

**Use**

Kit for measurement of amylase in serum, plasma and urine. Kinetic method CNPG3.

**Summary**

Amylase activity measurements are used in the diagnosis and treatment of pancreatitis.

**Principle**

Kinetic analysis Amylase hydrolyzes the CNPG3 into glucose polymers + 4-NP. The rate of increase in absorbance, due to the p-nitrophenol, is proportional to the amylase activity in the sample.

**Reagents**

<b>R1</b>	MES buffer ph 6.0	90.0 mmol/l
	sodium chloride	500.0 mmol/l
	potassium sulphocyanide	0.60 mol/l
	calcium acetate	7.2 mmol/l
	CNPG3	2.7 mmol/l

**Reagent Preparation**

Reagents are liquid and ready to use. Keep out the reagent from refrigerator only for the use and recap it immediately

**Storage and stability**

- Store the kit at 2-8°C.
- After opening, the R1 vial is stable up to 60 days if recapped immediately and protected from contamination, evaporation, direct light, and stored at the correct temperature.

**Caution:** Avoid to use pipet and to handle the sample or the reagent, because saliva and sweat contain amylase.

**Precaution in Use**

The product is not classified as dangerous (DLg. N. 285 art. 28 l. n. 128/1998). However the reagent should be handled with caution, according to good laboratory practice. Caution: the reagents contain Sodium Azide (0.095%) as preservative. Avoid swallowing and contact with skin, eyes and mucous membranes.

**Waste Management**

Please refer to the local legal requirements.

**Specimen Collection and Preparation**

- Serum or heparinized plasma.
- Urine.
- Do not use samples with haemolysis.
- The amylase is stable up to 60 days at 2-8°C

**Note**

- The kit, according to this method, must be used in manual procedures. About automatic use follow specific applications.
- Avoid direct light, contamination and evaporation.
- In case of complaint or quality control request, refer to the lot number on the package or the lot number on the single vials.

**Procedure**

Wavelength	λ: 405 (400-440) nm
Working Temperature	37°C
Optical path	1 cm
Reaction	"kinetic" (increasing)

Bring the reagent at 15-25°C before using it

**-- Monoreagent Procedure "sample starter"**

	BLANK	SAMPLE
<b>Working Reagent</b>	1000 µl	1000 µl
<b>Distilled Water</b>	25 µl	--
<b>Sample</b>	--	25 µl

Mix, and after 1' at 37°C, measure the absorbance decrease during 3 minutes. Calculate the absorbance variation ΔE/min from readings executed.

**Calculation**

$$\text{Amylase [U/l]} = \Delta E/\text{min} \times 3178$$

The reagent performances are related to 37°C, 1 cm and 405 nm

**Reference Values**

Sierum or plasma	35 – 115 U/L
Urine	13 – 680 U/L

Reference values are considered indicative since each laboratory should establish reference ranges for its own patient population. The analytical results should be evaluated with other information coming from patient's clinical history.

**ANALYTICAL PERFORMANCES**
**Linearity**

Reaction is linear up to a concentration of 1000 U/L. Samples with values exceeding 1000 U/L must be diluted with saline solution. Then, multiply, the result for diluting factor.

**"Intra-Assay" precision (within-Run)**

Determined on 20 samples for each control (N-H) (Normal- High). Results:

MEAN (U/l)	N = 85.50	H = 207.73
S.D.	N = 1.60	H = 2.78
C.V.%	N = 1.87	H = 1.37

**"Inter-Assay" precision (between-Run)**

Determined on 20 samples for each control (N-H) (Normal- High). Results:

MEAN (U/l)	N = 88.65	H = 207.73
S.D.	N = 2.53	H = 4.03
C.V.%	N = 2.86	H = 1.95

**Analytical sensitivity**

The test sensitivity in terms of detection limit is: 5.2 U/L

**Correlation**

A study made in comparison of this method with a similar one, on 20 samples, has given a correlating factor  $r = 0.99$

$$y = 1.0867x + 5.6708$$

**Interferences**

No interference was observed by the presence of:

Bilirubin	≤ 25 mg/dl
Triglycerides	≤ 1000 mg/dl
Hemoglobin	≤ 200 mg/dl

For a comprehensive review of interfering substances, refer to the publication by Young.

**Quality controls**

It's necessary, each time the kit is used, to make the quality controls and to check that values obtained are within the acceptance range provided in the insert. Each laboratory should establish its own mean and standard deviation and adopt a quality control program to monitor laboratory testing.

**Bibliography**


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**Simbols**

**CE** CE Mark (requirement of 98/79 regulation)

**IVD** in vitro medical device

**LOT** Batch Code

 Use by

 Storage temperature limits  
 Read instruction for use

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