AMYLASE

(KINETIC)

ISO 9001:2008
ISO 13485:2003

CLINICAL SIGNIFICANCE

Increased levels are observed in acute pancreatic duct obstraction, peptic ulcers, biliary disease, bacterial paraotitis mumps and other intestinal obstructions.

PRINCIPLE

$CNPG_3$ + α-amylase+H_2O → Glucose+ maltotrioise + α-CNP+ $CNPG_2$

α-Amylase hydrolyses 2-chloro-4 nitrophenyl alpha-D-maltotrioside ($CNPG_3$) to release 2 chloro nitrophenol and form 2-chloro-4-nitrophenyl alpha-D-maltotrioside ($CNPG_2$) maltotrioside (G_3) and glucose (G). The rate of formation of the CNP can be quantitated spectrophoto-metrically at 405 nM which is proportional to alpha amylase activity in the sample.

REAGENTS COMPOSITION

$CNPG_3$	1.7 mMol/L
Sodium chloride	250 mMol/L
Calcium acetate	4.5 mMol/L
MES buffer pH 6.0	75 mMol/L
Potassium thiocyanate	650 mMol/L
Sodium Azide	15 mMol/L

Working Reagent Preparation

All reagents are ready to use.

STORAGE AND STABILITY

All reagents are stable up to expiry date mentioned on each label.

SAMPLE

Serum or plasma which has no sign of haemolysis. Common anticoagulants except EDTA and citrated have no interference on this assay.

Avoid EDTA and citrated Plasma.

PROCEDURE FOR AUTO ANALYSERS

Pippette into test tubes suitably labeled with Patient ID.

Reagent ..... µL	500
Sample ..... µL	10

Mix well. Take one minute reading at 405 nM after a delay of 60 seconds at 37°C. Avoid Mouth pipetting to eliminate ***contamination of saliva.***

NOTE: Programme the analyser using system parameters. A specific programme data sheet may be provided for each analyser upon request.

Reagent, sample volume and factor can be altered proportionately.

RESULTS

Compute

ΔA / Minute × 3806

SYSTEM PARAMETERS

Reaction	Kinetic
Direction of Reaction	upwards
Temperature	37ºC
Wavelength	405 nM (400- 410 nM)
Factor	3806
Linearity	2000 U/L
Absorbance Range	0-2 Å
Cuvette Path Length	1 cm
Delay Time	60 seconds
Interval	60 seconds
Number of Readings	1
Blank limit	<1.00
Reagent Volume	**500 µL**
Sample Volume	**10 µL**

EXPECTED VALUES

25 To 98 U/L

As with all diagnostic methods, the final diagnosis should not be made on the result of a single test as well as laboratory diagnosis must be confirmed with clinical manifestations.

QUALITY CONTROL

To ensure adequate quality control, each run should be accompanied with a standard quality control serum. The accuracy of the test must be established against the values of control serum calibrated as per this methodology. It should be realised that the use of quality control material checks both instrument and reagent functions together.

Factors which might affect the performance of this assay include proper instrument functions, temperature control, cleanliness of glasswares, accuracy of volumetric systems, temperature control and timings.

WARNING

This reagent system is for ***invitro*** use only. This reagent system is containing preservatives and components that have not established for safety if contacted on broken skin or eye or taken orally. In case of such incident wash off with plenty of water, or consult a physician.

BIBLIOGRAPHY

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