Calprotectin, Fecal by Immunoassay

Inflammatory bowel disease (IBD) represents a spectrum of chronic disorders that affect the gastrointestinal (GI) tract. Crohn disease (CD) and ulcerative colitis (UC) are the major IBD disorders. ¹ Calprotectin is a marker of gut inflammation with good sensitivity for detecting IBD. ¹ Fecal lactoferrin, an iron-binding protein, is another useful marker of intestinal inflammation in IBD,² but more clinical evidence is available for fecal calprotectin.³

Disease Overview

Prevalence

IBD: 286/100,000 in United States⁴

Physiology

- Calprotectin is a calcium-binding protein⁵ and accounts for 60% of soluble protein in neutrophils³
- Calprotectin concentration in feces is proportional to the level of inflammation in patients with UC³; the relationship is more variable in patients with CD⁵
- Calprotectin is stable in stool samples³

Diagnostic Issues

- IBD symptoms may be vague and similar to those of irritable bowel syndrome (IBS) (eg, diarrhea, abdominal pain)
  - IBS is much more prevalent than IBD
- Differentiation of IBD from IBS may require invasive procedures
- Calprotectin testing may be useful as a screen for differentiating IBS and IBD,² reducing the necessity of invasive procedures

Monitoring Issues

- Monitoring by endoscopy is invasive
- Calprotectin measurement can be used to help differentiate quiescent from active IBD³
- Mucosal healing is associated with sustained remission and is the goal of IBD treatment²
- Calprotectin levels correlate with endoscopic scoring systems that are used to assess mucosal healing and may be useful in evaluating mucosal healing³

Test Interpretation

Clinical Validation

Screening performance for IBD

- Sensitivity: 93% in adults; 92% in children⁶
- Specificity: 96% in adults; 76% in children⁵
- More sensitive and specific than serum inflammatory markers³,⁷
- Individuals with high pretest probability of IBD (>75%) should be referred directly to endoscopy due to the risk of false-negative calprotectin results⁵,⁸
- Screening for elevated fecal calprotectin in individuals with low pretest probability for IBD may result in cost savings by reducing need for unnecessary procedures⁸
  - Confirm positive results by endoscopy and follow negative result clinically

Tests to Consider

<table>
<thead>
<tr>
<th>Test Name</th>
<th>Code</th>
<th>Method</th>
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<tbody>
<tr>
<td>Calprotectin, Fecal by Immunoassay</td>
<td>3002859</td>
<td>Quantitative Chemiluminescent Immunoassay</td>
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- Aids in differentiation of IBD from IBS and other functional disorders of the GI system
  - Not specific for IBD
- Aids in monitoring IBD and prediction of relapse

See Related Tests
### Results

<table>
<thead>
<tr>
<th>Results</th>
<th>Range</th>
<th>Clinical Significance</th>
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</thead>
<tbody>
<tr>
<td>Normal</td>
<td>≤50 μg/g</td>
<td>Likely to rule out IBD in adults with &lt;75% prior probability</td>
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<tr>
<td>Borderline</td>
<td>51-120 μg/g</td>
<td>Reevaluation in 4-6 weeks is recommended</td>
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<tr>
<td>Abnormal</td>
<td>≥121 μg/g</td>
<td>Supports diagnosis of IBD</td>
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### Limitations

- Calprotectin is not specific for IBD and is also elevated in:
  - GI infections
  - Colorectal cancer
  - Celiac disease
  - Mild elevations may be seen with nonsteroidal anti-inflammatory drug or aspirin use
- Calprotectin concentration alone is not diagnostic for IBD
- Calprotectin does not distinguish celiac disease from UC
  - Results may fluctuate as disease activity fluctuates
  - GI bleeding can cause mild increases in fecal calprotectin concentrations
- Concentrations of fecal biomarkers may vary in different stool samples from a single patient

### References


### Related Information

**Inflammatory Bowel Disease - IBD**

### Related Tests

**Lactoferrin, Fecal by ELISA 0061164**

**Method:** Qualitative Enzyme-Linked Immunosorbent Assay