Amylase Test Kit
Kinetic Colorimetric

Quantitative determination of Amylase in human Serum / Plasma / other body fluids
Only for *In Vitro* Diagnostic use

ORDER INFORMATION

REF	Pack Size
AMYMONO 25	25 X 1 ml
AMYMONO 50	50 X 1 ml
AMY 25	1 X 25 ml
AMY 50	2 X 25 ml
AMY 50	1 X 50 ml
AMY 100	1X100 ml
AMY 1000	1X1000 ml
AMY 5000	1X5000 ml
AMY 10000	1X10000 ml

CLINICAL SIGNIFICANCE
Amylase is secreted by the pancreas into the duodenum where it aids the catabolism of carbohydrates to simple sugars. Damage to the pancreas or obstruction to the pancreatic duct causes the enzyme to enter the blood stream. Elevated levels are found in acute pancreatitis, perforated / penetrating peptic ulcers, paraotitis (mumps). Patients with chronic pancreatic disorders having pancreatic cell destruction do not have high levels as less amylase is produced by the pancreas.

Method
Kinetic photometric test.

PRINCIPLE
2-chloro-4-nitrophenyl-alpha-D-maltotrioside (Gal G2 CNP) is hydrolyzed by alpha-amylase to produce 2-chloro-4-nitrophenol (CNP). The amount of 2-chloro-4-nitrophenol, monitored at 405 nm, is directly proportional to alpha-amylase activity.

REAGENT
Reagent I : Gal G2 CNP Substrate reagent

REAGENT PREPARATION
The Reagent is ready to use.

REAGENT STORAGE AND STABILITY
Store at 2-8ºC, once opened.
Reagent is stable until the expiry date shown on the label when stored tightly closed and if contaminations are prevented during their use.

WARNING AND PRECAUTIONS
- For in vitro diagnostic use.
- Do not use components beyond the expiration date.
- Do not mix materials from different kit lot numbers.
- Exercise the normal precautions required for handling all laboratory reagents.
- The reagent contains preservative. Do not swallow. Avoid contact with skin and mucous membranes.
- For detailed information refer Material Safety Data Sheet.

WASTE MANAGEMENT
Please refer to local legal requirements.

MATERIALS REQUIRED BUT NOT PROVIDED
- NaCl solution 9 g/L
- General laboratory equipment

SAMPLE COLLECTION AND PRESERVATION
Serum: Use non - haemolysed serum.
Plasma: Use heparin. Do not use EDTA, Oxalate or Fluoride.
Do not use hemolytic samples!
Stability in serum or plasma:
7 days at 4 – 8°C
1 year at –20°C in case of immediate freezing.
Freeze only once! Discard contaminated specimens!
Stability in urine:
1 day at 20 – 25°C
10 days at 4 – 8°C
3 weeks at –20°C in case of immediate freezing.
Freeze only once! Discard contaminated specimens!
If the urine sample is tested with the delay its pH should be adjusted to approximately 7.0.

ASSAY PROCEDURE
Operating Instructions
- Check reagent inventories at least daily to ensure that quantities are sufficient for the planned work load.
- Bring all reagents, standard and samples to room temperature 18 - 28ºC, prior to analysis.

AUTOMATED PARAMETERS	
Wavelength	405 nm
Cuvette	1 cm light path
Reaction Temperature	37°C
Measurement	Against distilled water
Reaction Type	Kinetic test
Reaction Direction	Increasing
Sample Volume	20 µl
Reagent Volume	1000 µl
Delay/Lag/time	60 Secs
Interval time	30 Secs
No. of Readings	04
Blank Absorbance limit	< 0.800
Factor	3806
Low Normal at 37°C	0 IU/L
High Normal at 37°C	130 IU/L
Linearity at 37°C	2000 IU/L

MANUAL ASSAY PROCEDURE
Pipette into Test Tubes

	Serum/Plasma	Urine
Sample	20 µl	10 µl
Reagent	1000 µl	1000 µl

Mix well and let stand for 1 min. at 37°C. Read initial absorbance and start timer simultaneously. Measure absorbance increase every minute for 2 minutes (Δ A/min).

SAMPLE DILUTIONS
- This method is linear upto a concentration of 2000 IU/L (serum / plasma) or upto 6000 IU/L (urine).
- Samples above this concentration should be diluted 1:2 & retested. Multiply the final result by 2.

CALCULATION

SERUM	Δ A/min. x 3806 = IU/L Amylase
URINE	Δ A/min. x 7908 = IU/L Amylase

CLIBRATORS AND CONTROLS
For the calibration of automated photometric systems the commercially available suitable multi-calibrator is recommended.
This method is traceable to the molar extinction coefficient. This method has been standardized against the original IFCC [International Federation of Clinical Chemistry and Laboratory Medicine] formulation from 1998.
It is recommended to run a normal and a pathological control serum which is commercially available to verify the performance of the measured procedure. The value of controls should fall within the established limit.

PERFORMANCE CHARACTERISTICS
WITHIN RUN

Sample	Mean Concentration	SD	CV %
Randox 2	95.93	1.57	1.64%
Randox 3	297.36	0.79	0.27%

RUN TO RUN

Sample	Mean Concentration	SD	CV %
Randox 2	95.68	1.52	1.59%
Randox 3	297.68	0.61	0.21%

LINEARITY
This method is linear upto a concentration of 2000 IU/L (serum / plasma) or upto 6000 IU/L (urine). Samples above this concentration should be diluted 1:2 & retested. Multiply the final result by 2.

Limit of detection: The limit of detection for α-Amyase is 3 IU/L.

METHOD COMPARISON
A comparison of α-Amylase with a commercially available assay (x) using 59 samples gave following results: $R^2 = 0.9900$

REFERENCE VALUES

	SERUM	URINE
37°C Upto	130 IU/L	490 IU/L

The reference values are to be considered as indicative only.
Laboratory should establish its own normal ranges.

LIMITATION OF THE PROCEDURE
- For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

INTERFERENCE
- Bilirubin: No interference found upto Bilirubin 50mg/dl.
- Hemoglobin: No interference found upto 500 mg/dL.
- Lipemia: No interference found upto 1200 mg/dL.
- These characteristics have been obtained using an automatic analyzer. Results may vary if a different instrument or a manual procedure is used.

BIBLIOGRAPHY
Ranson, JHC. Curr Prob Surg 1979; 16:1. Salt WB II, Schnker S. Medicine 1976; 55:269. Stefanini P, Ermini M, J Am Surg 1965; 110:866 Henry RJ, Chiamori N. Clin Chem 19610; 6:434. Kaufman RA, Tietz NW. Clin Chem 1980; 26:486

GLOSSARY OF SYMBOL

	Consult Instruction for Use
	Catalog Number
	Store between
	Manufacturer
	Keep away from sunlight



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