancreatitis.

TEST PRINCIPLE :

α-Amylase hydrolyzes the 2-chloro-p-nitrophenyl-α-D-maltotrioside (CNPG3) to release 2-chloro-nitrophenol and form 2-chloro-p-nitrophenyl-α- D-maltoside (CNPG2), maltotriose (G3) and glucose (G). The rate of increase in absorbance is measured at 405 nm and is proportional to the α- amylase activity in the sample

$$10\ CNPG3 \xrightarrow{\alpha\text{-amylase}} 9\ CNP + CNPG2 + 9G3 + G$$

REAGENTS COMPOSITION :

R1: Good's Buffer (pH 6.0) 36 mmol/l
NaCl 37 mmol/l
Potassium thiocyanate 250 mmol/l
Calcium acetate 3.6 mmol/l
Sodium azide 0.95 g/l
CNPG3 1.6 mmol/l

KIT CONTENTS :

CODE No. AM01

Pack size : (2x10 ml),

Reagent 1 2 x 10 ml

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2 - 8 ºC, and contaminations prevented during their use. Do not use reagents over the expiration date. Once opened the reagent is stable for 1 month On-board the analyser at approximately 10°C.

SAMPLES :

Serum, Heparin- and EDTA- plasma, Urine

INTERFERENCES

The following analyze were tested up to the levels indicated and found not to interfere with
- Ascorbic Acid: up to 30 mg/dL
- Bilirubin: no interference up to 50 mg/dL
- Hemoglobin: no interferences up to 150 mg/dL
- Triglycerides: no interference up to 2000 mg/dL

ASSAY CONDITIONS:

Wavelength : ..... 405 nm
Cuvette: ..... 1 cm light path
Constant temperature 37ºC
Reaction (Mode)..... Kinetic
Kinetic Factor..... 5172
Delay ..... 60 sec
Read time..... 180 sec
Linearity..... 1500 U/L
Unit..... U/L
Blanking..... D. Water
Slope of reaction..... Increasing

PROCEDURE :

Pipette into test tubes labeled Test (T) as follows:

For Serum / Plasma

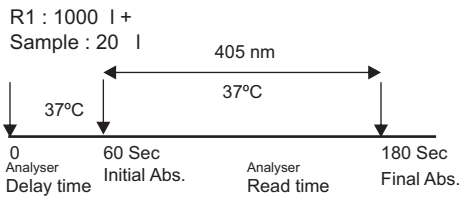
	T
Reagent R1	1000 l
Specimen	20 l

For Urine

	T
Reagent R1	1000 l
Specimen	10 l

Mix and read the change of absorption (A) between 60 sec and 180 sec at 37ºC

Assay Procedure summary (Serum/Plasma):



CALCULATIONS :

Amylase Activity in U/L = Abs/mint of Test x 5172

REFERENCE RANGE :

Serum/plasma : < 100 U/l
Spot Urine : < 455 U/l
24hrs. Urine : < 410 U/24h

The above reference range is guideline and all the laboratories must establish their own Age specific normal reference range. Final diagnosis should be made with correlation of clinical factors.

PRECAUTIONS :

1. Do not pipette by mouth. -Saliva and sweat contain α-amylase, therefore avoid contact of the reagent with skin.

   Reagents contain < 0.95 % sodium azide as a preservative. Avoid swallowing and/or contact with skin and mucinous membranes.

   Nitrocompounds are unfriendly to health. Do not swallow, avoid contact to skin. In case of skin contact wash off with plenty of water.
2. Use clean glassware and microtips while pipetting
3. Avoid contamination of the reagent during the assay process.
4. Before the assay begins, bring all the reagents to room temperature.
5. Do not freeze or expose the reagents to high temperature and protect from direct sunlight as it will affect the performance of the kit.
6. Programmes for specific autoanalysers are available on request.
8. For accuracy of results, the assay procedure, reagent preparation and storage has to be meticulously followed.
9. As with all the diagnostic procedures, the physician should evaluate data obtained by the use of this kit in light of other clinical information.

LINEARITY AND DETECTION LIMIT :

The linearity limit of the standard serum procedure is up to an amylase activity of 1500 U/l, for the standard urine procedure it is up to 3000 U/l . At higher activities the sample has to be diluted 1 + 5 with dist. water, the result multiplied by 6. The low detection limit for serum samples is equal to 5 U/L.

BIBLIOGRAPHY

1. Tietz, N. W. (Ed): Textbook of Clinical Chemistry., Philadelphia, W. B. Saunders Co., pp. 725-734(1986)
2. Klaus Lorentz. Clinical Chemistry, 46(5)644-649(2000)
3. Davidson, et al. Clin Chem. 38: 976-977(1992)
4. Junge, et al. Clin Biochem. 22: 109(1989)
5. Tietz, et al. Clin. Chem. 34: 2096-102(1988)

Manufactured by : **DIATEK Healthcare Pvt. Ltd.**
Amar Bangla Complex, NH - 2, Chakundi, Dankuni Hooghly - 712310 E-mail : diatek@rediffmail.com
Corporate Office : P-27, Kalindi Housing Scheme, Kalindi, Kolkata- 700089, Help line : 033 - 25223075