

## Pancreatic Elastase

sample type: **STOOL**

**Pancreatic Elastase (PE)** is a simple, noninvasive fecal marker for assessing exocrine pancreatic function, allowing the clinician to establish a prompt and reliable diagnosis with high degrees of sensitivity (90%-100%) and specificity (93%-98%) in suspected cases of pancreatic insufficiency. Sensitivity is lower in milder cases of pancreatic insufficiency, but is quite high (95%-100%) in moderate to severe cases.

### Pancreatic insufficiency may play a role in:

- Post-prandial bloating, pain or nausea
- Loose or watery stools
- Undigested food in the stool
- Hypochlorhydria
- Food intolerances
- Gastroesophageal reflux symptoms

### Clinical Advantages of Pancreatic Elastase:

PE is a digestive enzyme secreted exclusively by the human pancreas. Its unique qualities provide the following clinical advantages:

- PE has a strong correlation with the gold standard test for pancreatic insufficiency.
- PE results are not affected by pancreatic enzyme replacement therapy; therefore patients are not required to stop supplementation prior to stool collection.
- PE is not degraded during intestinal transit, nor is it affected greatly by increases or decreases in intestinal transit times.
- PE levels are 5-fold to 6-fold higher in feces than in duodenal juice, reflecting the extraordinary stability of PE in the gastrointestinal (GI) tract.
- PE is produced exclusively in the pancreas and as such has almost absolute pancreatic specificity. There is little or no interference by other enzymes in the GI tract.

### Specific Medical Indications:

- **Diabetes** — Reduced PE is found in over 50% of type 1 diabetics and 35% of type 2 diabetics.<sup>2</sup> Diabetes secondary to exocrine disease could be much more frequent than previously thought; studies have shown that low pancreatic elastase is closely related to glycemic control.
- **Gallstone or post-cholecystectomy** — Exocrine pancreatic function is frequently impaired in gallstone sufferers and post-cholecystectomy patients. There is a high prevalence of pathological changes in exocrine pancreatic function in patients with gallstones.
- **Osteoporosis** — Nearly one third of patients with osteoporosis have reduced concentrations of PE. Vitamin D levels may also be significantly decreased in these patients.<sup>11</sup>
- **Pancreatic function decreases with age.** Nutrient deficiency states may develop as a result of inadequate nutrient metabolism, particularly if undiagnosed or untreated for a prolonged time.
- **Cystic fibrosis patients** — PE can be used to diagnose enzyme need. PE is also useful in monitoring exocrine pancreatic function caused by:
  - Chronic pancreatitis
  - Autoimmunopathies and connective tissue diseases
  - Chronic Inflammatory Bowel Disease (IBD)

### • Ordering Options:

Stand alone test

### • Turn Around Time (TAT):

10 days

### • Add-On Test:

- CDSA, TAT — 14 days

- Digestive Function Analysis, TAT — 10 days

- When ordering as an Add-On, confirm that your kit has the Yellow Top Tube. If not, please call 800-522-4762 to order the "CDSA Add-On Kit."

### • CPT Code:

83516

### • Specimen Requirements:

10 ml stool (Requires Yellow Top Tube)

# Pancreatic Elastase 1



63 Zillicoa Street  
Asheville, NC 28801  
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Patient: **SAMPLE**  
**PATIENT**

Age: 34

Sex: F

MRN:

Order Number:

Completed: May 21, 2007

Received: May 16, 2007

Collected: May 02, 2007

Pancreatic Elastase 1		
Analyte	Result	Reference Range
Pancreatic Elastase 1	64	$\geq 201$ mcg/g

Commentary is provided to the practitioner for educational purposes, and should not be interpreted as diagnostic or treatment recommendations. Diagnosis and treatment decisions are the responsibility of the practitioner.

## Pancreatic Elastase 1:

The Pancreatic Elastase (PE1) assay is a simple, noninvasive method of assessing exocrine pancreatic function, contributing to a prompt and reliable diagnosis in suspected cases of pancreatic insufficiency. Reduced PE1 has been found in patients with diabetes, cholelithiasis and osteoporosis. PE1 has been shown to decline with age and can be used to monitor/adjust the dosage of pancreatic enzyme supplementation.

## Interpreting Pancreatic Elastase results:

- **PE values  $> 200$   $\mu\text{g}$**  suggest normal pancreatic function.
- **PE values of 100-200  $\mu\text{g}$**  suggest mild to moderate pancreatic insufficiency.
- **PE values  $< 100$   $\mu\text{g}$**  reflect moderate to severe pancreatic insufficiency.
- **The clinician should consider digestive enzyme supplementation if one or more of the following conditions is present:**
  - Loose, watery stools
  - Undigested food in the stools
  - Post-prandial abdominal pain
  - Nausea or colicky abdominal pain
  - Gastroesophageal reflux symptoms
  - Bloating or food intolerance
- **PE has a strong correlation** with the gold standard test for pancreatic insufficiency. Thus there is a direct correlation between PE and pancreatic function.
- **PE results are not affected** by pancreatic enzyme replacement therapy. Therefore, patients are not required to stop supplementation prior to providing a sample.
- **PE is not degraded** during intestinal transit, nor is it affected greatly by increases or decreases in intestinal transit times. Thus, its fecal concentration reflects pancreatic exocrine function, despite altered gut motility.
- **PE levels are 5-fold to 6-fold higher** in feces than in duodenal juice. This reflects the extraordinary stability of PE in the gastrointestinal (GI) tract.
- **PE is produced exclusively** in the pancreas and as such has almost absolute pancreatic specificity. There is little or no interference by other enzymes in the GI tract. What is measured is strictly the function of the pancreas.

SELAS RMS 1841 REV 3

For test kits, clinical support, or more information contact:

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Genova Diagnostics  
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Asheville, NC 28801-1074  
800-522-4762 • Fax: 828-252-9303

More detailed publications with references are also available: [www.GDX.net](http://www.GDX.net)