INTRODUCTION

1. ***Infinite*** α-Amylase is a reagent set for determination of amylase activity **based on kinetic method** using Gal G_2 - α CNP.
2. ***Infinite*** α-Amylase is a **ready-to-use reagent.**
3. ***Infinite*** α-Amylase can be determined in just **2½ minutes** at 37°C.
4. ***Infinite*** α-Amylase is **linear** upto 2000 **IU/l.**
5. ***Infinite*** α-Amylase is a **High Stability Reagent.**
6. ***Infinite*** α-Amylase can be used on any **Spectrophotometer, Discrete semiautomated and Automated analyzers.** Programme can be designed for any specific analyzer upon request.

PRINCIPLE

Amylase test involves use of a chromogenic substrate Gal G_2 - α CNP (2-chloro-4-nitrophenyl linked with galactosylmaltoside). The direct action of amylase with this susbtrate results in the 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.

Gal G_2 - α CNP $\xrightarrow{\alpha \text{ - Amylase}}$ **CNP + Gal G_2**

PREPARATION OF WORKING SOLUTION

The reagent is ready-to-use.

REAGENT STORAGE & STABILITY

The kit should be stored at 2-8°C 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°C.

DO NOT FREEZE THE REAGENT. Contamination of the reagent should be strictly avoided.

COMPONENTS & CONCENTRATION OF WORKING SOLUTION

Component	Concentration
• Buffer, pH 6.0	50 mmol/l
• Gal G_2 - α CNP	2.60 mmol/l
• KSCN	140 mmol/l
• Activators & Stabilizers	

SPECIMEN COLLECTION & PRESERVATION

Blood should be collected in a clean dry container. Avoid the use of plastic or siliconized container 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.

PROCEDURE

☐ Reaction type	Kinetic
☐ Reaction direction	Increasing
☐ Wavelength	405 nm.
☐ Flowcell temperature	37°C (± 0.2°C)
☐ Zero setting with	Distilled water
☐ Delay time	60 seconds
☐ No. of readings	4
☐ Interval	30 seconds
☐ Blank absorbance limit	< 0.500 Abs.
☐ Sample volume	0.02 ml (20 µl)
☐ Reagent volume	1.0 ml
☐ Factor	3806
☐ Linearity	2000 IU/l

Manual assay procedure

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

Perform the assay as given below :

1.0 ml procedure

Specimen	**0.02 ml (20 µl)**
Working solution	**1.0 ml**

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 30 seconds interval at 405 nm.

Calculation:

Calculate the average change in absorbance per minute.

(ΔAbs./30 seconds x 2)

Activity of amylase in IU/l = Δ Abs./min x 3806

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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.**

EXPECTED VALUES

< 96 IU/l at 37°C

NOTE :

1. The expected value of amylase is dependant 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.

PROCEDURE LIMITATIONS

1. Working reagent is considered unsatisfactory and should not be used if its absorbance exceeds 0.500 at 405 nm. against distilled water.
2. 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 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).

IVD	*In Vitro* Diagnostic Use		Date of Manufacturing
	Consult Instructions for use		Use by (YYYY-MM-DD)
REF	Catalogue Number		Temperature Limitation
LOT	Batch Code		Manufacturer

CE European Conformity

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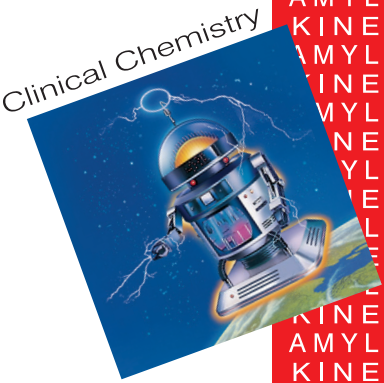

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