

## 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
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Bring up to the temperature of determination. Then add:

sample	20 $\mu$ l
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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 (run to run) n = 20	Mean [U/l]	SD [U/l]	CV [%]
level 1	57.84	0.49	0.85
level 2	379.68	4.71	1.24
Reproducibility (day to day) n = 80	Mean [U/l]	SD [U/l]	CV [%]
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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