

ANA BIO ISP α -AMYLASE

(Kinetic method using CNPG3)

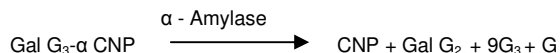
For Miura Instruments

Intended Use

Alpha amylase is a reagent set for determination of α -amylase activity based on kinetic method using CNPG3.

Principle

Amylase hydrolyzes the chromogenic substrate of CNP G₃ (2-chloro-4-nitrophenyl- α -D Maltotriose) to release of more than 90% of 2-chloro-4-nitrophenol. The colour intensity of the 2-Chloro-4-nitrophenol formed is directly proportional to the amylase activity in sample.



Components & Concentration of Reagents

Reagent	Component	Concentration
Reagent	MES buffer, pH 6.0	50 mmol/L
	CNPG3	≥ 2.6 mmol/L
	Potassium thiocyanate	≥ 140 mmol/L
	Stabilizers, excipients & surface active agents	

Reagent storage and stability

The kit should be stored at 2° - 8°C and is stable till the expiry date indicated on the label. **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°C.

Automation

This kit, though developed and manufactured to be used as manual assay and with I.S.E. Miura Analyzer, can be used also with other analyzers able to meet the specifications indicated in section "Reaction conditions – Test procedure" Application sheets are available for automatic instruments.

All applications not explicitly approved by KDPL. Cannot be guaranteed in terms of performance, and must there be established by the operator.

Calibration

For Calibration use the "Multicalibrator"

Calibration Stability

For the instrumentation series Miura, the calibration is recommended to be done every 10 days.

Materials required but not supplied in the kit

Calibrators and controls

Assay guidelines for Analyzer I.S.E. Miura

Analyte Name	Amylase	
Method Code	AMY	
Type	Kinetic	
Unit	IU/L	
Filter F1	405 nm	
Blank in	Not Use	
Step	Reaction Volume	U.M.
Volume reagent R1	200	μ l
Sample Volume	5	μ l
Final Incubation	60	Sec.
Kinetic reading time	192	Sec.

Normal range

Guidance value : <96 IU/L at 37°C

Note: Expected range varies from population to population and each laboratory should establish its own normal range.

Limitation

The reagent is linear up to 2000 IU/L. For higher value, dilute sample with normal saline and perform the assay. Multiply the final result by dilution factor to get the real value.

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, Wavelength setting, Expiration date of reagents and accuracy of prob aspiration.

Accuracy-Recovery

Amylase added to a serum matrix containing known amounts of Amylase gave an average recovery of 99%.

Interference

Avoid contamination of reagent, samples and glassware by saliva or sweat because they have a high α - Amylase content. Do not pipette by mouth.

There is no significant interference in samples containing up to 60 mg/dl of bilirubin, 500 mg/dl of haemoglobin and 100 mg/dl of ascorbic acid.

Precision of the Method

Within-run					
Range	U.M	Mean	S.D.	C.V.(%)	No. run
Low	IU/L	10	0.7	1.0	20
High	IU/L	1400	6.8	0.8	20
Between run					
Range	U.M	Mean	S.D.	C.V.(%)	No. run
Low	IU/L	12	0.8	3.0	20
High	IU/L	1480	15.6	1.3	20














Sensitivity

At 405 nm the activity of α – Amylase can estimate minimum of 4 IU/L.


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
 LOT	Batch No.		Product Expiry Date
 CONT	Content		Manufactured By
	Read Instructions		Date of Manufacture
	Storage Temperature		Keep Dry
 REF	Catalogue No.		Fragile
			Keep away from sun light



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