Overview

Useful For
Evaluation of patients suspected of having a gastrointestinal inflammatory process
Distinguishing inflammatory bowel disease (IBD) from irritable bowel syndrome (IBS), when used in conjunction with other diagnostic modalities, including endoscopy, histology, and imaging

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 postcollection 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 preservatives.
2. If sample is sent refrigerate, send immediately after collection.
3. If sample cannot be sent immediately, freeze and send frozen (preferred).

Additional Information:
1. Separate specimens must be submitted when multiple tests are ordered. Specimen 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 (T728)
**Specimen Minimum Volume**
1 gm

**Reject Due To**

| Other                | Specimens collected from diapers |

**Specimen Stability Information**

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
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<tbody>
<tr>
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<tr>
<td></td>
<td>Refrigerated</td>
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**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 eventually translocates across the epithelial barrier and enters the lumen of the gut. As the inflammatory process progresses, the released calprotectin is absorbed by the 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**

- < or =50.0 mcg/g (Normal)
- 50.1-120.0 mcg/g (Borderline)
- > or =120.1 mcg/g (Abnormal)

Reference values apply to all ages.

**Interpretation**
Calprotectin concentrations of 50.0 mcg/g and lower are not suggestive of an active inflammatory process within the gastrointestinal system. For patients experiencing gastrointestinal symptoms, consider further evaluation for
Calprotectin concentrations between 50.1 and 120.0 mcg/g are borderline and may represent a mild inflammatory process, such as in treated inflammatory bowel disease (IBD) or associated with NSAID or aspirin usage. For patients with clinical symptoms suggestive of IBD, retesting in 4 to 6 weeks may be indicated.

Calprotectin concentrations of 120.1 mcg/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.

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

Clinical Reference


Performance

Method Description

The QUANTA Lite Calprotectin assay 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. (Packet insert: QUANTA Lite Calprotectin ELISA kit, INOVA diagnostics, San Diego, CA, 2016)
No

Day(s) and Time(s) Test Performed
Monday through Friday; 8 a.m.

Analytic Time
3 days

Maximum Laboratory Time
5 days

Specimen Retention Time
7 days; extracted feces only, the specimen is discarded after processing

Performing Laboratory Location
Rochester

Fees and 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 Regional Manager. For assistance, contact Customer Service.

Test Classification
This test has been cleared or approved by the U.S. 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
83993

LOINC® Information

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<tr>
<th>Test ID</th>
<th>Test Order Name</th>
<th>Order LOINC Value</th>
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<td>Calprotectin, F</td>
<td>38445-3</td>
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<table>
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