

## Overview

### Useful For

Diagnosis of exocrine pancreatic insufficiency in case of unexplained diarrhea, constipation, steatorrhea, flatulence, weight loss, upper abdominal pain, and food intolerances

Monitoring of exocrine pancreatic function in cystic fibrosis, diabetes mellitus, or chronic pancreatitis

### Method Name

Enzyme-Linked Immunosorbent Assay (ELISA)

### NY State Available

Yes

## Specimen

### Specimen Type

Fecal

### Shipping Instructions

Preferred shipping temperature is frozen. Refrigerated or ambient specimens received more than 72 hours post collection will be rejected.

### Specimen Required

**Supplies:** Stool container, Small (Random), 4 oz (T288)

**Container/Tube:** Stool container

**Specimen Volume:** 5 g

#### Collection Instructions:

1. Collect a fresh random fecal specimen, no preservatives.
2. If specimen is sent refrigerate, send immediately after collection.
3. If specimen cannot be sent immediately, freeze and send frozen (preferred).

#### Additional Information:

1. Separate specimens must be submitted when multiple tests are ordered. If only a single specimen is collected, it must be split prior to transport.
2. Testing cannot be added on to a previously collected specimen.

### Forms

[If not ordering electronically, complete, print, and send 1 of the following forms with the specimen:](#)

[-General Request \(T239\)](#)

[-Gastroenterology and Hepatology Client Test Request](#)

### Reject Due To

Specimens collected from diapers    Reject

### Specimen Minimum Volume

1 g

**Specimen Stability Information**

Specimen Type	Temperature	Time	Special Container
Fecal	Frozen (preferred)	28 days	
	Ambient		
	Refrigerated		

**Clinical & Interpretive**
**Clinical Information**

Pancreatic elastase (PE) is a proteolytic enzyme produced in the pancreatic acinar cells. It is released as a zymogen, which is then converted to an active enzyme in the duodenum by trypsin. PE has an important role in digestion, and proteolytically degrades proteins preferentially at alanine residues.

Exocrine pancreatic insufficiency (EPI) is described as a reduction in pancreatic enzyme activity below the normal digestive threshold level. Clinical symptoms of EPI include steatorrhea, bloating, abdominal discomfort, and weight loss. EPI is most commonly caused by chronic pancreatitis but can also be associated with pancreatic cancer, pancreatic surgery, necrotizing acute pancreatitis, cystic fibrosis, inflammatory bowel disease (both Crohn's disease and ulcerative colitis), diabetes (types I and II), gastric surgery, short bowel syndrome, and Zollinger-Ellison syndrome. If left untreated, patients with EPI can experience weight loss and significant nutrient deficiencies. Treatment for EPI centers on administration of pancreatic enzyme replacement therapy.

Stool testing is a critical component for the diagnosis of EPI. The 72-hour fecal fat test is useful for evaluating for the presence of steatorrhea. However, this testing is cumbersome for the patient and not easily tolerated due to the requirement of consuming 100 g fat/day. An alternate to the 72-hour fecal fat test is the measurement of PE in stool. The amount of PE in stool is representative of pancreatic enzyme production; patients with EPI may have reduced concentrations of PE in feces.

**Reference Values**

<100 mcg/g (Severe Pancreatic Insufficiency)

100-200 mcg/g (Moderate Pancreatic Insufficiency)

>200 mcg/g (Normal)

Reference values apply to all ages.

**Interpretation**

Pancreatic elastase concentrations above 200 mcg/g are normal and are not indicative of exocrine pancreatic insufficiency.

Pancreatic elastase concentrations from 100-200 mcg/g are suggestive for moderate exocrine pancreatic insufficiency.

Pancreatic elastase concentrations below 100 mcg/g are consistent with exocrine pancreatic insufficiency.

**Cautions**

Normal concentrations do not exclude the possibility of EPI.

Consistency of raw fecal sample may affect analytical performance.

**Clinical Reference**

1. Leeds JS, Oppong K, Sanders DS: The role of fecal elastase-1 in detecting exocrine pancreatic disease. Nat Rev

Gastroenterol Hepatol. 2011;8:405-415

2. Capurso G, Traini M, Piciucchi M, Signoretti M, Arcidiacono PG: Exocrine pancreatic insufficiency: prevalence, diagnosis, and management. Clin Exp Gastroenterol. 2019;12:129-139

3. Chowdhury SD, Kurien RT, Ramachandran A, et al: Pancreatic exocrine insufficiency: Comparing fecal elastase 1 with 72-h stool for fecal fat estimation. Indian J Gastroenterol. 2016;35:441-444

## Performance

### Method Description

The Immundiagnostik Pancreatic Elastase assay is an enzyme-linked immunosorbent assay (ELISA). Calibrators, controls, and diluted patient samples are added to a 96-well plate pre-coated with monoclonal antibodies to pancreatic elastase. If present, pancreatic elastase will bind to the antibodies on the surface of the microtiter wells. After a wash step, a peroxidase-labeled conjugate (mouse anti-pancreatic elastase) is added. After another washing step, substrate tetramethylbenzidine (TMB) is added, which reacts with the peroxidase. An acidic stop solution is added causing the color to change from blue to yellow. The intensity of the yellow color is directly proportional to the concentration of pancreatic elastase. A dose response curve of absorbance unit (optical density at 450 nm) vs. concentration is generated using the values obtained from the standards. Pancreatic elastase present in the patient samples is determined directly from this curve. (Package insert: IDK Pancreatic Elastase ELISA kit. Immundiagnostik AG; 2019)

### PDF Report

No

### Specimen Retention Time

Extracted feces: 7 days

### Performing Laboratory Location

Rochester

## Fees & Codes

### Test Classification

This test has been cleared, approved, or is exempt by the US 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

82653