

Alpha Amylase

(KINETIC)

INTENDED USE

Vitro amylase reagent is intended for the in vitro quantitative determination of amylase activity in serum on both automated and manual systems.

VITRO SCIENT.

Kinetic method - GALG2-CNP

METHOD

BACKGROUND

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 oligosaccharide at short chain producing 2-chloro-4-nitrophenol (CNP).

The increased extinction 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°C	Up to 55 U/l	Up to 373 U/l	Up to 205 U/l
30°C	Up to 73 U/l	Up to 365 U/l	Up to 295 U/l
37°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 cholesterol results should always be assessed in conjunction with the patient's medical history, clinical examination, and other findings.

REAGENTS

R₁	Goods Buffer pH 6,0	50 mmol/l
	GALG2-CNP	2.65 mmol/l
	Sodium chloride	300 mmol/l
	Calcium chloride	5 mmol/l
	Potassium	140 mmol/l
	thiocyanate	0.2 mmol/l
	EDTA	

• Reagent Preparation & Stability

reagents are supplied ready-to-use and stable up to the expiry date labeled on the bottles when properly stored refrigerated at 2 – 8 °C. Once opened, the opened vial is stable for 5 months at the specified temperature

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 °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 autoanalyzers are available upon request.

CALCULATION

Determine the change in absorbance per minute ($\Delta A/\text{min}$) from the linear portion of the reaction curve and calculate the amylase activity by using the following formulae:

$$\text{U/l} = 3060 \times \Delta A \text{ 405 nm/min}$$

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 alpha amylase 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 Vitro Technical Services.

INTERFERING SUBSTANCES

ORDERING INFORMATION

following substances doesn't interfere up to the concentration of:

Bilirubin conjugated 20 mg/dL
Bilirubin free 20 mg/dL
Hemoglobin 500 mg/dL
NaF 500 mg/dL
Ascorbic acid 500 mg/dL
Glucose 5,0 g/dL
Maltose 5,0 g/dL

REF	SIZE
1521	10 X 10 ml
1522	5 X 20 ml

WARNING & PRECAUTION

- Vitro alpha amylase reagent is for in vitro diagnostic use only. Normal precautions exercised in handling laboratory reagents should be followed.
- Warm up reagent to the corresponding 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 or if the absorbance is more than 0.600 at 405 nm.

PERFORMANCE CHARACTERISTICS

Sensitivity

The sensitivity is defined as the lower detection limit represents the lowest measurable alpha amylase activity that can be distinguished from zero.

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

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.

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)

SYMBOL DECLARATION

	Manufacturer
	Consult instructions for use
	Batch code (Lot #)
	Catalog number
	Temperature limitation
	In vitro diagnostic medical device
	Use by
	Caution. Consult instructions
	Keep away from light

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