

Amylase System Pack

(CNP_{G3} Method)

B Auto 400, Unicorn 480, Bonavera Chem 400, Beaconic B400 & Beaconic chem 400 (Fully Auto Biochemistry Analyzer)

| Code | Product Name | Pack Size |
|-------|--|-----------|
| UNI71 | Amylase system pack (CNP _{G3} method) | 2 x 20 ml |

Intended Use

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

Clinical Significance

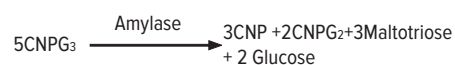
Amylase occurs in the salivary glands, fallopian tubes & in pancreas. Alpha-amylase is secreted by the pancreas from where it enters the duodenum, through the pancreatic duct. Any obstruction to these ducts causes alpha-amylase enzyme to enter the blood stream.

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:



CNP = 2-Chloro-4-nitrophenol

CNP-G₂ = 2-chloro-4-nitrophenyl-α-maltoside

Reagent Composition

Reagent 1 : Amylase Reagent

| | |
|--------------------|-------------|
| MES Buffer (pH6.0) | 50 mmol/L |
| CNP _{G3} | 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 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 |

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.

B Auto 400, Unicorn 480, Bonavera Chem 400, Beaconic B400 & Beaconic 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 | 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. Hohenwallnert, W.; J.Clin. chem. Clin. Biochem. 27,97(1989)

Symbols Used On Labels



Catalogue
Number



Manufacturer



See Instruction
for Use



Lot Number



Content



Storage Temperature



Expiry Date



In Vitro Diagnostics

BEA/24/AM3/UN/IFU Ver-00
01/05/2025

