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 ($\Delta OD/min.$)

**CALCULATION OF RESULTS:**

$\alpha$ Amylase Activity (U/L) = $\Delta A/min. \times 3178$

**NORMAL VALUE:**

- Serum, plasma Up to 90 U/L at 37°C
- Urine Up to 480 U/L at 37°C

Each Laboratory should establish its own normal range representing its patient population.

**LINEARITY:**

The procedure is linear up to 1500 U/L. If $\Delta A/min.$ exceeds 0.470, repeat test using serum diluted with normal saline (NaCl 0.9%) and repeat the assay, multiply result by dilution factor.

**QUALITY CONTROL:**

For accuracy it is necessary to run known controls with every assay.

**LIMITATIONS AND PRECAUTIONS:**

1. Saliva and sweat contain Amylase. To reduce possibility of contamination do not pipette by mouth and avoid contact of sample, reagent and pipette tips with skin.
2. Avoid direct exposure of reagent to sunlight.
3. Any slight changes of reagents to yellow coloration does not interfere with performance of the kit.
4. The Reagent contains Sodium Azide. Avoid direct contact with skin or mucous membrane. Do not swallow the reagent.

**REFERENCES:**


**PROCEDURE:**

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

<table>
<thead>
<tr>
<th>Addition Sequence</th>
<th>(T)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Working Reagent</td>
<td>1 ml</td>
</tr>
<tr>
<td>Sample</td>
<td>25 µl</td>
</tr>
</tbody>
</table>

**CONTENT :**

Reagent 1 : Amylase Reagent

**MATERIALS REQUIRED BUT NOT PROVIDED:**

- Clean & Dry Glassware.
- Laboratory Glass Pipettes or Micropipettes & Tips.
- Bio-Chemistry Analyzer.

**SAMPLES:**

Serum free of hemolysis, heparinised plasma, urine. $\alpha$ Amylase is reported to be stable in the sample for 5 days at 2 - 8°C.

**PREPARATION OF REAGENT & STABILITY:**

All Reagents are ready to use and are Stable till the expiry date mentioned on the label at 2-8°C and away from direct sunlight.

**GENERAL SYSTEM PARAMETERS:**

- Reaction type : Kinetic (Increasing)
- Wave length : 405 nm
- Temperature : 37°C
- Delay : 60 sec.
- Interval : 60 sec.
- No. of reads : 3
- Reagent volume : 1.0 ml
- Sample volume : 25 µl
- Factor : 3178
- Zero setting : Deionosed water
- Light path : 1 cm

**CODE NO.**

<table>
<thead>
<tr>
<th>CODE NO.</th>
<th>PACK SIZE</th>
<th>Reagent 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>S04C</td>
<td>2 x 10 ml</td>
<td>2 x 10 ml</td>
</tr>
<tr>
<td>S04D</td>
<td>2 x 20 ml</td>
<td>2 x 20 ml</td>
</tr>
<tr>
<td>S04F</td>
<td>5 x 10 ml</td>
<td>5 x 10 ml</td>
</tr>
</tbody>
</table>

**INTENDED USE:**

This diagnostic reagent kit is intended for "in vitro" Quantitative determination of Amylase activity from Serum/Plasma/Urine.

**CLINICAL SIGNIFICANCE:**

$\alpha$ 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:**

$\alpha$ Amylase catalyzes 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 $\alpha$ Amylase activity in the sample.

**REACTION:**

$\alpha$ Amylase

\[ \text{CNP-Gal-G}_2 + H_2O \rightarrow \text{CNP} + \text{Gal-G}_2 \]

**CONTENT :**

Reagent 1 : Amylase Reagent

** qualities and precautions:**

1. Saliva and sweat contains Amylase. To reduce possibilityofcontamination do not pipette by mouth and avoid contact of sample, reagent and pipette tips with skin.
2. Avoid direct exposure of reagent to the sunlight.
3. Any slight changes of reagents to yellow coloration does not interfere with performance of the kit.
4. The Reagent contains Sodium Azide. Avoid direct contact with skin or mucous membrane. Do not swallow the reagent.

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