

## Overview

### Useful For

Evaluating patients suspected of having a gastrointestinal inflammatory process

Distinguishing inflammatory bowel disease from irritable bowel syndrome, when used in conjunction with other diagnostic modalities, including endoscopy, histology, and imaging

### Testing Algorithm

For more information see [Inflammatory Bowel Disease Diagnostic Testing Algorithm](#).

For more information see [Ulcerative Colitis and Crohn Disease Therapeutic Drug Monitoring Algorithm](#).

### Special Instructions

- [Ulcerative Colitis and Crohn Disease Therapeutic Drug Monitoring Algorithm](#)
- [Inflammatory Bowel Disease Diagnostic Testing Algorithm](#)

### Method Name

Enzyme-Linked Immunosorbent Assay (ELISA)

### NY State Available

Yes

## Specimen

### Specimen Type

Fecal

### Shipping Instructions

Preferred shipping temperature is frozen. **Refrigerated or thawed specimens received more than 72 hours after collection will be rejected.**

### Specimen Required

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

**Submission Container/Tube:** Stool container

**Specimen Volume:** 5 g

#### Collection Instructions:

1. Collect a fresh random fecal specimen, no preservative.
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 ELASF / Pancreatic Elastase, 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
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### Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Fecal	Refrigerated	72 hours	
	Frozen (preferred)	7 days	

## Clinical & 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. 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

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with neutrophilic inflammation.

**Reference Values**

<50.0 mcg/g (Normal)

50.0-120 mcg/g (Borderline)

>120 mcg/g (Abnormal)

Reference values apply to all ages.

**Interpretation**

Calprotectin concentrations below 50.0 mcg/g 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 50.0 and 120 mcg/g are borderline and may represent a mild inflammatory process, such as in treated inflammatory bowel disease (IBD) or associated with nonsteroidal anti-inflammatory drug or aspirin usage. For patients with clinical symptoms suggestive of IBD, retesting in 4 to 6 weeks may be indicated.

Calprotectin concentrations above 120 mcg/g are suggestive of an active inflammatory process within the gastrointestinal system. Additional 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, 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.

Falsely decreased concentrations of fecal calprotectin may be observed in patients with neutropenia or granulocytopenia.

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.

**Clinical Reference**

1. Gisbert JP, McNicholl AG. Questions and answers on the role of faecal calprotectin as a biological marker in inflammatory bowel disease. *Digest Liver Dis.* 2009;41(1):56-66
2. Campeotto F, Butel MJ, Kalach N, et al. High faecal calprotectin concentrations in newborn infants. *Arch Dis Child Fetal Neonatal Ed.* 2004;89(4):F353-F355
3. Dabritz J, Musci J, Foell D. Diagnostic utility of faecal biomarkers in patients with irritable bowel syndrome. *World J*

Gastroenterol. 2014;20(2):363-375

4. Fagerberg UL, Loof L, Merzoug RD, Hansson LO, Finkel Y. Fecal calprotectin levels in healthy children studied with an improved assay. J Pediatr Gastroenterol Nutr. 2003;37(4):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 QUANTA Lite Calprotectin Extended Range assay is an enzyme-linked immunosorbent assay. 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 color 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. (Package insert: QUANTA Lite Calprotectin Extended Range ELISA kit. INOVA Diagnostics; 04/2019)

### 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

Rochester

## 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

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manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

**CPT Code Information**

83993

**LOINC® Information**

Test ID	Test Order Name	Order LOINC® Value
CALPR	Calprotectin, F	38445-3

Result ID	Test Result Name	Result LOINC® Value
CALPR	Calprotectin, F	38445-3