Amylase

Kinetic determination of serum Amylase

REF : AMY-MK – 05005 (5 X 5 ml)

INTENDED USE

NS Biotec Amylase reagent is intended for the in vitro quantitative determination of albumin in serum or plasma on both automated and manual systems.

CLINICAL SIGNIFICANCE

Measurements of amylase are used primarily in the diagnosis and treatment of the diseases of the pancreas Amylase is found primarily in the pancreas and salivary glands. When released in the digestive tract, the enzyme hydrolyzes starch. Amylase determinations are useful in the diagnosis of diseases of the pancreas and parotids. Elevated serum levels are associated with acute pancreatitis and other pancreatic disorders as well as mumps and bacterial parotitis.

ASSAY PRINCIPLE

Alpha amylase catalyzes the hydrolysis of 2-chloro-4-nitrophenyl-1-galactopyranosyl-maltoside (GALG2-CNP) to glucose polymers and p-nitrophenyl oligosaccaride at short chain producing 2-chloro-4-nitrophenol (CNP).

The increased extintion can be measured by spectrophotometry at 405nm and results proportional at the activity of alpha amylase present in the sample.

EXPECTED VALUES

	Serum/plasma	Random Urine	24 hrs urine
25^{0}C	Up to 55 U/l	Up to 373 U/l	Up to 205 U/l
30^{0}C	Up to 73 U/l	Up to 365 U/l	Up to 295 U/l
37^{0}C	Up to 100 U/l	Up to 450 U/l	Up to 410 U/l

Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference range. For diagnostic purposes, the amylase results should always be assessed in conjunction with the patient's medical history, clinical examination, and other findings.

REAGENTS

R_1	Goods Buffer pH 6,0	50	mmol/l
	GALG2-CNP	2.65	mmol/l
	Sodium chloride	300	mmol/ll
	Calcium chloride	5	mmol/ll
	Potassium	140	mmol/l
	thiocyanate	0.2	mmol/l
	EDTA		

- **Reagent Preparation & Stability**

All reagents are ready for use and stable up to the expiry date given on label when stored at 2 – 8^{0}C.

SPECIMEN

Serum, Heparinized plasma. Urine.

The activity of alpha amylase in serum or plasma is stable for 7 days at 2-8°C, one month at –20°C.

PROCEDURE

- **Manual Procedure**

Wavelength	405 nm
Cuvette	1 cm light path
Temperature	25, 30 or 37 ^{0}C
Zero adjustment	against reagent blank

Pipette into test tube or cuvette		
	Blank	sample
Reagent	1 ml	1 ml
Distilled water	25 µl	…..
Sample	…..	25 µl

- Mix, incubate for 1.0 minute, and start stopwatch simultaneously. Read again after exactly 1, 2, and 3 minutes.

- **Automated Procedure**

User defined parameters for different auto analyzers are available upon request.

CALCULATION

Determine the change in absorbance per minute (ΔA/min) from the linear portion of the reaction curve and calculate the amylase activity by using the following formulae:

U/l = 3060 × ΔA 405 nm/min

LINEARITY

When run as recommended, the assay is linear up to 1500 U/l

If result exceeds 1500 U/l specimen should be diluted 1+5 with 0.9% NaCl solution and reassayed. Multiply the result by 6.

SENSITIVITY

The sensitivity is defined as the change of analytical response per unit change in analyte concentration at a pathlength of 1 cm.

When run as recommended the sensitivity of this assay is 2 U/l

QUALITY CONTROL

It is recommended that controls (normal and abnormal) be included in:

- Each set of assays, or
- At least once a shift, or
- When a new bottle of reagent is used, or
- After preventive maintenance is performed or a clinical component is replaced.

Commercially available control material with established albumin values may be routinely used for quality control.

Failure to obtain the proper range of values in the assay of control material may indicate:

- Reagent deterioration,
- Instrument malfunction, or
- Procedure errors.

The following corrective actions are recommended in such situations:

- Repeat the same controls.
- If repeated control results are outside the limits, prepare fresh control serum and repeat the test.
- If results on fresh control material still remain outside the limits, then repeat the test with fresh reagent.
- If results are still out of control, contact NS Biotec Technical Services.

INTERFERING SUBSTANCES

- **Anticoagulants:**
  Heparin and EDTA are the only accepted anticoagulants.
- **Bilirubin:**
  No significant interference from free or conjugated bilirubin up to a level of 60 mg/dl.
- **Drugs:**
  Young in 1990 has published a comprehensive list of drugs and substances, which may interfere with this assay.
- **Haemoglobin:**
  Haemoglobin levels higher than 3.0 g/l increase the apparent albumin concentration significantly.
- **Lipemia:**
  Intralipid levels higher than 1.0 g/dl increase the apparent albumin concentration significantly.

WARNING & PRECAUTIONS

- NS Biotec albumin reagent is for in vitro diagnostic use only. Normal precautions exercised in handling laboratory reagents should be followed.
- The reagents should be brought to room temperature before use.
- The reagent and sample volumes may be altered proportionally to accommodate different spectrophotometer requirements.
- Valid results depend on an accurately calibrated instrument, timing, and temperature control.
- Don't use the reagent if it is turbid.

BIBLIOGRAPHY

1. Henry, R.J., Chiamori, N., Clin. Chem., 6;434, (1961)
2. Winn-Deen et Al., Clin. Chem. 24-10 (1989)
3. Lorentz, K., Clin. Chem. Clin. Biochem. 17,499 (1979)

	Consult Instruction for Use
	Caution Consult Accompanying Documents
IVD	In Vitro Diagnostic Medical Device
	Temperature Limitation
	Manufacturer
EC REP	Authorized Representative In The European Community
REF	Catalogue Number
LOT	Batch Code
	Use By

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