**General Information**

**Lab Order Codes:** PE1S

**Synonyms:** Elastase Stool, El 1; Elastase 1; Fecal Elastase

**CPT Codes:** 82656 – Elastase, pancreatic (EL-1), fecal, qualitative or semi-quantitative

**Test Includes:** Pancreatic stool elastase concentration measured in ug Elastase/g stool.

**Logistics**

**Test Indications:** Human pancreatic elastase (EL1) is a glycoprotein synthesized by the acinar cells that differs from other pancreatic proteases in that, in addition to extending a protolytic activity, it combines with bile acids and neutral steroids in the intestinal lumen to transport cholesterol and its metabolites along the intestinal tract. This unique function is possible because of the extraordinary stability of this enzyme during its passage. Elastase (EL1) concentration in stool is five times higher than pancreatic juice, therefore, fecal elastase (EL1) concentration accurately reflects the amount of enzyme secreted from the pancreas.

Exocrine pancreatic insufficiency is a major clinical manifestation of Cystic Fibrosis and its recognition is important for proper diagnosis and management. Fecal elastase (EL1) is a diagnostic test for pancreatic function in children with Cystic Fibrosis, since it remains intact during its intestinal transition and its concentration reflects the secretory capacity of the pancreas with 100% sensitivity. Whereas serum pancreatic levels quantify EL1 for the diagnosis or exclusion of an acute pancreatitis or an inflammatory episode of chronic pancreatitis or gallstone induced pancreatitis, the fecal EL1 level allows the diagnosis or exclusion of pancreatic exocrine insufficiency, which can be cause by chronic pancreatitis, Cystic Fibrosis, pancreatic tumor, cholelithiosis or diabetes mellitus.

Since tests for exocrine pancreatic function in children with Cystic Fibrosis have been difficult and unreliable, fecal elastase (EL1) (employing a monoclonal antibody) is reliable, non-invasive, highly specific, sensitive, easily reproducible and valid to assist without interruption of exogenous pancreatic enzyme therapy for pancreatic function in children and infants.

**Lab Testing Sections:** Urine/Stool - Sendouts

**Referred to:** Mayo Medical Laboratories (Test: FPANC) forward to Joli Diagnostics, Williamsville, NY
Phone Numbers:
MIN Lab: 612-813-6280
STP Lab: 651-220-6550

Test Availability: Daily, 24 hours

Turnaround Time: 8 – 10 days, test performed once weekly

Special Instructions: Pancreatic enzyme supplementation therapy should be discontinued prior to sample collection. A watery, diarrheal stool is not recommended for this test as some dilutions during the assay may give lower E1 concentrations than are actually present.

Specimen

Specimen Type: Stool, formed.
Note: Separate specimens must be submitted when multiple tests are ordered.

Container: Stool container with screw-top lid

Draw Volume: 1 g (Minimum: 1 g) formed stool

Processed Volume: Same as Draw Volume

Collection: Routine stool collection

Special Processing: Lab Staff: Stool samples should be frozen. Ship at frozen temperatures. Forward promptly.

Patient Preparation: None

Sample Rejection: Specimens other than stool, mislabeled or unlabeled specimens

Interpretive

Reference Range: | Age: All ages | Range: (ug Elastase/g stool) |
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<tbody>
<tr>
<td>Normal:</td>
<td></td>
<td>&gt;200</td>
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<tr>
<td>Moderate to slight exocrine pancreatic insufficiency:</td>
<td>100 to 200</td>
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<tr>
<td>Severe exocrine pancreatic insufficiency:</td>
<td>&lt;100</td>
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Critical Values: N/A
Limitations: N/A

Methodology: Enzyme Linked Immunosorbent Assay (ELISA)

References: Mayo Medical Laboratories November 2017

Updates: 10/16/2006: Test moved as a forward from Mayo to Inter Science. Note change in reference range, and CPT.
11/22/2010: Mayo moved test from a forward to Genova Diagnostics to Joli Diagnostics.
CPT update, previously listed as 82656. Updated reference range and units.
5/21/2013: CPT update, previously listed as 83516
3/3/2014: Update reference range for Normal (previously 200 to >500)