Overview

Useful For
Diagnosing acute pancreatitis

Method Name
Monoclonal Antibody Technique

NY State Available
Yes

Specimen

Specimen Type
Serum

Specimen Required
Container/Tube:

Preferred: Red top

Acceptable: Serum gel

Specimen Volume: 0.5 mL

Forms
If not ordering electronically, complete, print, and send a Gastroenterology and Hepatology Client Test Request (T728) with the specimen.

Specimen Minimum Volume
0.5 mL

Reject Due To

<table>
<thead>
<tr>
<th>Condition</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemolysis</td>
<td>Mild OK; Gross reject</td>
</tr>
<tr>
<td>Lipemia</td>
<td>Mild OK; Gross reject</td>
</tr>
<tr>
<td>Icterus</td>
<td>Mild OK; Gross reject</td>
</tr>
<tr>
<td>Other</td>
<td>NA</td>
</tr>
</tbody>
</table>

Specimen Stability Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum</td>
<td>Refrigerated (preferred)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ambient</td>
<td>7 days</td>
</tr>
<tr>
<td></td>
<td>Frozen</td>
<td></td>
</tr>
</tbody>
</table>
Clinical and Interpretive

Clinical Information
Amylases are a group of hydrolases that degrade complex carbohydrates into fragments.

Amylase is produced by the exocrine pancreas and the salivary glands to aid in the digestion of starch. It is also produced by the small intestine mucosa, ovaries, placenta, liver, and fallopian tubes.

Since the clinical use of amylase activity is usually to detect pancreatitis, the pancreatic amylase (p-amylase) form provides the single most useful test in the laboratory diagnosis of acute pancreatitis.

Total serum amylase continues to be the most widely used clinical test for the diagnosis of acute pancreatitis. Its use has been justified on the basis of its accuracy of 95%. The problem with its use is that it has relatively low specificity of between 70% and 80%.

Reference Values
0-<24 months: 0-20 U/L
2-<18 years: 9-35 U/L
> or =18 years: 11-54 U/L

Interpretation
Pancreatic amylase is elevated in acute pancreatitis within 12 hours of onset and persists 3 to 4 days. The elevation is usually 4-fold to 6-fold the upper reference limit. Macroamylase may cause less dramatic and more persistent elevations of p-amylase over weeks or months. This is usually accompanied by a reduced amylase clearance.

Values over the normal reference interval in patients with histories consistent with acute pancreatitis are confirmatory. Peak values are often 200 U/L or higher. Macroamylasemia may cause small, but persistent elevations of amylase.

An elevation of total serum alpha-amylase does not specifically indicate a pancreatic disorder since the enzyme is produced by the salivary glands, mucosa of the small intestine, ovaries, placenta, liver, and the lining of the fallopian tubes. Two isoenzymes, pancreatic and salivary, are found in serum. Pancreatic amylase has been shown to be more useful than total amylase when evaluating patients with acute pancreatitis.

Cautions
Pancreatic amylase results may be elevated in patients with macroamylase. This elevated pancreatic amylase is not diagnostic for pancreatitis. By utilizing serum lipase and urinary amylase values, the presence or absence of macroamylase may be determined.

Not useful for diagnosing pancreatic cancer.

Mild elevations up to 78 U/L may have little clinical significance.

Detection of chronic pancreatitis can only be aided by p-amylase during acute episodes.

Clinical Reference
**Performance**

**Method Description**
After the inhibition of salivary amylase with a combination of 2 monoclonal antibodies, pancreatic alpha-amylase activity is assayed by a coupled kinetic colorimetric procedure which gives rise to 415 nm absorption proportional to the paranitrophenol released by the action of alpha-amylase and alpha-glucosidase.

In this procedure, the first incubation step results in the inhibition of human salivary alpha-amylase by 2 monoclonal antibodies which do not affect pancreatic alpha-amylase. After a second incubation with the substrate (G7)-p-nitrophenyl (G1)-alpha-D-maltoheptoside, the activity of pancreatic alpha-amylase is measured. The alpha-amylase cleaves the substrate into fragments G2, G3, and G4. Further fragment hydrolysis by alpha-glucosidase yields p-nitrophenol and glucose. Enzyme activity is determined by the rate of increase of absorbance at 415 nm. Chromophore production is equimolar.

The simplified reaction is as follows:

P-amy

5 ET-G7PNP + 5 H2O -------> 2 ET-G5 + 2 G2PNP + 2 ET-G4
+ 2-G3PNP + ET-G3 + G4 PNP

alpha-glucosidase

2 G2PNP + 2 G3PNP + 14 H2O --------->5 PNP + 14G

**Abbreviations:** ET = ethylidene
G = glucose
PNP = p-nitrophenol


**PDF Report**
No

**Day(s) and Time(s) Test Performed**
Monday through Friday

**Analytic Time**
1 day (not reported on Saturday or Sunday)

**Maximum Laboratory Time**
4 days

**Specimen Retention Time**
7 days
Performing Laboratory Location
Rochester

Fees and Codes

Fees
- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their Regional Manager. For assistance, contact Customer Service.

Test Classification
This test has been cleared or approved by the U.S. Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

CPT Code Information
82150

LOINC® Information

<table>
<thead>
<tr>
<th>Test ID</th>
<th>Test Order Name</th>
<th>Order LOINC Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>PAMY</td>
<td>Amylase, Pancreatic, S</td>
<td>1805-1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Result ID</th>
<th>Test Result Name</th>
<th>Result LOINC Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>PAMY</td>
<td>Amylase, Pancreatic, S</td>
<td>1805-1</td>
</tr>
</tbody>
</table>