

**Quantitative determination of α-Amylase in serum / plasma / Urine
Only for *In Vitro* Diagnostic use**

ORDER INFORMATION

REF	Pack Size
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.

Method

Kinetic photometric test.

PRINCIPLE

2-chloro-4-nitrophenyl-alpha-D-maltotriose (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 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.

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 – 28 °C, 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

CALIBRATORS 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 %
Norm Control	71.22	2.69	3.77%
Path Control	159.37	4.38	2.75%

RUN TO RUN

Sample	Mean Concentration	SD	CV %
Norm Control	71.72	2.57	3.58%
Path Control	159.35	3.19	2.00%

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-Amylase is 3 IU/L.

METHOD COMPARISON

A comparison of Accucare 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		Lot Number
	Catalog Number		Date of Manufacturing
	Store between		Use By or Expiration Date
	Manufacturer		For <i>in vitro</i> Diagnostic use only
	Keep away from sunlight		Content of the kit



LAB-CARE DIAGNOSTICS (INDIA) PVT. LTD.
C1 Type, Shed No.: 3225, Chemical Zone,
GIDC Sarigam – 396155, Dist. Valsad, Gujarat, India.
Tel.: +91 22 2554 2109 /1558
Email: accucarediagnostics.com
Website: www.labcarediagnostics.com