Test Definition: ELASF

Pancreatic Elastase, Feces

Overview

Useful For

Evaluating patients with suspected exocrine pancreatic insufficiency, with symptoms 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 specimen and send frozen.
Additional Information:
1. **Separate specimens must be submitted when multiple tests are ordered**, with the exception of CALPR / Calprotectin, Feces. **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 Test Request (T728)

Specimen Minimum Volume

1 g

Reject Due To

Specimens collected from diapers	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Fecal	Frozen (preferred)	28 days	
	Ambient	72 hours	
	Refrigerated	72 hours	

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 a condition in which the pancreas does not produce sufficient digestive enzymes required to breakdown ingested food, leading to maldigestion and malabsorption.(1) Clinical symptoms of EPI include steatorrhea, bloating, abdominal discomfort, and weight loss.(2) 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 disease and ulcerative colitis), diabetes (types I and II), gastric surgery, short bowel syndrome, and Zollinger-Ellison syndrome.(2,3) 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.(4) 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. Current guidelines from the American Gastroenterological Association identify PE in stool as the most appropriate initial test for evaluation of patients with a high probability of pancreatic disease and clinical signs consistent with malabsorption (5). However, the guidelines acknowledge that this testing can be prone to false-positive results, especially in patients with a low pre-test probability for EPI. In a meta-analysis, PE in stool demonstrated a pooled sensitivity of 77% and a specificity of 88%, when compared to secretin stimulation testing. In patients with a low-pretest probability for EPI, the false-positive rate was estimated to by 11%. In addition, the sensitivity of fecal PE is higher in patients with severe EPI compared to patients with moderate or mild disease.(6)

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 to 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 of fecal pancreatic elastase (PE) do not exclude the possibility of exocrine pancreatic insufficiency (EPI), especially in cases of mild or moderate disease.

Decreased concentrations of fecal PE are not diagnostic for EPI, particularly in patients with low pre-test probability.

Consistency of raw fecal sample may affect analytical performance.

Clinical Reference

1. Phillips ME, Hopper AD, Leeds JS, et al. Consensus for the management of pancreatic exocrine insufficiency: UK practical guidelines. 2021;8(1):e000643
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. Leeds JS, Oppong K, Sanders DS. The role of fecal elastase-1 in detecting exocrine pancreatic disease. Nat Rev Gastroenterol Hepatol. 2011;8(7):405-415
4. 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(6):441-444
5. Whitcomb DC, Buchner AM, Forsmark CE. AGA clinical practice update o the epidemiology, evaluation, and management of exocrine pancreatic insufficiency: Expert review. Gastroenterology. 2023;165(5):1292-1301
6. Vanga RR, Tansil A, Sidiq S, et al. Diagnostic performance of measurement of fecal elastase-1 in detection of exocrine pancreatic insufficiency: Systemic review and meta-analysis. 2018;16(8):1220-1228

Performance

Method Description

The Immundiagnostik Pancreatic Elastase assay is an enzyme-linked immunosorbent assay. 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 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; 02/23/2023)

PDF Report
No

Day(s) Performed
Monday through Friday

Report Available
3 to 5 days

Specimen Retention Time
Extracted feces: 7 days

Performing Laboratory Location
Mayo Clinic Laboratories - Rochester Superior Drive

Fees & 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 account representative. For assistance, contact Customer Service.

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

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
ELASF	Pancreatic Elastase, F	25907-7

Result ID	Test Result Name	Result LOINC® Value
ELASF	Pancreatic Elastase, F	25907-7