

## Liquick Cor - AMYLASE

|                          | (EN)           |
|--------------------------|----------------|
| <b>Kit name</b>          | <b>Cat. No</b> |
| Liquick Cor-AMYLASE mini | 1-292          |
| Liquick Cor-AMYLASE 10   | 1-293          |
| Liquick Cor-AMYLASE 30   | 1-255          |
| Liquick Cor-AMYLASE 500  | 1-314          |

### INTENDED USE

Diagnostic kit for determination of  $\alpha$ -amylase activity intended to use for manual assay and in several automatic analyzers. The reagents must be used only for *in vitro* diagnostic, by suitably qualified laboratory personnel, only for the intended purpose, under appropriate laboratory conditions.

### INTRODUCTION

$\alpha$ -Amylase is a digestive enzyme secreted by salivary glands and pancreas. Low level of amylase is also found in skeletal muscle, adipose tissue and fallopian tubes.  $\alpha$ -Amylase is measured generally in pancreas diseases. Elevation of amylase activity is observed also due to inflammation of abdominal cavity or salivary glands.

### METHOD PRINCIPLE

2-Chloro-4-nitrophenyl- $\alpha$ -maltotrioidide (CNP-G3) is a direct substrate for determination of  $\alpha$ -amylase activity, which does not require the presence of ancillary enzymes.

10 CNP-G3  $\alpha$ -amylase  $\rightarrow$  9 CNP + CNP-G2 + 9 maltotriose + glucose

The rate of 2-chloro-4-nitrophenol formation can be monitored at 405 nm and is proportional to the  $\alpha$ -amylase activity.

### REAGENTS

| Package   | Liquick Cor-AMYLASE mini | Liquick Cor-AMYLASE 10  |
|-----------|--------------------------|-------------------------|
| 1-AMYLASE | 2 x 10 ml                | 6 x 10 ml               |
|           | Liquick Cor-AMYLASE 30   | Liquick Cor-AMYLASE 500 |
| 1-AMYLASE | 6 x 30 ml                | 4 x 500 ml              |

### Working reagent preparation and stability

Reagent is ready to use. The reagent when stored at 2-8°C is stable up to expiry date printed on the package. The reagent is stable for 12 weeks on board the analyzer at 2-10°C.

### Concentrations in the test

|   |               |
|---|---------------|
| MES buffer  | < 120 mmol/l  |
| calcium acetate   | < 7 mmol/l    |
| potassium hydroxide   | < 40 mmol/l   |
| potassium thiocyanate   | < 1100 mmol/l |
| 2-chloro-4-nitrophenyl- $\alpha$ -maltotrioidide preservative, stabilizer | < 2 mmol/l    |

### Warnings and notes

- Protect from direct sunlight!
- Prevent the reagent from microbiological contamination and from saliva and sweat  $\alpha$ -amylase! Saliva and sweat contain  $\alpha$ -amylase. Do not pipette by the mouth, avoid skin contact with reagent, specimens, tips, cuvettes. Ensure to use automatic pipettes and laboratory gloves.
- The reagents are usable when the absorbance of the working reagent is less than 0.070 (read against distilled water, wavelength  $\lambda=405$  nm, cuvette l = 1 cm, at temp. 25°C).

### ADDITIONAL EQUIPMENT

- automatic analyzer or photometer able to read at 405 nm;
- thermostat at 37°C;
- general laboratory equipment.

### SPECIMEN

Serum or plasma collected on heparin, free from hemolysis, urine.

Do not use anticoagulants: EDTA, citrates and oxalates as they inhibit amylase activity.

Serum / plasma can be stored for 7 days at 15-25°C or for one month at 2-8°C.<sup>7</sup>

Urine can be stored for 2 days at 15-25°C or for 10 days at 2-8°C.<sup>9</sup> Amylase is very unstable in acid urine. Adjust pH to approximately 7.0 before storage.

Nevertheless it is recommended to perform the assay with freshly collected samples!

### PROCEDURE

Applications for analysers are available on request.

### Manual procedure

|             |        |
|-------------|--------|
| wavelength  | 405 nm |
| temperature | 37°C   |
| cuvette     | 1 cm   |

Pipette into the cuvette:

|           |              |
|-----------|--------------|
| 1-AMYLASE | 1000 $\mu$ l |
|-----------|--------------|

Bring up to the temperature of determination. Then add:

|        |            |
|--------|------------|
| sample | 20 $\mu$ l |
|--------|------------|

Mix and incubate at adequate temperature. After about 1 min. read the absorbance against air or water. Repeat the reading after exactly 1, 2 and 3 minutes. Calculate the mean absorbance change per minute ( $\Delta A$ /min.).

If  $\Delta A$ /min exceeds 0.400, dilute the sample with 0.9% NaCl in the ratio of 1 to 4 and repeat the assay. Multiply the result by 5.

### Calculation

$\alpha$ -amylase activity [U/l] =  $\Delta A$ /min. x 3498

$\alpha$ -amylase activity [ $\mu$ kat/l] =  $\Delta A$ /min. x 58.3

### REFERENCE VALUES <sup>8</sup>

|                |          |              |
|----------------|----------|--------------|
| serum / plasma | U/l      | $\mu$ kat/l  |
|                | 20 – 104 | 0.34 – 1.77  |
| urine          | U/l      | $\mu$ kat/l  |
|                | 32 – 641 | 0.54 – 10.90 |

It is recommended for each laboratory to establish its own reference ranges for local population.

### QUALITY CONTROL

For internal quality control it is recommended to use the following controls for each batch of samples: CORMAY SERUM HN (Cat. No 5-172) and CORMAY SERUM HP (Cat. No 5-173) for determination in serum; CORMAY URINE CONTROL LEVEL 1 (Cat. No 5-161) and LEVEL 2 (Cat. No 5-162) for determination in urine.

For the calibration of automatic analyzers systems the CORMAY MULTICALIBRATOR LEVEL 1 (Cat. No 5-174; 5-176) or LEVEL 2 (Cat. No 5-175; 5-177) is recommended.

The calibration curve should be prepared every 8 weeks, with change of reagent lot number or as required e.g. quality control findings outside the specified range.

### PERFORMANCE CHARACTERISTICS

The following results have been obtained using automatic analyzer Biolis 24i Premium. Results may vary if a different instrument or a manual procedure is used.

- Sensitivity:** 2.5 U/l (0.042  $\mu$ kat/l).

- Linearity:** up to 1500 U/l (25  $\mu$ kat/l).

- Specificity / Interferences**

Haemoglobin up to 2.5 g/dl, ascorbate up to 62 mg/l, bilirubin up to 20 mg/dl and triglycerides up to 1000 mg/dl do not interfere with the test.

- Precision**

| Repeatability<br>(run to run) n = 20   | Mean<br>[U/l] | SD<br>[U/l] | CV<br>[%] |
|--|---------------|-------------|-----------|
| level 1                                | 57.84         | 0.49        | 0.85      |
| level 2                                | 379.68        | 4.71        | 1.24      |
| Reproducibility<br>(day to day) n = 80 | Mean<br>[U/l] | SD<br>[U/l] | CV<br>[%] |
| level 1                                | 56.13         | 0.90        | 1.60      |
| level 2                                | 379.77        | 7.68        | 2.02      |

- Method comparison**

A comparison between amylase values determined at **Biolis 24i Premium** (y) and at **Prestige 24i** (x) using 100 samples gave following results:

$y = 1.0039x + 0.2956$  U/l;

$R = 0.9982$  (R – correlation coefficient)

### WASTE MANAGEMENT

Please refer to local legal requirements.

### LITERATURE

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