

INFLAMMATORY BOWEL DISEASE

ENHANCED TESTING FOR DIAGNOSIS AND PROGNOSIS



Novel serological markers for inflammatory bowel disease (IBD) improve sensitivity and specificity to aid in differential diagnosis and provide valuable prognostic information about disease behavior.

Inflammatory Bowel Disease (IBD) Expanded Profile (162045)

Testing includes five IBD specific antibody markers

gASCA *Antisaccharomyces cerevisiae* antibodies
 ACCA *Antichitobioside* carbohydrate antibodies
 ALCA *Antilaminaribioside* carbohydrate antibodies
 AMCA *Antimannobioside* carbohydrate antibodies

pANCA Atypical perinuclear anti-neutrophil cytoplasmic antibodies

Anti-Glycan
Antibodies

Up to 97% specificity in differentiating UC from CD^{2,3,6,7,10}

Up to 85.5% sensitivity in identifying CD⁹

- Proprietary antibody testing utilizing IBDx technology
- Over a decade of scientific research demonstrating clinical value of Anti-Glycan Antibodies
- Stratifies into 3 prognostic levels of CD severity

Up to 70% sensitivity in identifying patients with UC¹¹

The Inflammatory Bowel Disease (IBD) Expanded Profile was developed to be both clinically appropriate and cost-effective for patients

Overcome Diagnostic Challenges

A combination of clinical findings, endoscopic, histopathologic, radiologic, and laboratory testing is used to establish the diagnosis of IBD. Diagnostic challenges arise when clinical presentation is indolent, invasive procedures are not obtainable, or results are inconclusive. In such cases, the IBD Expanded Profile may help clarify diagnosis and expedite therapeutic decisions.¹⁻¹²

- Aid in the prompt recognition of IBD¹
- Aid in differentiating between IBD and non-IBD¹ forms of colitis
- Assist in the differential diagnosis of UC vs CD in both adults and children¹
- Assist in the evaluation of patients with indeterminate colitis or IBD unclassified^{15,16}

Support Patient Prognosis and Treatment Decisions

The clinical course of Crohn's Disease is variable. Predictors of complicated disease may be used to help determine candidates for earlier and more aggressive intervention. The markers examined in LabCorp's IBD Expanded Diagnostic profile have been shown to be highly-specific predictors of aggressive disease behavior.^{1,2-8,10,13,14} Our profile may help physicians:

- Gain prognostic insight by identifying CD patients at risk for progression to complicated disease^{1,2-8,10,13,14}
- Stratify patients into disease severity/phenotypic subtypes^{1,2-8,10,13,14}
- Evaluate candidates for colectomy or IPAA and their post-surgical prognosis¹⁶⁻¹⁸

What are Anti-Glycan Antibodies?

The serum markers specific to Crohn's Disease — gASCA, ACCA, ALCA, and AMCA -- are antibodies directed against specific glycans (polysaccharides) found in microorganisms, such as *C. albican* and *S. cerevisiae*, which are responsible for the fungal microbiota dysbiosis observed in CD.^{2,19} These glycans modulate the immune system by acting as ligands for receptors and substrates for enzymes expressed by immune cells and intestinal epithelial cells.^{1,2} By targeting these important yeast cell wall epitopes, Anti-Glycan Antibodies may contribute to the altered immune response implicated in CD pathogenesis.

The diagnostic accuracy of Anti-Glycan Antibodies has been validated by more than a dozen independent, peer-reviewed studies (n>4000 IBD patients).

IBD Expanded Diagnostic Profile Founded on Scientific Excellence

Highly Specific for Crohn's Disease Diagnosis

- >95% specificity in distinguishing CD vs UC when 2 or more markers are positive^{2,3,6,7,10}
- 88 – 95% specificity to distinguish CD vs non-IBD gastrointestinal disorders¹⁴

Enhanced Sensitivity for CD with use of Anti-Glycan Antibodies

- Combined sensitivity of 85.5% for CD⁹
- Addition of Anti-Glycan Antibodies improves overall sensitivity for CD by 10 – 20% from ASCA alone^{2,3,10}
- 67% sensitivity in identifying CD patients who are ASCA negative⁹

Sensitive and Specific for Ulcerative Colitis Diagnosis

- pANCA positive/gASCA negative is between 51% and 57% sensitive and 94% and 97% specific for UC^{11,12}

Predictive of complicated disease and progression to more severe course

- Positivity of 2 or more of these markers predicts faster progression to more severe disease^{9,13,14}
- Patients with a higher number of Anti-glycan Antibodies and great levels have increased frequency of complicated disease behavior and need for abdominal surgery^{3,7,10,14}

A patient's antibody status (positive or negative) remains stable over time, irrespective of disease activity²⁰

LabCorp Offers Superior Service

- Comprehensive laboratory services for the gastroenterology specialist
- Broad network of managed care health plans
- Flexible connectivity options for test ordering and reporting
- More than 1700 patient service centers available nationwide
- Local account representation

References

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