

## DIAGNOSTIC KIT FOR DETERMINATION OF $\alpha$ -AMYLASE ACTIVITY



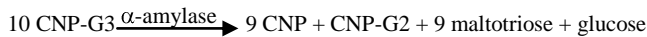
### HC – AMYLASE

#### 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- $\alpha$ -maltotrioxide (CNP-G3) is a direct substrate for determination of  $\alpha$ -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  $\alpha$ -amylase activity.

#### REAGENTS

##### Package

1-Reagent 6 x 98 ml

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 analyser at 2-10°C. Protect from light. Prevent the reagent from microbiological contamination and from saliva and sweat  $\alpha$ -amylase!

##### Concentrations in the test

MES	100 mmol/l
calcium acetate	6 mmol/l
potassium hydroxide	30 mmol/l
potassium thiocyanate	900 mmol/l
2-chloro-4-nitrophenyl- $\alpha$ -maltotrioxide	2.27 mmol/l

#### Warnings and notes

- Product for in vitro diagnostic use only.
- 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.
- 1-Reagent is classified as a harmful.

**Ingredients:** potassium thiocyanate, sodium azide;

**Xn** – Harmful.



**R 20/21/22-32:** Harmful by inhalation, in contact with skin and if swallowed. Contact with acids liberates very toxic gas.

**S 24-36-46:** Avoid contact with skin. Wear suitable protective clothing. If swallowed, seek medical advice immediately and show this container or label.

#### SPECIMEN

Serum, heparinized plasma free from hemolysis, urine.

Do not use EDTA, citrate and oxalate as anticoagulants because of amylase activity inhibition!

Urine – before storage pH should be adjusted to about 7.0.

Amylase activity remains stable in specimen up to 7 days at 15-25°C or up to 2 months at 2-8°C.

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

#### PROCEDURE

The reagent is ready to use.

This reagent may be used in automatic analyser Hitachi 911/912.

Application should be entered using handheld barcode scanner and attached barcodes sheet, according to procedure described below:

1. Delete previous version of application and calibrators assigned to it and restart the analyser.
2. Enter codes of calibrators according to the attached list.

3. Enter barcoded application and assign proper values to calibrators.
4. To activate entered application go to the tab UTILITY | APPLICATION | RANGE and change value of field DATA MODE from INACTIVE to ON BOARD. Confirm the change using UPDATE button.
5. Put reagents on board the analyser – they will be assigned to relevant tests automatically. Perform also measurement of level of reagents inside the bottles.
6. After calibration analyser is ready to use.

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

serum / plasma	U/l	$\mu$ kat/l
	24 – 65	0.41 – 1.10
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 CORMAY SERUM HN (Cat. No 5-172) and CORMAY SERUM HP (Cat. No 5-173) for determination in serum or CORMAY URINE CONTROL LEVEL 1 (Cat. No 5-161) and LEVEL 2 (Cat. No 5-162) for determination in urine with each batch of samples.

For the calibration of automatic analysers systems the CORMAY MULTICALIBRATOR LEVEL 1 (Cat. No 5-174; 5-176) is recommended. **Calibrator and 0.9% NaCl** should be used for calibration.

The calibration curve should be prepared every 12 weeks, with change of reagent lot number or as required e.g. quality control findings outside the specified range.

#### PERFORMANCE CHARACTERISTICS

These metrological characteristics have been obtained using the automatic analyser Hitachi 912. Results may vary if a different instrument or a manual procedure is used.

- **Sensitivity:** 6.8 U/l (0.114  $\mu$ kat/l).
- **Linearity:** up to 1950 U/l (32.57  $\mu$ 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	54.19	0.45	0.84
level 2	381.85	6.81	1.78

Reproducibility (day to day) n = 80	Mean [U/l]	SD [U/l]	CV [%]
level 1	55.55	2.06	3.71
level 2	393.72	12.94	3.29

##### ▪ Method comparison

A comparison between amylase values determined at Hitachi 912 (y) and at BS-400 (x) using 77 samples gave following results:

$$y = 1.0568x + 0.6365 \text{ U/l};$$

$$R = 0.9995$$

(R – correlation coefficient)

## **WASTE MANAGEMENT**

Please refer to local legal requirements.

## **LITERATURE**

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