Highly Sensitive IBD profile for identifying patients with Inflammatory Bowel Disease

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.*

Scientific Expertise

Profile developed with only those markers thathavebeen established in published peer reviewed journals and are clinically relevant

Crohn's disease risk levels and prognostic information validated prospectively in adults and children

Interpretive reports include suggestive disease form and risk stratification for CD patients

Clinical Application

Six-marker IBD profile identifies and differentiates patients with ulcerative colitis (UC) and Crohn's disease (CD) from other non-inflammatory gastrointestinal diseases

Reported up to 97% specificity in differentiating UC from CD[1,2,3]

Reported up to 70% specificity in identifying patients with UC[4,5]

Reported up to 85.5% sensitivity in identifying patients with CD using multiple markers[6]

56.4% Sensitivity in identifying CD patients who are anti Saccharomyces cerevisae antibody (ASCA) negative[6]

Three prognostic levels for CD severity are provided, allowing for improved treatment decisions[7,8,9]

Test combination formulated to be appropriate and cost effective for patients

Committed to Quality

The management and staff of Glycominds Diagnostics are committed to meeting customer expectations and all relevant regulatory requirements, while continously improving the qualtiy performance in every facet of our operations. All this is possible by maintaining our high standards due to our state of the art research, production facilities, and highly qualified staff.

GLYCOMINDS

www.ibdx.net

CE

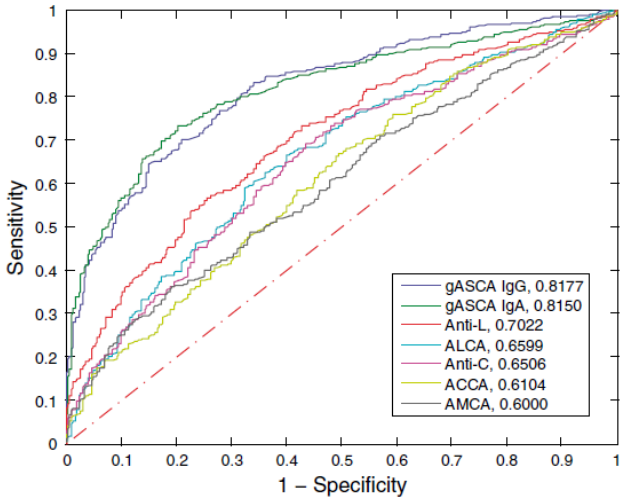
Six Marker Profile	Ulcerative Colitis	Chron's Disease	Chron's with High Risk of Aggressive Disease	Chron's with Very High Risk of Aggresive Disease
pANCA*	Positive (+) Up to 70% sensitivity	Negative (-)	Negative (-) or positive (+)	Negative (-) or positive (+)
gASCA IgG*	Negative (-)	Positive(+) 66.1% sensitivity	Two positive (+) markers	Three or more positive (+) markers
ALCA IgG	Negative (-)	Positive (+) 85.5% sensitivity		
ACCA IgA				
AMCA IgG			High risk**	Very high risk
ANTI-L IgA				

pANCA *is not provided by Glycominds* ****ASCA** *IgA was not included in the profile, as studies have shown there is little to no increase in clinical sensitivity or specificity for Crohn's disease when used in conjunction with gASCA IgG, ALCA IgG, ACCA IgA, Anti-L IgA and AMCA IgG*[9] ***Risk levels** *for aggressive Crohn's disease behavior are based on peer reviewed journals that included markers tested with prospective patient outcomes of disease severity and/or surgery*[2,7,8,9]

Receiver operating characteristic (ROC) curves of the seven anti-glycan markers (Chron's disease vs ulcerative colitis)

Of the 178 CD patients who were sero negative for both gASCA IgG and gASCA IgA, 6.74 % were positive for anti- L and 5.62 % were positive for anti-C.

Previous studies showed that ALCA, ACCA and AMCA identify 44% of ASCA sero negative CD patients[1]



*adopted from: Seow et. al. AJG 2009; 104(6): 1426-1434

Product	Catalog No	Test Size
IBDX gASCA IgG	S701100	8 * 12
IBDX ALCA IgG	L703100	8 * 12
IBDX ACCA IgA	C702100	8 * 12
IBDX AMCA IgG	M704100	8 * 12
IBDX ANTI-L IgA	AL706100	8 * 12

All kits are Quick and Easy to use with short incubation times and ready-to-use reagents.

Also, all our IBDX kits have break-a-well strips allowing high flexibility and economic use.

References

1. Dotan I, Fishman S, Dgani Y, et al. Antibodies against laminariboside and chitobioside are novel serologic markers in Crohn's disease. Gastroenterology. 2006; 131 :366-378.
2. Ferrante M, Liesbet H, Joossens M, et al. New serological markers in inflammatory bowel disease are associated with complicated disease behavior. Gut. 2007; 56: 1394-1403.
3. Papp M, Altorjay I, Dotan Net al. New serological markers for inflammatory bowel disease are associated with earlier age at onset, complicated disease behavior, risk for surgery, and NOD2/CARD15 genotype in a Hungarian IBD cohort. Am J Gastroenterol. 2008;103:665-681.
4. Jaskowski TD, Litwin CM, Hill HR. Analysis of serum antibodies in patients suspected of having inflammatory bowel fisease. Clin Vaccine I mmunol. 2006; 13(6) :655-660.
5. Quinton J-F, Sendid B, Reumaux D, et al. Anti-saccharomyces cerevisiae man nan antibodies combined with antineutrophil cytoplasmic autoantibodies in inflammatory bowel disease: Prevalence and diagnostic role. Gut. 1998;42:788-791
6. Malickova K, Lakatos PL, Bortlik M, Komarek V, Janatkova I, Lukas M. Anticarbohydrate antibodies as markers of inflammatory bowel disease in Central European cohort. Eur J Gastroenterol Hepatol. 201 O; 22(2): 144-150.
7. Rieder F, Schleder S, Wolf A, et al. Association of the novel serologic antiglycan antibodies anti-laminarin and anti-chitin with complicated Crohn's disease behavior. lnflamm Bowel Dis. 2010;16(2):263-274.
8. Rieder F, Schleder S, Wolf A, et al. Serum anti-glycan antibodies predict complicated Crohn's disease behavior: A cohort study. lnflamm Bowel Dis. 2010;16(8): 1367-1375.
9. Seow, Cynthia H, et al. "Novel Anti-Glycan Antibodies Related to Inflammatory Bowel Disease Diagnosis and Phenotype." The American Journal of Gastroenterology 2009; 104(6): 1426-1434.

GLYCOMINDS

www.ibdx.net

CE