**AMYLASE CNPG**

**Multi-Purpose (MPR)**

**Liquid Reagent**

**KIT SPECIFICATIONS:**

<table>
<thead>
<tr>
<th>Cat. No.</th>
<th>Quantity</th>
<th>Reagent</th>
<th>Storage</th>
</tr>
</thead>
<tbody>
<tr>
<td>AD153A</td>
<td>10 x 50 ml</td>
<td>AMYLASE CNPG3</td>
<td>2-8°C</td>
</tr>
<tr>
<td>AD163A</td>
<td>6 x 50 ml</td>
<td>AMYLASE CNPG3</td>
<td>2-8°C</td>
</tr>
<tr>
<td>AD173A</td>
<td>10 x 20 ml</td>
<td>AMYLASE CNPG3</td>
<td>2-8°C</td>
</tr>
</tbody>
</table>

**INTENDED USE:**

In Vitro Diagnostic reagent pack for the quantitative determination of amylase in serum, plasma and urine on automated and semi-automated analysers.

**SUMMARY AND EXPLANATION:**

Two types of amylase are present in human serum, salivary (type S) and pancreatic (type P). While type P is attributed almost totally to the pancreas, type S is found in a number of other tissues. The measurement of amylase is most widely used in the diagnosis of acute pancreatitis, where levels can be 50 times the normal value. Increased levels are also found in renal failure, pulmonary inflammation, disease of the salivary gland and macroamylasemia.

**PRINCIPLE OF THE TEST:**

Alpha-amylase hydrolyses 2-Chloro-4-nitrophenyl-alpha-D-maltoside (CNPG) to release chloro-nitrophenol and shorter chains of chloro-nitrophenyl-maltosides. The rate of formation of the chloro-nitrophenol can be detected spectrophotometrically at 405 nm and is directly proportional to the amount of amylase present in the sample.

**CNPG:** CH2Cl – amylase – chlorophenol-nitrophenol

**WARNINGS AND PRECAUTIONS:**

For In Vitro Diagnostics Use Only - For Professional Use Only

Carefully read instructions for use. Deviations from this procedure may alter performance of the assay.

Components, Colour and Appearance:

Reagent 1 – Yellow, clear solution liquid.

Any significant changes from the above could indicate that the assay might be compromised. Refer to Laboratory’s QC program for actions to be taken. In case of serious damage to the bottle and/or cap, resulting in product leakage and/or contamination, do not use the reagent pack and contact your distributor.

Safety precautions:

CAUTION: Take all necessary precautions required when handling laboratory reagents. Material Safety Data Sheet is available upon request.

Handling precautions:

- Do not use components past the expiry date stated on the Bottles.
- Do not Freeze Reagents.
- Do not use components for any purpose other than described in the “Intended Use” section.
- Do not interchange caps among components as contamination may occur and compromise test results.
- Refer to local legal requirements for safe waste disposal.

**INSTRUMENTS:**

Instrument applications are available upon request.

**COMPONENT COMPOSITION:**

<table>
<thead>
<tr>
<th>Component</th>
<th>Concentration in Test</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>µmol/l</td>
</tr>
<tr>
<td>Reagent 1</td>
<td>MOPS BUFFER 1x 40</td>
</tr>
<tr>
<td></td>
<td>40 mmol/l</td>
</tr>
<tr>
<td></td>
<td>Calcium Chloride</td>
</tr>
<tr>
<td></td>
<td>6 mmol/l</td>
</tr>
<tr>
<td></td>
<td>Potassium Thiocyanate</td>
</tr>
<tr>
<td></td>
<td>88.3 mmol/l</td>
</tr>
<tr>
<td></td>
<td>Sodium Chloride</td>
</tr>
<tr>
<td></td>
<td>298.45 mmol/l</td>
</tr>
<tr>
<td></td>
<td>CNPG</td>
</tr>
<tr>
<td></td>
<td>--</td>
</tr>
<tr>
<td></td>
<td>PRESERVATIVE</td>
</tr>
<tr>
<td></td>
<td>--</td>
</tr>
</tbody>
</table>

**REAGENT PREPARATION AND STABILITY:**

Reagent 1 is ready for use.

Before use, mix reagent by gently inverting each bottle.

If stored and handled properly:

- Unopened component is stable until expiry date stated on the label.
- Once open, component is stable for 2 months at 2-8°C.

**TYPE OF SPECIMEN:**

Use serum, heparin/EDTA plasma or urine as specimen.

It is recommended to follow NCELIS procedures, or similar standardised conditions, regarding specimen handling. Specimen should be collected in an appropriate sample container, with proper specimen identification.

- Serum/plasma should be separated from cells within 6 hours after collection.
- Stability: up to 2 months at 2-8°C.
- Collect urine without additives. Dilute 1:3 with deionised water. Multiply by dilution factor to recover patient's results.
- Stability: up to 10 days at 2-8°C.

**TEST PROCEDURE:**

**Materials required but not supplied:**

<table>
<thead>
<tr>
<th>Description</th>
<th>Catalog. No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Chemistry Calibrator</td>
<td>AD922</td>
</tr>
<tr>
<td>General Chemistry Control Level 1</td>
<td>AD922</td>
</tr>
<tr>
<td>General Chemistry Control Level 2</td>
<td>AD922</td>
</tr>
</tbody>
</table>

**Assay procedure:**

- **Waveband:** λ = 405 nm
- **Temperature:** 30°C or 37°C
- **Optical path:** 1 cm light path.

**Working Reagent**

- **Sample:**
  - 1 ml
  - 25 µl

- **Buffer:**
  - 10 ml

**Calculation:**

- **Serum/Plasma:**
  - V = 1 ml
  - OD = OD/min x 3120
  - Conversion factor: Qty in µkat/l = OD/min x 9525

- **Urine:**
  - V = 1 ml
  - OD = OD/min x 9631
  - Conversion factor: Qty in µkat/l = OD/min x 9255

**EXPECTED VALUES:**

<table>
<thead>
<tr>
<th>Specimen</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum/Plasma</td>
<td>0.1 µkat/l</td>
<td>20 µkat/l</td>
</tr>
<tr>
<td>Urine</td>
<td>0.1 µkat/l</td>
<td>10 µkat/l</td>
</tr>
</tbody>
</table>

**PERFORMANCE CHARACTERISTICS:**

Performance results can vary. Data obtained in each individual laboratory may differ from these values.

**Linearity:**

This assay is linear up to 1200 µl (20.4 µkat/l).

For samples with a higher concentration, dilute 1:1 with 0.9% NaCl (lgl) and re-assay. Multiply result by 2.

**Interfering substances:**

- **Results of study are as follows:**
  - Bilirubin (mixed isomers): Less than 10% interference up to 600 µmol/l Bilirubin.
  - Haemolysis: Less than 10% interference up to 5 g/l Haemoglobin.
  - Lepisma: Less than 10% interference up to 5 g/l Lepisma.

- **Sensitivity:**
  - The Lowest Detectable Level of amylase was estimated at 3.3 U/l.

**BIBLIOGRAPHY:**


**SYMBOLS:**

The following symbols are used in the labelling of Audit Diagnostics systems:

- **In Vitro Diagnostics:**
  - **ROV:** Catalogue No.
  - **IVD:** Code
  - **RLF:** Standard
  - **STR:** Buffer
  - **CE Mark:** Device comply with the Directives 98/79/EC

- **Stability:**
  - **Serum:**有效期 (Last day of the month)
  - **Urine:**有效期 (Last day of the month)

- **Method Comparison:**
  - Using 50 samples, a comparison between this amylase test (y) and another commercially available test (x), gave the following results:

  \[
  y = 0.957x + 0.424
  \]

  - r = 1.000
  - Sample range: 26 to 1915 U/l

- **Manufactured By:**
  - Audit Diagnostics
  - Business & Technology Park, Carrigaline, Co. Cork (Ireland)
  - Tel: 00353 (0) 21 – 453 653
  - Fax: 00353 (0) 21 – 453 653
  - E-mail: info@auditediagnostics.ie
  - Website: www.auditediagnostics.ie