AMYLASE SYSTEM PACK

Unicorn 480, Bonavera Chem 480 & Bonavera Chem 400

(Fully Auto Biochemistry Analyzer)

BEACON

Code	Product Name	Pack Size
UNI05	Amylase System Pack	2 x 20 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:

$$\text{CNP-Gal-G}_2 + \text{H2O} \xrightarrow{\alpha\ \text{Amylase}} \text{CNP} + \text{Gal-G}_2$$

REAGENT COMPOSITION

R1 : 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 reagent are stable till the expiry date stated on the bottle and kit label when stored at 2–8°C.

On board stability: Min. 30 days if refrigerated (2-10°) and not contaminated.

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.

CALIBRATION

Calibration with the Beacon Multicalibrator is recommended.

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 referance interval for the population it serves.

PERFORMANCE DATA

Data contained within this section is representative of performance on Beacon System.
Date 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

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 comparision between Amylase System Pack (y) and 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 upto 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 MENAGEMENT

Please refer to local legal requirement.

Parameter for Unicorn 480, Bonavera Chem 480 &

Bonavera chem 400 (Fully Auto Biochemistry Analyzer)

TEST NAME	AMYLASE
FULL NAME	AMYLASE
PRI WAVE	405 nm
SEC WAVE	630 nm
ASSAY/POINT	KINETIC
START	7
END	27
DECIMAL	2
UNIT	U/L
LINEARITY RANGE LOW	10
LINEARITY RANGE HIGH	1500
SAMPLE VOLUME	5 µ l
REAGENT 1 (R1) VOLUME	200 µl
REAGENT 1 (R2) VOLUME	-
SUBSATRATE DEPLETED	-
LINEARITY	1500 U/L
OUT OF LINEARITY RANGE	-
CALIBRATION TYPE	2 Point linear
POINTS	2
BLANK TYPE	Reagent
CONCENTRATION BLANK	0.00
CONCENTARTION STD	Refer calibrator value sheet.
SAMPLE VOLUME	5 µ l

NOTE

The program is made as per the in house testing, it can be modified as per requirements.

REFERENCES

1. J. F. Ziva, and P. R. Pannall, “Plasma Enzymes in Diagnosis” in Clinical Chemistr in Diagnosis and Treatment. Lloyd London 1979 : Chapter XV : 341-2.
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5. Shepherd, MDS. and Mazzachi, RD. The Clin. Biochem. 1983; 4 : 61-7.
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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