

Pancreatic elastase

Gastrointestinal Health Marker Guide

What this marker measures

Pancreatic elastase is a stool marker of pancreatic exocrine function. It is used to help diagnose or exclude pancreatic exocrine insufficiency (PEI) and to monitor pancreatic function in conditions such as cystic fibrosis, diabetes, and chronic pancreatitis¹⁻⁵.

This assay is issued under the European IVDR framework (the assay is classified IVDR Class C) with ARTG listing for use in Australian markets

Assay indications

Adapted from the instructions for use

Pancreas elastase is mainly bound to bile salts during intestinal passage and is not degraded. The stool concentration reflects the secretory capacity of the pancreas.

- Diagnosis or exclusion of exocrine pancreas insufficiency in case of unexplained diarrhoea, constipation, steatorrhoea, flatulence, weight loss, upper abdominal pain, and food intolerances
- Monitoring of exocrine pancreas function in cystic fibrosis, diabetes mellitus, or chronic pancreatitis

Clinical associations*

Consider this marker when your patient presents with:

Pancreatic function

Low faecal elastase-1 may indicate reduced pancreatic exocrine function and can support detection of moderate-to-severe PEI.

Malabsorption symptoms

Consider when patients present with steatorrhoea, oily or floating stools, unexplained weight loss, bloating, diarrhoea, or fat-soluble vitamin deficiency

High-risk conditions

Consider in chronic pancreatitis, relapsing acute pancreatitis, cystic fibrosis, pancreatic cancer, previous pancreatic surgery, or other contexts where PEI is suspected.

**In addition to the assay's intended use, all clinical associations have been reviewed by the Microba science team to ensure clinical validity supported by Microba's cited literature.*

Interpreting the result

OUT OF RANGE LOW

Below 100 mcg/mL. Low pancreatic elastase

May indicate severe PEI. Further investigation is warranted if clinically indicated. Interpret alongside symptoms, nutritional markers and other diagnostic tests; watery or liquid stools may yield falsely low results.

BORDERLINE

100 – 200ug/ml Borderline/ indeterminate pancreatic elastase

May indicate reduced exocrine pancreatic function or mild-to-moderate PEI, but results should be interpreted with symptoms, risk factors and other diagnostic tests. Watery or liquid stools may yield falsely low results.

WITHIN RANGE

≥ 200ug/ml within the expected range

PEI is less likely, particularly moderate-to-severe PEI. No intervention is typically needed unless symptoms or risk factors remain clinically concerning.

Treatment guidance

Consider the cause of low pancreatic elastase.

CLINICAL MANAGEMENT - OUT-OF-RANGE

- Out-of-range result: referral to a medical specialist is warranted if cause unknown.

CLINICAL MANAGEMENT - BORDERLINE

- Borderline result: Repeat testing or further assessment may be appropriate, particularly if the sample was watery/liquid or symptoms of malabsorption are present.

CLINICAL MANAGEMENT - MEDICATION

- Pancreatic enzyme replacement therapy (PERT) may improve diarrhoea or malabsorption symptoms when borderline pancreatic elastase is accompanied by clinical features suggestive of pancreatic exocrine insufficiency⁶⁻⁸.



Tips for discussing out-of-range results

Your pancreatic elastase result gives us insight into whether your pancreas is releasing enough enzymes to digest food properly. A low result may mean you are not getting enough digestive enzymes into the gut, which can affect nutrient absorption. We'll investigate the cause and determine the right next steps

Evidence grading for patient management insights

The letter grades shown next to each patient management insight show the quality of the research behind it. Every insight provided has been through a rigorous review of the scientific literature and graded using the NHMRC Levels of Evidence, so you can see exactly how strong the evidence is before applying it in practice.

Grade	Description
A	Body of evidence can be trusted to guide practice
B	Body of evidence can be trusted to guide practice in most situations
C	Body of evidence provides some support for recommendation, but care should be taken in its application
D	Body of evidence is weak, and recommendation must be applied with caution
PP H	Body of evidence is observational only and must be applied with caution
PP IV	Body of evidence is in vitro and must be applied with a high degree of caution