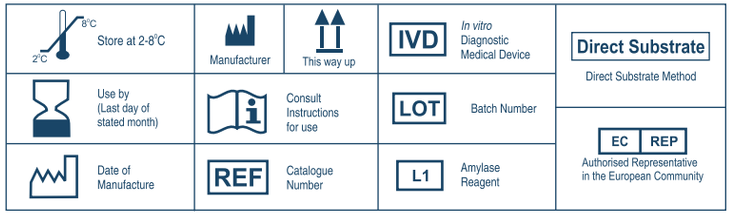
SBio α AMYLASE KIT

(Direct Substrate Method)

(For invitro diagnostic use only)

REF	90202230	90212275
Pack Size	2 x 30 ml	2 x 75 ml

CE



INTENDED USE

α Amylase Kit is used for the determination of Amylase Activity in Serum, Plasma or Urine.

PRINCIPLE OF THE TEST

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 Amylase activity in the sample.

$$\text{CNP - Gal - G2} + H_2O \xrightarrow{\alpha\ \text{Amylase}} \text{CNP} + \text{Gal - G2}$$

CLINICAL SIGNIFICANCE

Although found in many tissues, amylase is most prominent in pancreatic juice and saliva. Increased plasma levels in humans are found in Salivary trauma (including anaesthetic intubation). Mumps - due to inflammation of the salivary glands. Pancreatitis because of damage to the cells that produce amylase. Renal failure due to reduced excretion.

PRESENTATION	**2 x 30 ml**	**2 x 75 ml**
L1 : Amylase Reagent	2 x 30 ml	2 x 75 ml

COMPOSITION

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

STORAGE / STABILITY

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

SAMPLE REQUIRED

Serum, heparinised plasma, urine is required.

REAGENT PREPARATION

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

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.

This product requires the handling of human specimen. It is recommended that all human sourced material are considered potentially hazardous and are handled in accordance with the OSHA standard on blood borne pathogens.

Appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.

Handle specimen, solid and liquid waste and test components in accordance with local regulations and NCCLS guidelines M29, or other published biohazard safety guidelines.

PROCEDURE

Wavelength/filter : 405 nm / (Hg405) / violet
Temperature : 37° C
Light path : 1 cm

MATERIAL REQUIRED BUT NOT PROVIDED

General laboratory instrumentation like Spectrophotometer/ Analyzer,Thermostatic Cuvette holder, Cuvettes, Micropipettes, Test tubes, Waterbath, Stopwatch/Timer.

For Serum as Sample:

Pipette into a clean dry test tube labeled 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 minute & repeat the absorbance reading after every 1, 2, & 3 minutes. Calculate the mean absorbance change per minute (Δ A/ min).

For Urine as Sample:

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

Addition Sequence	(T) 37° C
Amylase Reagent (L1)	1.0 ml
Sample	0.01 ml

Mix well and read the initial absorbance A_0 after 1 minute & repeat the absorbance reading after every 1, 2, & 3 minutes. Calculate the mean absorbance change per minute (ΔA/ min).

CALCULATIONS

α Amylase activity in U/L (Serum) = ΔA/ min. x 3954
α Amylase activity in U/L (Urine) = ΔA/ min. x 7830

QUALITY CONTROL

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

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

SPECIFIC PERFORMANCE CHARACTERISTICS

Linearity:

The procedure is linear upto 1000 U/L at 37°C. If the absorbance change (Δ A/min.) exceeds 0.300, use only the value of the first two minutes to calculate the result, or dilute the sample 1 + 9 with normal saline (NaCl 0.9%) and repeat the assay (Results x 10).

Limit of detection:

The limit of detection for α Amylase is 4 U/L.

Interferences:

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination.

Precision:

Precision studies were performed with two controls using NCCLS protocol EP5-A. The results of the precision studies are shown below:

Sample	Within-run		Between-run		Total	
	Mean	CV%	Mean	CV%	Mean	CV%
Control 1	81.19	4.26	81.06	1.92	162.25	6.18
Control 2	187.3	3.49	191.71	2.50	379.01	5.99

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.

REFERENCE RANGE

Serum : upto 90 U/L at 37°C
Urine : upto 490 U/L at 37°C

It is recommended that each laboratory establish its own normal range representing its patient population*.

NOTE

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. The reagent may be used in several automated analyzers. Instructions are available on request. Do not use turbid, deteriorated or leaking reagents.

REFERENCES

1. IFCC methods for the measurement of catalytic concentrations of enzymes, J. Clin. Chem. Acta. (1999) 281: 5.
2. Clinical Chemistry, Principles, Procedures, Correlations, Michael L. Bishop et. al., 5th Edition.

Mfd. for:

Singapore Biosciences PTE Ltd.
11 Yishun Street 51, # 04-23, The Criterion, Singapore 767971.

EC REP

CMC Medical Devices & Drugs S.L.,
C/ Horacio Lengo No. 18, CP 29006, Malaga, Spain.

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