

Liquick Cor - AMYLASE

	(EN)
Kit name	Cat. No
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

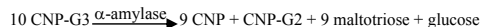
Diagnostic kit for determination of α -amylase activity intended to use for manual assay and in several automatic analyzers. The reagents must be used only for *in vitro* diagnostic, by suitably qualified laboratory personnel, only for the intended purpose, under appropriate laboratory conditions.

INTRODUCTION

α -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. α -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- α -maltotrioidide (CNP-G3) is a direct substrate for determination of α -amylase activity, which does not require the presence of ancillary enzymes.



The rate of 2-chloro-4-nitrophenol formation can be monitored at 405 nm and is proportional to the α -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- α -maltotrioidide preservative, stabilizer	< 2 mmol/l

Warnings and notes

- Protect from direct sunlight!
- Prevent the reagent from microbiological contamination and from saliva and sweat α -amylase! Saliva and sweat contain α -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.⁷

Urine can be stored for 2 days at 15-25°C or for 10 days at 2-8°C.⁹ 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 μ l
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Bring up to the temperature of determination. Then add:

sample	20 μ 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 ($\Delta A/\text{min}$).

If $\Delta A/\text{min}$ 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

$$\alpha\text{-amylase activity [U/l]} = \Delta A/\text{min} \cdot x \cdot 3498$$

$$\alpha\text{-amylase activity } [\mu\text{kat/l}] = \Delta A/\text{min} \cdot x \cdot 58.3$$

REFERENCE VALUES⁸

serum / plasma	U/l	$\mu\text{kat/l}$
	20 – 104	0.34 – 1.77
urine	U/l	$\mu\text{kat/l}$
	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 $\mu\text{kat/l}$).

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

- 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:

$$y = 1.0039x + 0.2956 \text{ U/l;}$$

$$R = 0.9982 \quad (R - \text{correlation coefficient})$$

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

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