LIQUIZYME

α AMYLASE

(Direct Substrate Method)

BEACON

Code	Product Name	Pack Size
LS003A	Liquizyme α Amylase	2 x 10 ml
LS003C	Liquizyme α Amylase	5 x 10 ml
LS003D	Liquizyme α Amylase	10 x 10 ml
LS003E	Liquizyme α Amylase	10 x 1.0 ml
LS003H	Liquizyme α Amylase	4 x 10 ml
LS003I	Liquizyme α Amylase	1 x 120 ml

Intended Use

Diagnostic reagent for quantitative *in vitro* determination of alpha-Amylase in human serum, plasma and urine.

Clinical Significance

α-Amylase is derived mainly from the salivary glands and the exocrine pancreas. α-Amylase catalyses the hydrolysis of α-1-4 glucosidic linkages of starch and other related polysaccharides to produce maltose and other oligosaccharides. The enzyme is a relatively small molecule which is rapidly cleared by the kidneys and excreted in the urine. α-Amylase is most frequently measured in the diagnosis of acute pancreatitis when serum levels may be grossly elevated. In acute pancreatitis α-amylase starts to rise approximately 4 hours after the onset of pain, reaches a peak at 24 hours and remains elevated for 3-7 days. Hyperamylasmia is also associated with other acute abdominal disorders, biliary dysfunction, salivary gland disorders, ruptured ectopic pregnancy and macroamylasamia.

Principle

α Amylase catalyzes the hydrolysis of a 2 -cholo-4 nitro phenol salt to chloro. niro phenol (CNP). The rate of hydrolysis is measured as an increse in absorbance due to the formation of chloro nitrophenol, which is propotional to the amylase activity in the sample.

Reaction:

$$\text{CNP-Gal-G2} + \text{H2O} \xrightarrow{\alpha\ \text{Amylase}} \text{CNP} + \text{Gal-G2}$$

Reagent Composition

Reagent 1 : Amylase Reagent

MES buffer : >45 mmol/L
Calcium Chloride : >6 mmol/L

Reagent Preparation

Reagent is liquid, ready to use.

Stability And Storage

The unopened reagents are stable till the expiry date stated on the bottle and kit label when stored at 2–8°C.

Material Required But Not Provided

- Clean & Dry container.
- Laboratory Glass Pippetes or Micropippetes & Tips.
- Colorimeter or Bio-Chemistry Analyzer.

Specimen Collection And Handling

Use serum, plasma (heparin, EDTA), urine.
It is recommended to follow NCCLS procedures (or similar standardized conditions).

Stability

In Serum / Plasma :

7 days : at 20 – 25°C
7 days : at 4 – 8°C
1 year : at - 20°C

In Urine :

2 days : at 20 – 25°C
10 days : at 4 – 8°C
3 weeks : at -20°C

Discard contaminated specimens.

Quality Control

It's recommended to run normal and abnormal control sera to validate reagent performance.

Unit Conversion

U/l x 0.017 = µkat/l

Expected Values

at 37°C

Serum : up to 90 U/L
Urine : up to 480 U/L

It is recommended that each laboratory verify this range or derives reference interval for the population it serves.

Performance Data

Data contained within this section is representative of performance on Beacon system. Data obtained in your laboratory may differ from these values.

Limit of quantification : 10.0 U/L

Linearity : 1500 U/L

Measuring range : 10.0 – 1500 U/L

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Precision

Intra-assay precision Within run (n=20)	Mean (U/L)	SD (U/L)	CV (%)
Sample 1	75	1.39	1.87
Sample 2	267	3.50	1.31

Inter-assay precision Run to run (n=20)	Mean (U/L)	SD (U/L)	CV (%)
Sample 1	256	0.83	0.32

Comparison

A comparison between Beacon Amylase (y) and a commercially available test (x) using 20 samples gave following results :

y = 1.004x - 0.940 U/L

r = 0.999

Interferences

Following substances do not interfere:

haemoglobin up to 2.5 g/l, bilirubin up to 40 mg/dl, triglycerides up to 2000 mg/dl.

Note:

Saliva and skin contain alpha-amylase therefore never pipette reagents by mouth and avoid contamination of samples and reagents. However trace contamination can affect results.

Warning And Precautions

For in vitro diagnostic use. To be handled by entitled and professionally educated person.

Reagents of the kit are not classified like dangerous but contain less than 0.1% sodium azide - classified as very toxic and dangerous substance for the environment.

Waste Management

Please refer to local legal requirements.

Assay Procedure

Wavelength : 405 nm

Cuvette : 1 cm

Addition Sequence	Volume
Amylase Reagent	1000 µl
Sample	25 µl

Mix, incubate 1 min. at 37°C and then measure the intial absorbance of calibrator and sample against reagent blank. Measure the absorbance change exactly after 1, 2 and 3 min. Calculate 1 minute absorbance change (ΔA/min).

Calculation

Using factor:

Amaylase activity (U/L) = f x ΔA/min

f = factor

f = 3178 (a t 405 nm)

Applications for automatic analysers are available on request.

Assay Parameters For Photometers

Mode	Kinetic
Wavelength 1 (nm)	405
Sample Volume (µl)	25
Reagent Volume (µl)	1000
Lag time (sec.)	60
Kinetic Interval (sec.).	60
No. of Interval	3
Kinetic Factor	3178
Reaction temp. (°C)	37
Reaction Direction	Increasing
Normal Low (U/L)	0
Normal High (U/L)	90
Linearity Low (U/L)	10
Linearity High (U/L)	1500
Blank with	Water
Unit	U/L

References

1. J. F. Ziva, and P. R. Pannall, “Plasma Enzymes in Diagnosis” in Clinical Chemistry in Diagnosis and Treatment. Lloyd London 1979 : Chapter XV : 341-2.
2. Foo, Y. A. and Brosalki, S. B. Ann. Clin. Biochem. 1986; 23: 624-37.
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6. Young D.S. Effects of Drugs on Clinical Laboratory Tests Third Edition 1990 : 3 : 34.6.
7. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics. Burtis, C.A., Ashwood, E.R., Bruns, D.E.; 5th edition, WB Saunders Comp., 2012.
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Symbols Used On Labels

REF	Catalogue Number		Manufacturer
	See Instruction for Use	LOT	Lot Number
CONT	Content		Storage Temperature
	Expiry Date	IVD	In Vitro Diagnostics

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