Lifechem™ α-AMYLASE-LR

(CNPG3 METHOD)

CLINICAL SIGNIFICANCE:

α-Amylase originates from pancreas and partial glands. The α-1→4 glucosidic linkages of starch and other related polysaccharides are catalyzed by α- Amylase to produce maltose and other related polysaccharides.

α-Amylase is increased due to inflammation of salivary glands, inflammation of pancreas or cancer of pancreas, blockage of, or severe damage to the intestine (bowel infarction), a stomach ulcer, gallstones, cystic fibrosis, pregnancy and diabetic ketoacidosis and a ruptured ectopic pregnancy.

α-Amylase is decreased due to an uncommon condition called Macroamylasemia, a severe liver disease. Some factors which may effect the test are medication, including warfarin, aspirin, birth control pills, diseases like hepatitis, chronic kidney disease which may cause high level, when the kidneys are no longer able to remove amylase from the blood.

TEST PRINCIPLE:

The direct amylase assay involves the use of a chromogenic substrate $CNPG_3$ (2-chloro-4-nitrophenyl linked with Galactomaltoside) which acts upon α- Amylase to release more than 95% of 2-chloro –4-nitrophenol (CNP), and form 2-chloro-4nitrophenyl-α- D-maltoside ($CNPG_2$), maltotriose (G_3) and Glucose (G). The rate of formation of 2-chloro-4-nitrophenol is proportional to the α- Amylase activity in the sample, which can be monitored by the kinetic assay at 405 nm.

$$CNPG_3 \xrightarrow{\alpha\text{- Amylase}} CNP + CNP\,G_2 + G_3 + G$$

NORMAL RANGES:

Serum	:	25-140 IU/L
Urine	:	1-17 IU/L/Hr.

KIT CONTENTS:

	Code No. KAA1 (5x5 ml)
α-Amylase reagent	5x5 ml

SPECIMEN:

1. Unhemolysed serum, urine.
2. E.D.T.A, Oxalate or Citrate inhibit amylase activity and hence cannot be used.
3. Amylase in serum is reported to be stable for one week at room temperature and for 2 months when stored at 2-8^{0}C.

WORKING REAGENT PREPARATION:

The reagent is ready-to-use and is stable at 2-8^{0}C till the expiry date mentioned on the labels. When opened care should be taken to avoid contamination.

PROCEDURE:

Pipette into test tube as follows:

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Working reagent	1.0 ml
Sample	0.025 ml

Mix thoroughly and transfer the assay mixture immediately to the thermostated cuvette and record the first reading after 1 minute and subsequently two more readings with 30 seconds interval at 405 nm.

CALCULATIONS:

Calculate the average change in absorbance per minute (ΔAbs/30 seconds x 2)

QUALITY CONTROL:

It is recommended to include Assayed Quality control serum (Level I & II) with each assay batch to verify the performance of the procedure. Failure to obtain the proper range of values in the assay of control sera may indicate reagent deterioration, instrument malfunction or procedural errors.

SYSTEM PARAMETERS:

Reaction Type	: Kinetic	No. of Readings	: 3
Wave length	: 405 nm	Units	: IU/L
Flow Cell temp	: 37^{0}C	Blank	: D.Water
Sample volume	: 25 µl	Linearity	: 2000 IU/L
Reagent volume	: 1000 µl	Blank Abs limit	: < 0.8
Factor	: 4640	Low Normal	: 25
High Normal	: 140	Reaction Direction	: Increasing
Delay Time	: 60 seconds	Read Time	: 30 seconds

NOTES:

1. Saliva and sweat contain α- Amylase. To avoid possible contamination do not pipette by mouth and avoid contact of the reagent and pipette tips with the skin.
2. The expected values of amylase are dependent on the substrate used in the formulation. Results cannot be compared with the kits based on formulations using other substrates.
3. Reagent should not be used if its absorbance exceeds 0.800 at 405 nm, against distilled water.
4. If the amylase activity is above 2000 IU/L dilute the specimen suitably with normal saline. In such case the results obtained should be multiplied by dilution factor to obtain correct amylase activity.

LINEARITY:

The linearity of this kit is up to 2000 IU/L.

BIBLIOGRAPHY :

1. Winn-Deen, E.S. *et. al.*, (1988) Clin.chem., 34/10, 2005-2008.
2. I.D.P. Wooton and H. Freeman, Microanalysis Medical Biochemistry (1982)
3. Young DS, Effects of Drugs on Clinical Laboratory tests, Third Edition:1990:3:34-6.

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