LIQUIZYME

# Alpha Amylase

(CNPG3 Method)

BEACON

| Code | Product Name | Pack Size |
|---|---|---|
| LS004A | Liquizyme Alpha Amylase(CNPG3 method) | 4 x 10 ml |
| LS004B | Liquizyme Alpha Amylase(CNPG3 method) | 2 x 10 ml |
| LS004C | Liquizyme Alpha Amylase(CNPG3 method) | 5 x 10 ml |
| LS004D | Liquizyme Alpha Amylase(CNPG3 method) | 10 x 10 ml |
| LS004E | Liquizyme Alpha Amylase(CNPG3 method) | 10 x 1.0 ml |
| LS004F | Liquizyme Alpha Amylase(CNPG3 method) | 1 x 120 ml |

**Intended Use**

Diagnostic reagent 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.

**Reagent Deterioration**

Turbidity or precipitation in any kit component indicates deterioration and the component must be discarded. Values outside the recommended acceptable range for the Beacon Norm & Path control may also be an indication of reagent instability and associated results are invalid. Sample should be retested using fresh vial of reagent.

**Precaution**

To avoid contamination, use clean laboratory wares. Use clean, dry disposable pipette tips for dispensing. Close reagent bottles immediately after use.
Avoid direct exposure of reagent to light. Do not blow into the reagent bottles.
This reagent is only for IVD use and follow the normal precautions required for handling all laboratory reagents.

**Material Required But Not Provided**

- Clean & Dry container.
- Laboratory Glass Pipettes or Micropipettes & Tips.
- Colorimeter or Bio-Chemistry Analyzer.

**Specimen Collection And Handling**

Use serum, plasma (heparin, EDTA), urine.
It is recommended to follow NCCLS procedures (or similar standardized conditions).

**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**

It is recommended that each laboratory establish its own reference values. The following value may be used as guide line.

Serum / plasma : 25 - 86 U/L

Urine : < 470 U/L

Results obtained for patient samples are to be correlated with clinical findings of patient for interpretation and diagnosis.

**Performance Data**

Data contained within this section is representative of performance on Beacon system. Data obtained in your laboratory may differ from these values.

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**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 | 75.60 | 2.19 | 2.89 |
| Sample 2 | 298.20 | 4.80 | 1.61 |

| Inter-assay precision Run to run (n=20) | Mean (U/L) | SD (U/L) | CV (%) |
|---|---|---|---|
| Sample 1 | 139.06 | 2.19 | 1.57 |

**Comparison**

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

y = 1.0028x+0.2451 U/L

r = 1.0

**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.

**Assay Procedure**

Wavelength : 405 nm

Cuvette : 1 cm

| Addition Sequence | Volume |
|---|---|
| Amylase Reagent | 1000 µl |
| Sample | 25 µl |

Mix, incubate 1 min. at +37°C and then measure the intial absorbance of calibrator and sample against reagent blank. Measure the absorbance change exactly after 1, 2 and 3 min. Calculate 1 minute absorbance change (ΔA/min).

**Calculation**

Using factor:

Amaylase activity (U/L) = f x ΔA/min

f = factor

f = 3178 (at 405 nm)

**Applications for automatic analysers are available on request.**

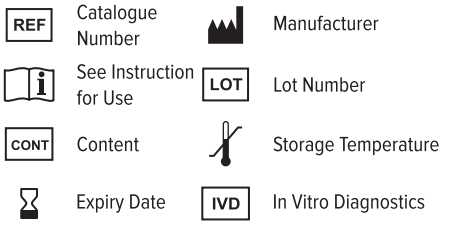
**Assay Parameters For Photometers**

| Mode | Kinetic |
|---|---|
| Wavelength 1 (nm) | 405 |
| Sample Volume (µl) | 25 |
| Reagent Volume (µl) | 1000 |
| Lag time (sec.) | 60 |
| Kinetic Interval (sec.). | 60 |
| No. of Interval | 3 |
| Kinetic Factor | 3178 |
| Reaction temp. (°C) | 37 |
| Reaction Direction | Increasing |
| Normal Low (U/L) | 25 |
| Normal High (U/L) | 86 |
| Linearity Low (U/L) | 2.0 |
| Linearity High (U/L) | 2000 |
| Blank with | DI Water |
| Unit | U/L |

**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**




BEA/24/AM3/LS/IFU Ver-02
21/09/2025