

# AMYLASE SYSTEM PACK

B Auto 200, Unicorn 230, Unicorn 120 & Bonavera Chem 200  
( Fully Auto Biochemistry Analyzer)

Code	Product Name	Pack Size
BA205	Amylase System Pack	2x20 ml
BA205A	Amylase System Pack	2 x10 ml

## INTENDED USE

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

## CLINICAL SIGNIFICANCE

$\alpha$ -Amylase is derived mainly from the salivary glands and the exocrine pancreas.  $\alpha$ -Amylase catalyses the hydrolysis of  $\alpha$ -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.

$\alpha$ -Amylase is most frequently measured in the diagnosis of acute pancreatitis when serum levels may be grossly elevated. In acute pancreatitis  $\alpha$ -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

$\alpha$  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 =  $\mu$ 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.



# BEACON

## 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

## 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:

$y = 1.004x - 0.940 \text{ U/L}$

$r = 0.999$

## 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 B Auto 200, Unicorn 230, Unicorn 120 & Bonavera Chem 200 ( Fully Auto Biochemistry Analyzer)

TEST NAME	AMYLASE
FULL NAME	AMYLASE
PRI WAVE	405 nm
SEC WAVE	630 nm
ASSAY/POINT	KINETIC
START	4
END	14
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**

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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