



α AMYLASE KIT

(Direct Substrate Method)

(For veterinary invitro diagnostic use only)

INTENDED USE

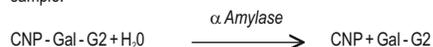
α Amylase kit is used for the determination of Amylase Activity in serum or plasma.

SUMMARY

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, parotitis (mumps). Patients with chronic pancreatic disorders having pancreatic cell destruction do not have high levels as less amylase is produced by the pancreas.

PRINCIPLE

α Amylase catalyses the hydrolysis of a 2 - chloro - 4 nitro phenol salt to chloro nitrophenol (CNP). The rate of hydrolysis is measured as an increase in absorbance due to the formation of chloro nitrophenol, which is proportional to the α Amylase activity in the sample.



EXPECTED VALUES

Species	Amylase (U/L)
Dog	226 - 1063
Cat	550 - 1458
Cow	24 - 40
Horse	4-41
Pig	500-1500
Sheep	300-1200
Goat	300-1200
Rabbit	1200 - 2000
Buffalo	200-1000

It is recommended that each laboratory establish its own range as reference ranges may vary between laboratories.

PRESENTATION

REF	1126030210
Pack Size	2 x 10 ml
L1 Amylase Reagent	2 x 10 ml

COMPOSITION

Goods buffer 50mM; pH 6.0; GAL G2 CNP substrate 2.6mM; Sodium Chloride 300mM; Calcium Acetate 5.0mM; Preservatives.

STORAGE / STABILITY

Contents are stable at 2-8°C till the expiry mentioned on the label.

REAGENT PREPARATION

Reagents are ready to use. Do not pipette with mouth.

SAMPLE MATERIAL

Serum, heparinised plasma.

α Amylase is reported to be stable in the serum/plasma for 5 days at 2-8°C.

SAMPLE WASTE AND DISPOSAL

Do not reuse the reagent containers, bottles, caps or plugs due to the risks of contamination and the potential to compromise reagent performance.

Appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents. Handle specimens, solid and liquid waste and test components in accordance with local regulations and NCCLS guidelines M29, or other published biohazard safety guidelines.

MATERIALS REQUIRED BUT NOT PROVIDED

Photometer analyzer with standard thermostatic cuvette holder, micropipette and appropriate laboratory equipment.

PROCEDURE

Wavelength / filter	: 405 nm / (Hg 405) / Violet
Temperature	: 37°C
Light path	: 1 cm

For Serum/Plasma as Sample:

Pipette into a clean dry test tube labelled as Test (T):

Addition Sequence	(T) 37°C
Amylase Reagent (L1)	1.0 ml
Sample	0.02 ml

Mix well and read the initial absorbance A_0 after 1 min. & repeat the absorbance reading after every 1, 2, & 3 mins. Calculate the mean absorbance change per minute ($\Delta A / \text{min}$).

CALCULATIONS

α Amylase Activity in U/L (Serum/plasma) = $\Delta A / \text{min} \times 3954$

QUALITY CONTROL

The following process is recommended for QC during the assay of α Amylase. *Define and establish acceptable range for your laboratory.

- Two levels of control (Normal and Abnormal) are to be run on a daily basis.
- If QC results fall outside acceptance criteria, recalibration may be necessary.
- Review QC results and run acceptance criteria following a change of reagent lot.

SPECIFIC PERFORMANCE CHARACTERISTICS

LOD : 2.0 U/L

LOQ : 3.0 U/L

Lower Limit : 2.0 U/L

Higher Limit : 1000 U/L

If the values exceed this limit, dilute the sample with normal saline (NaCl 0.9 %) and repeat the assay.

Calculate the value using the proper dilution factor.

Interferences:

Sample when spike with interferences such as upto 10 mg/dl. Bilirubin 2000 mg/dl intralipid and 1000 mg/dl Haemoglobin does not affect the ability of the kit to determine the amylase concentration.

Precision:

Within run

Within run	n	Mean	SD	% CV
Sample 1	10	91	1.50	1.64
Sample 2	10	334	1.56	0.46
Sample 3	10	48	1.09	2.26

Between run

Between run	n	Mean	SD	% CV
Sample 1	10	92	1.48	1.61
Sample 2	10	334	1.64	0.72
Sample 3	10	48	1.19	2.45

Method comparison:

Comparative studies were done to compare our reagent with another commercial α Amylase Assay. No significant differences were observed. Details of the comparative studies are available on request.

NOTE

In vitro diagnostic reagent for laboratory and professional use only Not for medicinal use. The reagent contain sodium azide 0.1% as preservative. Avoid contact with skin and mucosa. On disposal flush with large quantities of water. Only clean and dry glassware must be used. Anticoagulants like oxalate and EDTA bind Calcium, which is needed for α Amylase activity and should not be used. Heparin may be used. Saliva and sweat contain α Amylase. Avoid contamination of reagent and sample during use. For users to convert the values obtained by this method to the EPS substrate methods, multiply the results obtained by 2.45. Do not use turbid, deteriorated or leaking reagent

REFERENCES

- IFCC methods for the measurement of catalytic concentrations of enzymes, J. Clin. Chem. Acta. (1999) 281:5.
- Clinical Chemistry, Principles, Procedures, Correlations, Michael L. Bishop et. al., 5th Edition.
- Duncan and Prasse's Veterinary Laboratory Medicine: Clinical Pathology, Kenneth S. Latimer, ISBN Jane Wardrop , 6th Edition - 2010.
- Clinical Biochemistry of Domestic Animals, Sixth Edition, 2008 by Kaneko J.J., Harvey J.W. & Bruss M.L.
- Data on file: Coral Clinical Systems.

System Parameters

Reaction	: Kinetic	Interval	: 60 Sec.
Wavelength	: 405 nm	Sample Vol.	: 0.02 ml
Zero Setting	: Distilled Water	Reagent Vol.	: 1.00 ml
Incub. Temp.	: 37°C	Standard	: ---
Incub. Time	: ---	Factor	: 3954
Delay Time	: 60 Sec.	React. Slope	: Increasing
Read Time	: 180 Sec.	Linearity	: 1000 U/L
No. of read.	: 4	Units	: U/L

SYMBOL KEYS

2°C Store at 2-8°C	Manufacturer	In vitro Diagnostic Medical Device	Direct Substrate Direct Substrate Method
Use by (Last day of stated month)	Consult Instructions for use	Batch Number	
Date of Manufacture	Catalogue Number	Amylase Reagent	This way up



Manufactured by:

Coral Clinical Systems

A Division of Tulip Diagnostics (P) Ltd.

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