

**PRODUCT CODE**  
CZ002

**INTENDED USE**

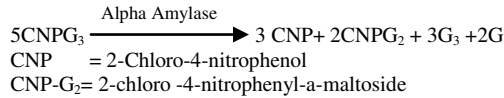
The reagent is intended for *in vitro* quantitative determination of amylase in serum, plasma & urine.

**CLINICAL SIGNIFICANCE**

Amylase occurs in the salivary glands, fallopian tubes & in pancreas. Alpha-amylase is secreted by the pancreas from where it enters the duodenum, through the pancreatic duct. Any obstruction to these ducts causes alpha-amylase enzyme to enter the blood stream. Elevated levels seen in acute pancreatitis, peptic ulcers, biliary disease, parotitis & other intestinal obstructions. Decreased levels are seen in chronic pancreatic disorders having pancreatic cell destruction.

**PRINCIPLE**

The alpha amylase liquicolor colorimetric test comprises a new substrate; 2-chloro-4-nitrophenyl-maltotrioxide (CNPG<sub>3</sub>). The substrate reacts directly with alpha amylase and does not require presence of ancillary enzymes. The release of 2-chloro 4-nitrophenol (CNP) from the substrates and resulting absorbance increase per minute is directly related to the alpha-amylase activity.



**REAGENT COMPOSITION**

**ALPHA AMYLASE REAGENT**

MES buffer (pH6.0)	50 mmol/L
CNPG	2.27 mmol/L
Calcium acetate	60 mmol/L
Sodium chloride	70 mmol/L
Potassium Thiocyanate	253 mmol/L
Sodium azide	0.95 g/L

**REAGENT PREPARATION**

Reagent is ready-to-use.

**STORAGE AND STABILITY**

Reagent is stable up to the expiry date when stored at 2-8°C.

**SPECIMEN**

Serum, heparinized Plasma, Urine  
No loss of activity within 5 days at 4-25°C

**PRECAUTION**

- To avoid contamination, use clean laboratory wares. Avoid direct exposure of reagent to light.
- Saliva and sweat contains alpha amylase. To avoid possible contamination do not pipette by mouth and avoid contact of the reagent and pipette tips with the skin.
- The reagent solution contains sodium azide, do not swallow. Avoid contact with skin and mucous membrane.

**ASSAY**

Wavelength : Hg 405 nm (400 - 410 nm)  
Cuvette : 1 cm light path  
Temperature : 25°C/ 37°C  
Measurement : Against water (increased absorbance)

**PROCEDURE**

Pipette into cuvette	25°C	37°C
Reagent Solution	1000 µL	1000 µL
Sample	20 µL	10 µL
Mix well; incubate 1 minute at the desired temperature. Read the absorbance at the same time, start stop watch, Read the absorbance again exactly after 1, 2 and 3 minutes.		

**CALCULATION**

From the reading determine the mean absorbance change per minute ( $\Delta A / \text{min}$ ) and employ this for the calculation of alpha amylase activity in the sample. Use the following factors:

$$U/L (25^\circ C) = \Delta A / \text{min} \times 9864$$

$$U/L (37^\circ C) = \Delta A / \text{min} \times 24820$$

**Conversion factor from traditional unit (U/L) in SI - units**

**(Kat/L):**

$$1 U / L = 16.67 \times 10^{-9} \text{ Kat} / L$$

$$= 16.67 \times 10^{-3} \text{ ukat} / L$$

$$1 \text{ ukat} / L = 60 U / L$$

**Linearity**

Up to 1500 u/l, If the absorbance change per minute exceeds  $\Delta A / \text{min} = 0.300$ , dilute 0.1 ml sample with 0.5 ml NaCl solution (0.9%) and repeat the assay using this dilution. Multiply the result by 6.

**NORMAL RANGE**















	25°C	37°C
Serum, plasma up to	120 U/L	220 U/L
Urine up to	600 U/L	1000 U/L
24 – h Urine up to	450 U/24 h	900 U/24 h

Each laboratory should establish reference ranges for its own patients' population.

**QUALITY CONTROL**

All control sera with values determined by this method can be used.

**SYMBOL ON LABELS**

Symbols	Signify	Symbols	Signify
	Catalogue Number		Pack Size
	Expiry Date		Volume
	Storage Condition		Lot Number
	Instruction for Use		In Vitro Diagnostics
	Manufacturing Date		Manufacturer
	Number of Tests		For Single Use Only
	EC Representative		European conformity

**BIBLIOGRAPHY**

- Junge, W.,etal., 22. 109 (1989), Clin Biochem
- Hohenwallner, W.,. 27, 97 (1989), J. Clin. Cham, Clin. Biochem.