

Alpha Amylase

CNPG₃- Liquicolor -Colorimetric test (BR-160/
BR-120)

PRODUCT CODE CZ002

INTENDED USE

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

CLINICAL SIGNIFICANCE

α -Amylase is found primarily in the pancreas and salivary gland. Elevated serum levels are associated with acute or chronic pancreatitis. Amylase activity in serum tends to increase rapidly after an attack of pancreatitis and may be demonstrated as early as six to eight hours after its onset. Levels stay elevated for one to three days and then return rapidly to normal, reflecting the efficient renal clearance of the enzyme. Decreased amylase levels have been found in abscesses of the liver, acute hepatocellular damage, cirrhosis, cancer of the liver and bile duct and cholecystitis.

PRINCIPLE

The alpha amylase liquicolor colorimetric test comprises a new substrate; 2-chloro-4-nitrophenyl-maltotrioxide (CNPG₃). 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.

Alpha Amylase

5CNPG₃ -----→ 3 CNP+ 2CNPG₂ + 3G₃ +2G

CNP = 2-Chloro-4-nitrophenol

CNP-G₂= 2-chloro -4-nitrophenyl-a-maltoside

REAGENT COMPOSITION

ALPHA AMYLASE REAGENT

MES buffer (pH6.0)	50 mmol/L
CNPG	2.1 mmol/L
Calcium acetate	6 mmol/L
Sodium chloride	325 mmol/L
Potassium Thiocyanate	900 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

APPLICATION ON AUTO BIOCHEMISTRY ANALYSERS

BR-160 AUTO BIO CHEMISTRY ANALYSER					
TEST NAME	AMAYLASE		SAMPLE VOLUME	3	
FULL NAME	ALPHA AMAYLASE				
	PRI.	SEC.	REAGENT VOLUME	R1	R2
WAVE LENGTH	405	630	300	NONE	
ASSAY /POINT	KINETIC	START	END		
		3	10		
DECIMAL PLACE	2				
UNIT	uL				
LINEARITY RANGE	LOW	HIGH			
	10	1500			

Alpha Amylase

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BR-120 AUTO BIO CHEMISTRY ANALYSER					
TEST NAME	AMAYLASE		SAMPLE VOLUME	3	
FULL NAME	ALPHA AMAYLASE				
WAVE LENGTH	PRI 405	SEC. NONE	REAGENT VOLUME	R1 300	R2 NONE
ASSAY /POINT	KINETIC	STAR T 23	EN D 33		
DECIMAL PLACE	2				
UNIT	u/L				
LINEARITY RANGE	LOW 10	HIGH 1500			

LINEARITY

Up to 1600 U/L.

NORMAL RANGE

Serum / plasma: <125 U/L

Urine: <470 U/L

It is recommended that each laboratory establishes its own reference range.

PRECAUTION

- 1- To avoid contamination, use clean laboratory wares. Avoid direct exposure of reagent to light.
- 2- 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.
- 3- The reagent solution contains sodium azide, do not swallow. Avoid contact with skin and mucous membrane.

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

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

