

Quantitative Determination of Alfa Amylase in Serum/Plasma or Urine
Only For *In vitro* Diagnostic Use

ORDER INFORMATION

REF	Cont.
AMYSLR 10	1 X 10 ML
AMYSLR 25	1 X 25 ML
AMYM 25	25 X 1 ML

CLINICAL SIGNIFICANCE

α 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.

PRINCIPLE

2-chloro-4-nitrophenyl-alpha-D-maltotrioxide (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 COMPOSITION

Reagent I : Gal G2 CNP Substrate reagent

SAMPLE COLLECTION AND PRESERVATION

Serum , plasma or urine diluted 1:2.
Specimen are stable for at least 30 days when stored at 2 - 8°C.

REAGENT PREPARATION

The reagent Supplied is ready to use.

REAGENT STORAGE AND STABILITY

Store at 2-8°C, 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.

REFERENCE VALUES

	SERUM	URINE
37°C Upto	130 U/l	490 U/l

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

AUTOMATED PARAMETERS	
Wavelength	405 nm
Cuvette	1 cm light path
Reaction Temperature	37°C
Measurement	Against distilled w
Reaction Type	Kinetic test
Reaction Direction	Increasing
Sample Volume	20 μ l
Reagent Volume	1000 μ l
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 U/l
High Normal at 37°C	130 U/l
Linearity at 37°C	2000 U/l

MANUAL ASSAY PROCEDURE

PIPETTE INTO TEST TUBES

	Serum/Plasma	Urine
Sample	20 μ l	10 μ l
Reagent	1000 μ l	1000 μ l

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).

CALCULATION

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

LINEARITY

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

QUALITY CONTROL

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.

BIBLIOGRAPHY

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Henry RJ, Chiamori N. Clin Chem 19610; 6:434. Kaufman RA, Tietz NW. Clin Chem 1980; 26:486.