

AMYLASE SYSTEM PACK

Unicorn 480, Bonavera Chem 480 & Bonavera Chem 400

(Fully Auto Biochemistry Analyzer)

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



BEACON

INTENDED USE

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

CLINICAL SIGNIFICANCE

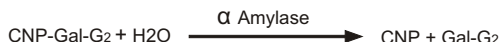
α -Amylase is derived mainly from the salivary glands and the exocrine pancreas. α -Amylase catalyses the hydrolysis of α -1-4 glucosidic linkages of starch and other related polysaccharides to produce maltose and other oligosaccharides. The enzyme is a relatively small molecule which is rapidly cleared 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. Hyperamylasemia is also associated with other acute abdominal disorders, biliary dysfunction, salivary gland disorders, ruptured ectopic pregnancy and macroamylasemia.

PRINCIPLE

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

REACTION:



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°C) 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 = μ kat/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.

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 comparison 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 MANAGEMENT

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 µl
REAGENT 1 (R1) VOLUME	200 µl
REAGENT 1 (R2) VOLUME	-
SUBSTRATE DEPLETED	-
LINEARITY	1500 U/L
OUT OF LINEARITY RANGE	-
CALIBRATION TYPE	2 Point linear
POINTS	2
BLANK TYPE	Reagent
CONCENTRATION BLANK	0.00
CONCENTRATION STD	Refer calibrator value sheet.
SAMPLE VOLUME	5 µl

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 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.
3. Bais, R. Am. Jnl. of Clin. Path. 1982; 78 : 184-8.
4. Clinical, Chemistry Infobase: A Scientific & Management Encyclopedia. Pesce-Kaplan Publishers 1996; 2619-2620.
5. Shepherd, M.D. and Mazzachi, R.D. The Clin. Biochem. 1983; 4 : 61-7.
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.
8. Wachtel, M. et al, Creation and verification of Reference Intervals. Laboratory Medicine 1995; 26 : 593-7.
9. National Committee for Clinical Laboratory Standards. User evaluation of Precision Performance of Clinical Chemistry Devices. NCCLS, 1984, NCCLS Publication EP5-T.



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		