

## AMYLASE CNPG<sub>3</sub> Multi-Purpose (MPR) Liquid Reagent

### KIT SPECIFICATIONS:

Cat. No.	Quantity	Reagent	Storage
GL153A	10 x 50 ml	AMYLASE CNPG <sub>3</sub>	2-8°C
GL163A	6 x 50 ml	AMYLASE CNPG <sub>3</sub>	2-8°C
GL173A	10 x 20 ml	AMYLASE CNPG <sub>3</sub>	2-8°C

### INTENDED USE:

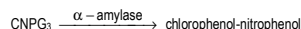
In Vitro Diagnostic reagent pack for the quantitative determination of amylase in serum, plasma and urine on automated and semi-automated analysers.

### SUMMARY AND EXPLANATION: 1

Two types of amylase are present in human serum, salivary (type S) and pancreatic (type P). While type P is attributed almost totally to the pancreas, type S is found in a number of other tissues. The measurement of amylase is most widely used in the diagnosis of acute pancreatitis, where levels can be 50 times the normal value. Increased levels are also found renal failure, pulmonary inflammation, disease of the salivary gland and macroamylasemia.

### PRINCIPLE OF THE TEST: 1

Alpha -amylase hydrolyses 2-Chloro-4-nitrophenyl- $\alpha$ -malto-trioside (CNPG<sub>3</sub>) to release chloro-nitrophenol and shorter chains of chloro-nitrophenyl-malto-oligosaccharides. The rate of formation of the chlorophenol-nitrophenol can be detected spectrophotometrically at 405 nm and is directly proportional to the amount of  $\alpha$ -amylase present in the sample.



### WARNINGS AND PRECAUTIONS:

For In Vitro Diagnostics Use Only - For Professional Use Only  
Carefully read instructions for use. Deviations from this procedure may alter performance of the assay.

#### Components Colour and Appearance:

Reagent 1: Clear, colourless liquid.

Any significant changes from the above could indicate that the assay might be compromised. Refer to Laboratory's QC program for actions to be taken. In case of serious damage to the bottle and/or cap, resulting in product leakage and/or contamination, do not use the reagent pack and contact your distributor.

#### Safety precautions:

**CAUTION:** Take all necessary precautions required when handling laboratory reagents. Material Safety Data Sheet is available upon request.

#### Handling precautions:

- Do not use components past the expiry date stated on the Bottles.
- Do not Freeze Reagents.
- Do not use components for any purpose other than described in the "Intended Use" section.
- Do not interchange caps among components as contamination may occur and compromise test results.
- Refer to local legal requirements for safe waste disposal.

### INSTRUMENTS:

Instrument applications are available upon request.

### COMPONENT COMPOSITION:

Component	Ingredients	Concentration in Tests
Reagent 1	MES Buffer pH 6.25	49.69 mmol/l
	Calcium Chloride	6 mmol/l
	Potassium Thiocyanate	898.3 mmol/l
	Sodium Chloride	299.45 mmol/l
	CNPG <sub>3</sub>	---
	PRESERVATIVE	---

### REAGENT PREPARATION AND STABILITY:

Reagent 1 is ready for use.

Before use, mix reagent by gently inverting each bottle.

If stored and handled properly:

- Unopened component is stable until expiry date stated on the label.
- Once open, component is stable for 2 months at 2-8°C.

### TYPE OF SPECIMEN: 1

Use serum, heparin/EDTA plasma or urine as specimen.

It is recommended to follow NCCLS procedures (or similar standardised conditions) regarding specimen handling. Specimen should be collected in an appropriate sample container, with proper specimen identification.

- Serum/plasma should be separated from cells within 8 hours after collection.  
*Stability<sup>2</sup>:* up to 2 months at 2-8°C
- Collect urine without additives. Dilute 1:3 with deionised water. Multiply by dilution factor to recover patient's results.  
*Stability<sup>2</sup>:* up to 10 days at 2-8°C.

### TEST PROCEDURE:

Materials required but not supplied:

Description	Catalog. No.	Description	Catalog. No.
General Chemistry Calibrator	GL983	Photometer	N/A
General Chemistry Control Level 1	GL922	General Laboratory Equipment	N/A
General Chemistry Control Level 2	GL932		

#### Assay procedure:

Wavelength:  $\lambda$ : 405 nm  
Temperature: 30°C or 37°C  
Optical path: 1 cm light path.

Working Reagent	Blank	Sample
	Sample	1 ml
	---	25 $\mu$ L

Gently mix and incubate at 30°C or 37°C for 1 minute, then measure the change of Optical Density per minute ( $\Delta$ OD/min) over the following 3 minutes.

#### Factor Calculation:

Serum *Urine*  
U/I =  $\Delta$ OD/min x 3120 U/I =  $\Delta$ OD/min x 9361  
U/I =  $\Delta$ OD/min x 3175 U/I =  $\Delta$ OD/min x 9525  
<sup>1</sup>The above factors should be validated using General Chemistry Calibrator (AD973).

#### Enzyme Calibration:

Using recommended Calibrator, calibrate the assay:

- When using a new reagent kit or changing lot number.
- Following preventive maintenance or replacement of a critical part of the photometer used.
- When Quality Controls are out of range.

#### Quality Control:

All clinical laboratories should establish an Internal Quality Control program. Verify instrument and reagent performance with recommended controls or similar. The values obtained for QC should fall within manufacturer's acceptable ranges or should be established according to the Laboratory's QC program.

Controls should be assayed:

- Prior to reporting patient results.
- Following any maintenance procedure.
- At intervals established by the Laboratory Q.C. Programme.

### CALCULATION:

Serum *Urine*  
U/I =  $\Delta$ OD/min x 3120 U/I =  $\Delta$ OD/min x 9361  
U/I =  $\Delta$ OD/min x 3175 U/I =  $\Delta$ OD/min x 9525  
<sup>1</sup>The above factors should be validated using General Chemistry Calibrator (GL973).  
(Conversion factor: Qty in  $\mu$ kat/l = Qty in U/I x 0.017).

### EXPECTED VALUES:

	U/I at 37°C	$\mu$ kat/l at 37°C
Serum/plasma	Up to 82	Up to 1.39
Urine	Up to 380	Up to 6.46

Each laboratory should establish its own reference range. Amylase results should always be reviewed with the patient's medical examination and history.

### PERFORMANCE CHARACTERISTICS:

Performance results can vary. Data obtained in each individual laboratory may differ from these values.

#### Linearity:

This assay is linear up to 1200 U/I (20.4  $\mu$ kat/l).

For samples with a higher concentration, dilute 1:1 with 0.9% NaCl (9g/l) and re-assay. Multiply result by 2.

#### Interfering substances:

Results of study are as follows:

Bilirubin (mixed isomers): Less than 10% interference up to 600  $\mu$ mol/l Bilirubin.  
Haemolysis: Less than 10% interference up to 5 g/l Haemoglobin.  
Lipemia: Less than 10% interference up to 5 g/l Intralipid.

#### Sensitivity:

The Lowest Detectable Level of amylase was estimated at 3.3 U/I.

#### Precision:

Within Run				Between Run			
N = 20	Mean (U/I)	SD	% CV	N = 20	Mean (U/I)	SD	% CV
Level 1	143	1.49	1.05	Level 1	145	1.55	1.07
Level 2	392	2.20	0.56	Level 2	382	4.02	1.05

#### Method Comparison:

Using 50 samples, a comparison, between this amylase test (y) and another commercially available test (x), gave the following results:

















$$y = 0.975x - 6.424 \quad r = 1.000 \quad \text{Sample range: 26 to 1915 U/I}$$


### BIBLIOGRAPHY:

- Burtis CA, Ashwood ER. Tietz Fund. Of Clin. Chem. 5<sup>th</sup> ed.; 30-54, 372-378 and 964.
- Tietz NW, ed. Clinical Guide to Laboratory Tests, 3<sup>rd</sup> ed. Philadelphia, PA: WB Saunders, 1995, 46-51.
- Hohenwallner W, Hagele EO, Scholer A et al. Ber Oster Ges Klin Chem. 1983; 6:101-112.

### SYMBOLS:

The following symbols are used in the labelling of Glenbio Ltd systems:

	In Vitro Diagnostics		Catalogue No
	Batch Code		Content
	Reagent		Antibody
	Calibrator		Substrate
	Buffer		Aqueous Standard
	CE Mark - Device comply with the Directives 98/79/EC		Reconstitute with
	Expiry Date (Last day of the month)		Manufactured By
	Biological risk		Consult Instruction for Use

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