Calprotectin Gut Inflammation Test

Overview

Intended Use

Evaluation of Calprotectin in stool samples of patients suspected of having gastrointestinal inflammation.

Method Name

Enzyme-Linked Immunosorbent Assay (ELISA)

Specimen

Specimen Type

Fecal

Shipping Instructions

Specimen Required
Supplies: Stool container
Submission Container/Tube: Stool container
Specimen Volume: 2 g

Collection Instructions

1. 1. Collect a fresh random fecal specimen, no preservative.
2. Freshly collected specimen is the ideal. If collected ahead of time, refrigerate until ready to ship.

Rejection Criteria

Results may not be clinically applicable to children less than 4 years of age who have mildly increased fecal calprotectin levels.

Specimen Stability Information

Specimen Used	Sample Type	Temperature	Acceptable Time to Ship
Stool sample	Fresh solid/liquid	Room temperature	Immediately after collection
	Refrigerated fresh sample	4◦C	Before 72 hrs
	Frozen	-20◦C / -80◦C	Anytime

Clinical and Interpretive

Clinical Information

Calprotectin, formed as a heterodimer of S100A8 and S100A9, is a member of the S100 calcium-binding protein family. It is expressed primarily by granulocytes and, to a lesser degree, by monocytes/macrophages and epithelial cells. In neutrophils, calprotectin comprises almost 60% of the total cytoplasmic protein content. Activation of the intestinal immune system leads to recruitment of cells from the innate immune system, including neutrophils. The neutrophils are then activated, which leads to release of cellular proteins, including calprotectin. Calprotectin is eventually translocated across the epithelial barrier and enters the lumen of the gut. As the inflammatory process progresses, the released calprotectin is absorbed by fecal material before it is excreted from the body. The amount of calprotectin present in the feces is proportional to the number of neutrophils within the gastrointestinal mucosa and can be used as an indirect marker of intestinal inflammation.

Calprotectin is most frequently used as part of the diagnostic evaluation of patients with suspected inflammatory bowel disease (IBD). Patients with IBD may be diagnosed with Crohn disease or ulcerative colitis. Although distinct in their pathology and clinical manifestations, both are associated with significant intestinal inflammation. Elevated concentrations of fecal calprotectin may be useful in distinguishing IBD from functional gastrointestinal disorders, such as irritable bowel syndrome (IBS). When used for this differential diagnosis, fecal calprotectin has sensitivity and specificity both of approximately 85%. However, it must be remembered that increases in fecal calprotectin are not diagnostic for IBD, as other disorders such as celiac disease, colorectal cancer, and gastrointestinal infections, may also be associated with neutrophilic inflammation.

Reference Values

< 80 µg/g (Normal)
80 - 160 µg/g (Gray-zone/Borderline)
> 160 µg/g (Elevated)

Interpretation

Calprotectin concentrations of 80 µg/g and lower are not suggestive of an active inflammatory process within the gastrointestinal system. For patients experiencing gastrointestinal symptoms, consider further evaluation for functional gastrointestinal disorders. Calprotectin concentrations between 80 - 160 µg/g are Gray-zone/borderline and may represent a mild inflammatory process, such as in treated inflammatory bowel disease (IBD) or associated with nonsteroidal anti-inflammatory drug (NSAID). For patients with clinical symptoms suggestive of IBD, retesting in 4 to 6 weeks may be indicated.

Calprotectin concentrations of 160 µg/g and higher are suggestive of an active inflammatory process within the gastrointestinal system. Further diagnostic testing to determine the etiology of the inflammation is suggested.

Cautions

- Elevations in fecal calprotectin are not diagnostic for inflammatory bowel disease (IBD), and normal fecal calprotectin concentrations do not exclude the possibility of IBD. Diagnosis of IBD should be based on clinical evaluation, endoscopy, histology, and imaging studies.
- Borderline results in fecal calprotectin may be observed in patients taking nonsteroidal anti-inflammatory drugs (NSAID), aspirin, or proton-pump inhibitors.
- For borderline results, repeat testing in 4 to 6 weeks is suggested.
- Elevations in fecal calprotectin may be observed in other disease states associated with neutrophilic inflammation of the gastrointestinal system, including celiac disease, colorectal cancer, and gastrointestinal infections.
- False negative results could occur in patients who have granulocytopenia due to bone marrow depression.
- Due to the lack of homogenous distribution of calprotectin in fecal material, variability in results may be seen when patients are monitored over time, particularly in samples with high calprotectin concentrations.
- Test results should be interpreted in conjunction with information available from clinical assessment of the patient and other diagnostic procedures.
- Results may not be clinically applicable to children less than 4 years of age who have mildly increased fecal calprotectin levels.
- Patients with IBD fluctuate between active (inflammatory) and inactive stages of the disease.
- These stages must be considered when interpreting results of the fecal calprotectin assay.

Clinical Reference

1. Gisbert JP, McNicholl AG, Golmollon F: Questions and answers on the role of faecal calprotectin as a biological marker in inflammatory bowel disease. Digest Liver Dis. 2009;41:56-66
2. Campeotto F, Butel MJ, Kalach N, et al: High faecal calprotectin concentrations in newborn infants. Arch Dis ChildFetal. 2004;89:F353-F355
3. Dabritz J, Musci J, Foell D: Diagnostic utility of faecal biomarkers in patients with irritable bowel syndrome. World J Gastroentero. 2014;20(2):363-375
4. Fagerberg, UL, Loof L, Merzoug RD, et al: Fecal calprotectin levels in healthy children studied with an improved assay. J Pediatr Gastr Nutr. 2003;37:438-472
5. Sherwood RA, Walsham NE, Bjarnason I: Gastric, pancreatic, and intestinal function. In: Rifai N, Horwath AR, Wittwer CT, eds. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics. 6th ed. Elsevier; 2018:1398-1420

Performance

Method Description

The Flore' Calprotectin Gut Inflammation test is an enzyme-linked immunosorbent assay (ELISA). Briefly, polyclonal capture antibodies specific for human calprotectin are immobilized on a 96-well plate. Calibrators, controls, and diluted patient samples are added to the wells of the plate. If present, calprotectin will bind to the capture antibodies on the plate. After a wash step, a solution containing an enzyme-labelled antibody is added. After another wash step, a substrate solution that will change color in the presence of the enzyme is added. The absorbance of the colored produced is proportional to the amount of calprotectin in the patient sample. Lastly, the control and patient results are calculated based on a curve generated from the kit calibrators.

PDF Report: Yes

Day(s) Performed: Monday through Friday

Report Available in: 3-5 days

Performing Laboratory Location: Flore' Laboratories

Test Classification:
This test has been cleared, approved or is exempt by the U.S. Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Flore' Laboratories in a manner consistent with CLIA requirements.

CPT Code Information: 83993

LOINC® Information: LOINC Value : 38445-3