

# Calprotectin, Fecal by Immunoassay

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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.<sup>1</sup> Fecal calprotectin is a marker of gut inflammation with good sensitivity for detecting IBD.<sup>1</sup> Fecal lactoferrin, an iron-binding protein, is another useful marker of intestinal inflammation in IBD,<sup>2</sup> but more clinical evidence is available for fecal calprotectin.<sup>3</sup>

## **Disease Overview**

### Prevalence

IBD: 286/100,000 in United States<sup>4</sup>

### Physiology

- Calprotectin is a calcium-binding protein<sup>2</sup> and accounts for 60% of soluble protein in neutrophils<sup>3</sup>
- Calprotectin concentration in feces is proportional to the level of inflammation in patients with UC<sup>3</sup>; the relationship is more variable in patients with CD<sup>5</sup>
- Calprotectin is stable in stool samples<sup>3</sup>

#### **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,<sup>2</sup> reducing the necessity of invasive procedures

#### Monitoring Issues

- Monitoring by endoscopy is invasive
- Calprotectin measurement can be used to help differentiate quiescent from active IBD<sup>3</sup>
- Mucosal healing is associated with sustained remission and is the goal of IBD treatment<sup>2</sup>
- Calprotectin levels correlate with endoscopic scoring systems that are used to assess mucosal healing and may be useful in evaluating mucosal healing<sup>3</sup>

## Test Interpretation

### **Clinical Validation**

Screening performance for IBD

- Sensitivity: 93% in adults; 92% in children<sup>6</sup>
- Specificity: 96% in adults; 76% in children<sup>6</sup>
- More sensitive and specific than serum inflammatory markers<sup>3,7</sup>
- Individuals with high pretest probability of IBD (>75%) should be referred directly to endoscopy due to the risk of false-negative calprotectin results<sup>6,8</sup>
- Screening for elevated fecal calprotectin in individuals with low pretest probability for IBD may result in cost savings by reducing need for unnecessary procedures<sup>8</sup>
  - Confirm positive results by endoscopy and follow negative result clinically

### Results

Results	Range	Clinical Significance
Normal	≤50 µg/g	Likely to rule out IBD in adults with <75% prior probability
Borderline	51-120 µg/g	Reevaluation in 4-6 weeks is recommended

## Featured ARUP Testing

#### Calprotectin, Fecal by Immunoassay 3002859

Method: Quantitative Chemiluminescent Immunoassay (CLIA)

- 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

Results	Range	Clinical Significance
Abnormal	≥121 µg/g	Supports diagnosis of IBD

#### 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<sup>9</sup>

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### **Related Information**

#### Inflammatory Bowel Disease - IBD

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