**AMYLASE FL**

**AM F060 CH**
6 x 10 ml

**AM F120 CH**
12 x 10 ml

**AM F245 CH**
12 x 20 ml

**SUMMARY OF TEST**

Assays of amylase activity in serum and urine are largely of use in the diagnosis of diseases of the pancreas and in the investigation of pancreatic function. In acute pancreatitis, a transient rise in serum amylase activity occurs within 2 to 12 h of the onset; levels return to normal by the third or fourth day. A four- to six-fold elevation in amylase activity above the reference limit is usual, with maximal levels attained in 12 to 72 h. In acute pancreatitis associated with hyperamylasemia, serum amylase activity may be normal; the spuriously normal amylasemia may be unmasked either by serial dilution of the serum. A significant amount of the serum amylase is excreted in the urine, and therefore elevation of serum activity is reflected in the rise of urinary amylase activity. Urine amylase, as compared with serum amylase, appears to be more frequently elevated, reaches higher levels, and persists for longer periods. The urinary clearance of amylase is markedly increased in acute pancreatitis; in quiescent chronic pancreatitis, both serum and urine activities are usually subnormal. In some important groups of nonpancreatic disorders, reasons for hyperamylasemia are known. Although about 25% of the serum amylase is normally eliminated in the urine, in renal insufficiency the serum amylase activity is increased up to two-fold of the upper reference limit and in proportion to the extent of renal impairment. Neoplastic hyperamylasemia is an increasingly recognized entity for which clinical chemists must be constantly alert. Additionally, tumors of the lung and serous tumors of the ovary can produce hyperamylasemia. Mumps (infective parotitis) and maxillofacial surgery can cause a two-fold elevation, and salivary gland irradiation can produce a transient 8- to 18-fold elevation of serum amylase activity. Biliary tract diseases such as cholecystitis can cause an increase of 10- to 40-fold elevations of the serum amylase activity as a result of either primary or secondary pancreatic involvement. It has been established that some 200 methods for the assay of amylase have been described. The present method is based on a chromogenic substrate of 

**COMPONENTS:**
- CNP-G3 2.3 mM
- NaCl 350 mM
- Calcium buffer pH 6.0 100 mM
- Stabilizers and non-reactive components.

**STORAGE:**

- Solution: 600 ml (liquid) blue cap
- Vials: 12 x 10 ml (liquid) blue cap

**STABILITY:**

Up to expiration date on labels at 2-8°C.

**PRECAUTIONS**

- DO NOT PIPETTE BY MOUTH!
- Keep away from direct light sources.
- DO NOT PIPETTE BY MOUTH!

**TEST PROCEDURE**

- Wavelength: 405 nm
- Lightpath: 1 cm
- Temperature: 37°C

**EXPECTED VALUES**

<table>
<thead>
<tr>
<th>Sample</th>
<th>Lower limit</th>
<th>Upper limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum</td>
<td>&lt; 96 U/l</td>
<td>&lt; 480 U/l</td>
</tr>
<tr>
<td>Urine</td>
<td>&lt; 180 U/l</td>
<td>&lt; 800 U/l</td>
</tr>
</tbody>
</table>

**RESULTS**

Perform calculation in units per litre, multiplying the EU/ml by the factor as it is indicated.

Calculation in µIU: \( \frac{\text{µIU}}{\text{µIU}} \times 3178 \)

Calculation in µkat/l: \( \frac{\text{µkat/l}}{\text{µkat/l}} \times 0.0167 = \text{µkat/l} \)

**QUALITY CONTROL AND CALIBRATION**

It is suggested to perform an internal quality control. For this purpose the following human based control sera are available:

- QUANTINORM CHEMA: 10 x 5 ml
- QUANTIPATH CHEMA: 10 x 5 ml

Please contact Customer Care for further informations.

**TEST PERFORMANCE**

**Linearity**

The method is linear up to 3000 U/l. If a ∆/∆Min of 0.500 is exceeded, it is suggested to dilute sample 1+9 with saline and to repeat the test, multiplying the result by 10.

**Interferences**

- No interference was observed by the presence of:
  - Hemoglobin ≤ 500 mg/dl
  - Bilirubin ≤ 50 mg/dl
  - Lipids ≤ 1200 mg/dl

**Precision**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Mean (U/l)</th>
<th>SD (U/l)</th>
<th>CV%</th>
</tr>
</thead>
<tbody>
<tr>
<td>intra-assay (n=10)</td>
<td>67.89</td>
<td>0.97</td>
<td>1.42</td>
</tr>
<tr>
<td>sample 1</td>
<td>171.87</td>
<td>2.61</td>
<td>1.52</td>
</tr>
<tr>
<td>inter-assay (n=21)</td>
<td>67.81</td>
<td>1.93</td>
<td>2.85</td>
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<tr>
<td>sample 1</td>
<td>175.16</td>
<td>4.92</td>
<td>2.81</td>
</tr>
</tbody>
</table>

**METHODS COMPARISON**

A comparison between Chema and a commercially available product gave the following results:

<table>
<thead>
<tr>
<th>Amylase Chema</th>
<th>x</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amylase competitor</td>
<td>y</td>
</tr>
<tr>
<td>n = 181</td>
<td></td>
</tr>
</tbody>
</table>

\[ y = 1.071x - 0.54 \text{ U/l} \]
\[ r^2 = 0.997 \]