ANA BIO CLR α-AMYLASE

(Kinetic method using Gal G_3-α CNP)

Intended Use

Alpha amylase is a reagent set for determination of α-amylase activity based on kinetic method using Gal G_3-α CNP.

Principle

Amylase hydrolyzes the chromogenic substrate of CNP G_3 (2-chloro-4-nitrophenyl-α-D Maltotrioside) to release of more than 90% of 2-chloro-4-nitrophenol, which can be monitored by kinetic assay at 405 nm. The increase in absorbance is directly proportional to the amylase activity in sample.

$$\text{Gal } G_3\text{-}\alpha \text{ CNP} \xrightarrow{\alpha \text{ - Amylase}} \text{CNP} + \text{Gal } G_2 + 9G_3 + G$$

Reagent provided

1. Reagent

Working reagent preparation

The reagent is ready-to-use.

Reagent storage and stability

The reagent kit should be stored at 2-8℃ and is stable till the expiry date indicated on the label. The reagent is ready-to-use and stable till expiry, when stored at 2-8℃. **DO NOT FREEZE THE REAGENT.** Contamination of the reagent should be strictly avoided.

Specimen collection and preservation

Blood should be collected in a clean dry container. Plastic or siliconized container should be avoided as it may prolong clotting time. Although serum is preferred, plasma with heparin can be used. EDTA, Oxalate or Citrate inhibit the amylase activity and hence cannot be used. Amylase activity is stable in serum for 20 days at 2-8℃.

Assay guidelines for Analyzer

Reaction type	Kinetic
Reaction slope	Increasing
Wavelength	405 nm
Flow cell temperature	37℃
Zero setting with	Distilled water
Delay time	60 seconds
Interval	60 seconds
No. of readings	3
Sample Volume	25 µl (0.025ml)
Reagent Volume	1000 µl (1.0ml)
Factor	3178
Linearity	2000 IU/L

Assay guidelines for Manual procedure

Prewarm at 37℃ the required amount of working solution before use.

Reagent	**Test**
Working Reagent	1000 µl (1.0 ml)
Sample	25 µl (0.025ml)

Mix thoroughly and transfer the assay mixture immediately to the thermostated cuvette and start the stop watch simultaneously. Record the first reading at 60th second and subsequently three more readings with 60 seconds interval at 405 nm.

Note

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.

Calculation

Activity of amylase in IU/L = ΔAbs/min. x 3178

Normal Range

<96 IU/L at 37°C

Note:

1. The expected values of amylase are dependent on the substrate used in the formulation. Results cannot be compared with kits based on formulation using other substrates.
2. Since the expected values are affected by age, sex, diet and geographical location, each laboratory is strongly urged to establish its own reference range for this procedure.

Limitations

- Working reagent is considered unsatisfactory and should not be used if its absorbance exceeds 0.500 at 405 nm against distilled water.
- If the amylase activity is above 2000 IU/L, then dilute the specimen suitably with normal saline. In such case the results obtained should be multiplied by dilution factor to obtain correct amylase activity.

Quality Control

To ensure adequate quality control, it is recommended that each batch should include a normal and an abnormal commercial reference control serum. It should be realized that the use of quality control material checks both instrument and reagent functions together. Factors which might affect the performance of this test include proper instrument function, temperature control, cleanliness of glassware, and accuracy of pipetting.

References

1. Winn – Deen, E.S. David H. Siglet E. and chavzer R., *Clin. Chem.* 34/10, 2005-2008(1988).
2. Junge W. *et al., clin. Biochem.* 22,109(1989).

Symbols

IVD In Vitro Diagnostics. | Caution. | Keep away from sun light. | Date of Manufacture.

LOT Batch No. | Read Instructions. | Fragile. | Product Expiry Date.

CONT Content. | Storage Temperature. | Keep Dry. | Manufactured By.

REF Catalogue No.

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