ßiomaghreb

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IN VITRO DIAGNOSTIC USE

IVD

ALPHA AMYLASE Direct Kinetic colorimetric method CNPG

	07018	20 x 3 ml (60 T)
REF	07025	10 x 10 ml (100 T)
REF	07032	5 x 3 ml (15 T)

CINICAL SIGNIFICANCE

 α -Amylases are hydrolytic enzymes which break down starch into maltose. In the human body $\alpha\textsc{-Amylases}$ originate from various organs: pancreatic amylase is produced by the pancreas and released into the intestinal tract; salivary amylase is synthesized in the salivary glands and secreted into saliva. The amylase present in the blood is eliminated through the kidney and excreted into the urine. Therefore, elevation of amylase activity in serum is reflected in a rise of urinary amylase activity. Measurement of α -Amylase in serum and urine is mainly used for diagnosis of pancreatic disorders as well as for detecting the development of complications.

PRINCIPLE

Kinetic colorimetric determination of the amylase activity in serum, plasma or urine depending on the reaction:

5 CNPG₃ α -amylase 3 CNP + 2 CNPG₂ + 2 G₃ + 2 Glucose

α-Amylase hydrolyses 2-chloro-4-nitrophenyl-D-maltotrioside (CNPG₃) to release 2-chloronitrophenol and form 2-chloro-4-nitrophenyl-D-maltoside (CNPG2), maltriose (G2) and glucose (G). The rate of formation of 2-chloro-nitrophenol measured by the variation in optical density at 405 nm per minute is proportional to the amylase activity in the sample.

REAGENT COMPOSITION

Reagent CNPG₃ ready for use:

2-chloro-4-nitrophenyl-α-D-	
maltotrioside (CNPG ₃)	2.5 mmol/l
Buffer MES pH = 6	50 mmol/l
NaCl	250 mmo/l
Ca (CH3 COO)	4.5 mmol/l
KSCN	375 mmol/l
Sodium Azide	152 mmol/l

REAGENT PREPARATION

- The reagent supplied is ready to use.

- Do not use the reagent if the OD of the reagent blank is greater than 0.500 at 405 nm

SAFETY CAUTIONS

Biomaghreb reagents are intended for use by qualified personnel for in vitro use (do not pipette by mouth).

- · Refer to the current SDS available on request or at www.biomaghreb.com;
- · Verify the integrity of the reagents before use; and
- · Disposal of waste: comply with the legislation in force.

For safety reasons, treat any specimen or reagent of biological origin as potentially infectious. Respect the legislation in force.

SAMPLE PREPARATION

- Serum or plasma collected on heparin or iodoacetate (EDTA or citrate must not be used).
- · Embarrassing haemolysis

Urine

NOTE

The reagent should be stored at 15° - 25°C before use. DO NOT PIPE BY MOUTH to avoid contamination with salivary amylase

PRESERVATION AND STABILITY

. The reagent is stable at 2-8° until the expiry date, and for 30 days at room temperature (20-25°C)

ADDITIONAL EQUIPMENT

- · Basic equipment of the medical analysis laboratory;
- · Spectrophotometer or Clinical Biochemistry Analyzer.

LINEARITY

- . The reaction is linear up to 2000 U/L.
- If the ΔDO per min is > 0.630 repeat the determination by diluting the sample 1/10 with NaCL 0.9 α/L

PROCEDURE

Wavelength	405 nm
Temperature	37°C
Tank	1 cm thick

Adjust the Zero of the spectrophotometer to air or distilled water.

In a tube introduce: • α -amylase Reagent Equilibrate to 37°C, add	1000 µl	
• Sample	Serum 25 µl or Urine 10 µl	
Mix and incubate at 37°C for 1 minute. Read the initial absorbance and start timer immediatety. Read again at constant intervals for 3 minutes		

CALCULATION

 α -amylase (U/L) Sérum = $\Delta D.0 / min / x 3178$

 α -amylase (U/L) Urine = $\Delta D.0 / min / x 7829$

REFERENCE VALUES

	37°C
Serum, plasma	< 100 U/I
Urine	< 380 U/I

REFERENCES

- Kaufman RA. Tietz NW-Clin Chem.26: 8461 (1980) ;
- Ranson JHC.Curr Prob Surg, 16:1 (1979);
- Young DS. et al, v. clin chem, 21 (1975).









Limitation







Sufficient

for < n > essais

REF

Version B