Amylase System Pack

(CNPG3 Method)

B Auto 200, Unicorn 230, Unicorn 120 & Bonavera Chem 200 , Beaconic chem 200, Beaconic B200, Beaconic analyzer 120, Bonavera chem 100 (Fully Auto Biochemistry Analyzer)

Code	Product Name	Pack Size
BA271	Amylase syatem pack ($CNPG_3$ method)	2 x 20 ml
BA271A	Amylase syatem pack($CNPG_3$ method)	2 x 10 ml

Intended Use

For quantitative in vitro determination of alpha-Amylase in human serum, plasma and urine.

Clinical Significance

Amylase occurs in the salivary glands, fallopian tubes & in pancreas. Alpha-amylase is secreted by the pancreas from where it enters the duodenum, through the pancreatic duct. Any obstruction to these ducts causes alpha-amylase enzyme to enter the blood stream.

Elevated levels seen in acute pancreatitis, peptic ulcers, biliary disease, parotitis & other intestinal obstructions.

Decreased levels are seen in chronic pancreatic disorders having pancreatic cell destruction.

Principle

Reaction:

$$5CNPG_3 \xrightarrow{\text{Amylase}} 3CNP + 2CNPG_2 + 3\text{Maltotriose} + 2\text{ Glucose}$$

CNP = 2-Chloro-4-nitrophenol
CNP-G2= 2-chloro -4-nitrophenyl-a-maltoside

Reagent Composition

Reagent 1 : Amylase Reagent

MES Buffer (pH6.0)	50 mmol/L
CNPG3	2.27 mmol/L
Calcium chloride	60 mmol/L
Sodium chloride	70 mmol/L
Activator	900 mmol/L

Reagent Preparation

Reagent is liquid, ready to use.

Risk & safety

Material Safety data sheets (MSDS) will be provided on request.

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.

On board stability: Min 30 days if refrigerated (+8-+14°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 s 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 is recommended to use Beacon Norm & Path to verify the performance of the assay. Each laboratory has to establish its own internal quality control scheme and procedure for corrective action, if control do not recover within the acceptable range.

Unit Conversion

U/L x 0.017 = µkat/l

Expected Values

at 37°C

Serum : 25-86 U/L

Urine :< 470 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 : 2.0 U/L

Linearity : 2000 U/L

Measuring range : 2.0 – 2000 U/L

Precision

Intra-assay precision Within run (n=20)	Mean (U/L)	SD (U/L)	CV (%)
Sample 1	73.9	2.0	2.7
Sample 2	860.8	10.1	1.2

Inter-assay precision Run to run (n=20)	Mean (U/L)	SD (U/L)	CV (%)
Sample 1	74.3	2.0	2.7

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Comparison

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

y = 1.0464x

r = 0.9909

Interferences

No interference for

Bilirubin	Up to 10 mg/dL
Ascorbic acid	Up to 50 mg/dL
Hemoglobin	Up to 1000 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.Reagents must be disposed off in accordance with local regulations.

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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	2000
Sample Volume	5 µl
Reagent 1 (R1) Volume	200 µl
Reagent 2 (R2) Volume	-
Substrate Depleted	-
Linearity	2000 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

References

1. Junge, W., et al.; Clin. Biochem. 22, 109(1989)
2. Hohenwallnern, W.; J.Clin. chem. Clin. Biochem. 27,97(1989)

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

BEA/24/AM3/SB/IFU Ver-00
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JAS-ANZ BSCIC ISO 9001 : 2015 BSCIC ISO 13485:2016