A **TECHNICAL** REVIEW

LabCorp
Laboratory Corporation of America

Bowel Disorders Evaluation Rule-out Cascade

Applying exclusionary criteria to assist diagnosis

Disorders of the lower gastrointestinal tract in adults and children are among the most common conditions and may pose a difficult diagnostic problem. Approximately 1 in 20 of all general practitioners' consultations involve these conditions, and their symptoms are often ill-defined.[1] Those disorders include a wide range of pathologic conditions, including irritable bowel syndrome (IBS), inflammatory bowel disease (IBD) that includes Crohn's disease (CD), ulcerative colitis (UC), and indeterminate colitis; microscopic colitis, infectious colitis, small intestinal bacterial overgrowth, celiac disease, and colon neoplasia (including colon cancer).[2]

The most prevalent condition is IBS. It is estimated that, in Europe and North America 10% to 15% of the population is affected.[3] Studies show that the incidence rate of Crohn's disease increased from 0.1 (three decades ago) to 4.6 (in 2003) per 100,000 children, and the incidence of UC from 0.5 to 3.2 per 100,000 children.[4] The prevalence of IBD among adults is approaching 0.3%.[5] Studies have shown that the prevalence of celiac disease increased at least four times during the last 50 years and approaches 1%.[6–8] It is estimated that less than 5% of celiac disease cases in the US are currently diagnosed.[8]

Recently, another condition termed "gluten sensitivity," distinct from celiac disease, emerged as an important and often underdiagnosed and undertreated disease.[8,9] It is reported that as much as 12% of the healthy population may have serological evidence of gluten sensitivity.[9]

Difficulties in differential diagnosis of those conditions often prompt clinicians to use an exclusion approach by performing tests to rule out the alternative etiologies.[2] Interestingly, one study shows that most of the celiac disease serological test requests now come from general practitioners rather than gastroenterologists.[10] Another study reports that 72% of general practitioners endorsed IBS as a diagnosis of exclusion.[2] The "gold standard" for diagnosing many of these conditions continues to be endoscopy with biopsies for histological examination.[11] In recent years, however, the introduction of a number of tests for new serological markers may allow for reduction in the number of intestinal biopsies.[12]

To assist clinicians — through the use of exclusionary criteria — in diagnosing bowel disorders, LabCorp has introduced the **Bowel Disorders Evaluation Rule-out Cascade.** (This profile is intended to be used only in conjunction with other clinical and laboratory findings as an aid in diagnosis.)

Bowel Disorders Cascade

STEP 1: Celiac Disease Screen

The cascade begins with a celiac screen that includes simultaneous detection of both IgA and IgG antibodies to both deamidated gliadin peptide (DGP) and human tissue transglutaminase (tTG). The screen performance is reported to achieve a clinical sensitivity of 98.6% and specificity of 97.0% for patients with celiac disease or controls.[12] When the result is positive, testing stops and the interpretive comment on the report would read:

> **Suggestive of celiac disease or other gluten-sensitive enteropathies. Subsequent testing for Endomysial Antibody, IgA (164996) and/or genetic testing for Celiac Disease HLA DQ Association (167082) may be indicated for further patient evaluation.**

The Celiac Disease Screen may be negative if the patient is on a gluten-free diet because antibodies to tTG and DGP are usually no longer present.[12,13] A gluten challenge would be necessary to avoid false-negative results. Genetic testing for HLA DQ2/DQ8 may be considered if the patient does not wish to undergo a gluten challenge. A negative genetic test result effectively rules out celiac disease.[13,14] A positive genetic test result increases suspicion of celiac disease but is not diagnostic. A positive endomysial antibody test is highly specific for celiac disease. **When the result is negative, then testing reflexes to the second step.**

STEP 2: Inflammatory Bowel Disease (IBD) Screen

Inflammatory bowel disease screen includes testing for IgG antibodies to anti-*Saccharomyces cerevisiae* (ASCA), and atypical perinuclear antineutrophil cytoplasmic antibodies (pANCA). This panel of tests will aid in serological identification of patients with IBD and in differentiation between its three clinical forms: CD, UC, and indeterminate colitis. When the marker of CD (ASCA IgG) is positive, the clinical sensitivity for CD is reported to as high as 74.4% and specificity for IBD generally is reported to be as high as 95.9%.[15] When atypical pANCA (a marker of UC) is positive, the clinical sensitivity for UC is reported to be as high as 70% and the specificity as high as 80%.[16] The results of the ASCA and pANCA markers cannot rule out inflammatory bowel disease; neither can their presence strictly confirm its diagnosis.[17]

Testing for step two is described below and the interpretive comment on the report would be one of the following (depending on the combination of results): When ASCA IgG is positive and atypical pANCA is negative, testing stops and the comment would read:

Suggestive of Crohn's disease. Subsequent testing with the Crohn's Disease Prognostic Profile (162020) that includes antiglycan antibodies AMCA, ALCA, ACCA, and gASCA may aid in the differentiation of clinical forms of CD and prognosis of disease progression.

When ASCA IgG is negative or equivocal and atypical pANCA is positive testing stops and the comment would read:

Suggestive of ulcerative colitis.

When both, ASCA IgG and atypical pANCA, are positive testing stops and the comment would read:

Suggestive of IBD. Subsequent testing with the Crohn's Disease Prognostic Profile (162020) that includes antiglycan antibodies AMCA, ALCA, ACCA, and gASCA may aid in the differentiation of clinical forms of IBD and prognosis of disease progression.

When all results are negative, testing reflexes to the third step.

STEP 3: Nonceliac Gluten Sensitivity Screen

The nonceliac gluten sensitivity screen includes testing for IgG antibodies to native gliadin with reported clinical sensitivity of up to 87% (for untreated clinically defined celiac disease patients) and specificity of up to 91%.[18] Recent reports show that there is a significant subset of patients that has normal histology for celiac disease, negative for antibodies to DGP and tTG, positive for antigliadin antibodies and clinically undistinguishable from those with celiac disease. Those patients constitute the so-called nonceliac "gluten sensitivity" group and many of them will benefit from gluten-free diet. This group of patients is also reported to have increased mortality.[8] When the result is positive, the testing stops and the interpretive comment on the report would read:

Suggestive of nonceliac gluten sensitivity. The patient may benefit from a gluten-free diet.

When all results are negative, the testing stops and the interpretive comment on the report would read:

Suggestive of irritable bowel syndrome (IBS). Careful evaluation of the patient's history, physical examination, and application of Rome III diagnostic criteria may help to rule in or rule out the diagnosis of IBS. Subsequent testing for Fecal Calprotectin (123255) may be recommended. If IBD is strongly suspected, subsequent testing with the Crohn's Disease Prognostic Profile (162020) that includes antiglycan antibodies AMCA, ALCA, ACCA, and gASCA may aid in differential diagnosis.

References

1. Rubin G, De Wit N, Meineche-Schmidt V, et al. The diagnosis of IBS in primary care: Consensus development using nominal group technique. *Family Prac.* 2006;.23:687-692.
2. Spiegel BMR. Do physicians follow evidence-based guidelines in the diagnostic work-up of IBS? *Nature Clinical Practice. Gastroenterology Hepatology.* 2007 Jun; 4(6):296-297.
3. World Gastroenterology Organization Global Guideline. *Irritable Bowel Syndrome: A Global Perspective*. April 20, 2009.
4. IBD Working Group of the European Society for Paediatric Gastroenterology, Hepatology, and Nutrition. Inflammatory bowel disease in children and adolescents: Recommendations for diagnosis—The Porto Criteria. *J Pediatric Gastroenterol Nutr.* 2005 Jul; 41(1):1-7.
5. Carter MJ, Lobo AJ, Travis SPL, on behalf of the IBD Section of the British Society of Gastroenterology. Guidelines for the management of inflammatory bowel disease in adults. *Gut.* 2004; 53(Suppl V):v1-v16.
6. Celiac Disease News. Available at: http://www.celiac.nih.gov/NewsletterSpring09.aspx. Accessed August 24, 2009.
7. Green PHR, Cellier C. Celiac disease. *N Engl J Med.* 2007 Oct 25; 357(17):1731-1743.
8. Green PHR. Mortality in celiac disease, intestinal inflammation, and gluten sensitivity. *JAMA.* 2009 Sep 16; 302(11):1225-1226.
9. Hadjivassiliou M, Grünewald RA, Kandler RH, et al. Neuropathy associated with gluten sensitivity. *J Neurol Neurosurg Psychiatry.* 2006; 77:1262-1266.
10. Evans K, Malloy AR, Gorard DA. Changing patterns of coeliac serology requests. *Alimentary Pharmacology & Therapeutics*. http://www.medscape.com/viewarticle/703618_print. Accessed October 16, 2009.
11. Ferrante M, Henckaerts L, Joossens M, et al. New serological markers in inflammatory bowel disease are associated with complicated disease behavior. *Gut.* 2007; 56:1394-1403.
12. INOVA Diagnostics Inc. *QUANTA Lite™ h-tTG/DGP Screen*. April 2007. Revision 0.
13. Snyder CL, Young DO, Green PHR, Taylor AK. Celiac disease. *GeneReviews.* Available at: www.genetests.org. Accessed March 16, 2011.
14. Sollid LM, Lie BA. Celiac disease genetics: Current concepts and practical applications. *Clin Gastroenterol Hepatol.* 2005; 3(9):843-851.
15. INOVA Diagnostics Inc. *Quanta Lite™ ASCA (S* cerevisiae*) IgG*. May 2005. Revision USA7.
16. Jaskowski TD, Litwin CM, Hill HR. Analysis of serum antibodies in patients suspected of having inflammatory bowel disease. *Clin Vaccine Immunol.* 2006 Jun; 13(6):655-660.
17. Papp M, Norman GL, Altorjay I, Lakatos PL. Utility of serological markers in inflammatory bowel diseases: Gadget or magic? *World J Gastroenterol.* 2007 Apr 14; 13(14):2028-2036.
18. INOVA Diagnostics Inc. *Quanta Lite™ Gliadin IgG.* April 2005. Revision USA11.

Additional Related Studies

Ball AJ, Hadjivassiliou M, Sanders DS. Is gluten sensitivity a "No Man's Land" or a "Fertile Crescent" for Research? *Am J Gastroenterol.* 2010 Jan; 105:222-223.
Ford R. Which serological tests best identify gluten reactions? Available at: http://www.drrodneyford.com.
Wangen S. Testing for non-celiac gluten intolerance. Available at: http://www.IBSTreatmentCenter.com. Accessed August 27, 2010.

STEP1 Celiac Disease Screen (Simultaneous Detection of tTG and DGP IgG/IgA)

Prevalence: Up to 1%	Clinical Sensitivity: 98.6%	Clinical Specificity: Up to 97%

- **<20 units** → (continue to Step 2)
- **≥ 20 units** → Stop → Suggestive of celiac disease or other gluten-sensitive enteropathies. Subsequent testing for Endomysial Antibody, IgA (164996) and/or genetic testing for Celiac Disease HLA DQ Association (167082) may be indicated for further patient evaluation.

STEP 2 Inflammatory Bowel Disease (IBD) Screen (ASCA IgG, Atypical pANCA)

Prevalence: Up to 0.3%	Clinical Sensitivity	Clinical Specificity
	ASCA IgG (CD): Up to 74.4%	ASCA IgG (IBD): Up to 95.9%
	Atypical pANCA: Up to 70% (Differential diagnosis of UC)	ASCA IgG: Up to 80% (Differential diagnosis of UC)

- **All Negative** → (continue to Step 3)
- **ASCA IgG: ≥25 units Atypical pANCA: Negative** → Stop → Suggestive of Crohn's disease. Subsequent testing with the Crohn's Disease Prognostic Profile (162020) that includes antiglycan antibodies AMCA, ALCA, ACCA, and gASCA may aid in the differentiation of clinical forms of CD and prognosis of disease progression.
- **ASCA IgG: <25 units Atypical pANCA: Positive** → Stop → Suggestive of ulcerative colitis.
- **ASCA IgG: ≥25 units Atypical pANCA: Positive** → Stop → Suggestive of IBD. Subsequent testing with the Crohn's Disease Prognostic Profile (162020) that includes antiglycan antibodies AMCA, ALCA, ACCA, and gASCA may aid in the differentiation of clinical forms of IBD and prognosis of disease progression.

STEP 3 Nonceliac Gluten Sensitivity Screen (Antigliadin IgG)

Prevalence: Up to 12%	Clinical Sensitivity: Up to 87%	Clinical Specificity: Up to 91%

- **<20 units** → Stop → Suggestive of irritable bowel syndrome (IBS). Careful evaluation of the patient's history, physical examination, and application of Rome III diagnostic criteria may help to rule in or rule out the diagnosis of IBS. Subsequent testing for Fecal Calprotectin (123255) may be recommended. If IBD is strongly suspected, subsequent testing with the Crohn's Disease Prognostic Profile (162020) that includes antiglycan antibodies AMCA, ALCA, ACCA, and gASCA may aid in differential diagnosis.
- **≥20 units** → Stop → Suggestive on nonceliac gluten sensitivity. The patient may benefit from a gluten-free diet.

Note: Biopsy with histological evaluation remains the "gold standard" for the diagnosis of many bowel disorders.[11]

Relevant Assays

Test Name	Test Number
Bowel Disorders Evaluation Rule-out Cascade	164085
Calprotectin, Fecal	123255
Celiac Disease HLA DQ Association	167082
Crohn's Disease Prognostic Profile	162020
Endomysial Antibody, IgA	164996

For the most current information regarding test options, including specimen requirements and CPT codes, please consult the online Test Menu at **www.LabCorp.com.**

labcorp

Use a keyword, test name or number

Inflammatory Bowel Disease (IBD) Expanded Profile

TEST: 162045 CPT: 83516(x3); 86036; 86671

Synonyms	• Atypical pANCA • Glycominds • IBDX
Test Includes	Antichitobioside carbohydrate antibodies (ACCA); antilaminaribioside carbohydrate antibodies (ALCA); antimannobioside carbohydrate antibodies (AMCA); anti-*Saccharomyces cerevisiae* antibodies (gASCA); atypical perinuclear antineutrophil cytoplasmic antibody (pANCA).
Expected Turnaround Time	4 - 7 days Turnaround time is defined as the usual number of days from the date of pickup of a specimen for testing to when the result is released to the ordering provider. In some cases, additional time should be allowed for additional confirmatory or additional reflex tests. Testing schedules may vary.
Related Information	• Inflammatory Bowel Disease (IBD) Profile
Related Documents	For more information, please view the literature below.

Bowel Disorders Evaluation Rule-out Cascade: Applying Exclusionary Criteria to Assist Diagnosis

Crohn's Disease Prognostic Serological Marker Profile

Inflammatory Bowel Disease Expanded Profile

- Sample Report

SPECIMEN REQUIREMENTS

Specimen	Serum
Volume	1 mL
Minimum Volume	0.5 mL
Container	Red-top tube or gel-barrier tube
Storage Instructions	Refrigerate
Causes for Rejection	Hemolysis; lipemia; heat-treated specimen; gross bacterial contamination

TEST DETAILS

Use	Aids in the diagnosis of inflammatory bowel disease (IBD) and the differential diagnosis of Crohn's disease (CD) and ulcerative colitis (UC); prognostic aid for clinical management of patients with CD.
Limitations	Results of this panel should be used in conjunction with clinical findings and other laboratory tests.
Methodology	Enzyme immunoassay (EIA) for ACCA, ALCA, AMCA, gASCA; indirect fluorescent antibody (IFA) for atypical pANCA
Reference Interval	When the only positive marker is pANCA, the interpretive comment on the report will read: "Suggestive of ulcerative colitis."

When only one of ACCA, ALCA, AMCA, or gASCA is positive and pANCA is negative, the interpretive comment will read: "Suggestive of Crohn's disease. Pattern is not conclusive for disease behavior risk stratification."

When only one of ACCA, ALCA, AMCA, or gASCA is positive and pANCA is positive, the interpretive comment will read: "Suggestive of inflammatory bowel disease. Pattern is not conclusive for any specific disease form."

When any two of ACCA, ALCA, AMCA, or gASCA are positive and pANCA is positive or negative, the interpretive comment will read: "Suggestive of Crohn's disease with high risk of aggressive disease behavior (development of strictures or fistulae)."

When any three or more of ACCA, ALCA, AMCA, or gASCA are positive and pANCA is positive or negative, the interpretive comment will read: "Suggestive of Crohn's disease with the very high risk of aggressive disease behavior (development of strictures or fistulae)."

When all markers are negative, the interpretive comment on the report will read: "Pattern is not suggestive of inflammatory bowel disease."

Additional Information

Inflammatory bowel disease is a chronic disorder of the lower gastrointestinal tract that may occur in three forms: Crohn's disease (CD), ulcerative colitis (UC), and indeterminate colitis (IC). Its prevalence in the adult population approaches 0.3%.[1] The differential diagnosis of the different forms of IBD is often difficult, time-consuming, and invasive.[2] The gold standard for diagnosis is endoscopy with biopsies for histologic examination.[3] In recent years, however, a number of serological markers have been introduced. The most commonly employed serological markers of IBD are anti-*Saccharomyces cerevisiae* antibody (ASCA) and atypical perinuclear antineutrophil cytoplasmic antibody (pANCA). ASCA positivity is found predominantly in patients with CD, while pANCA positivity is found predominantly in patients with UC.[2] A combination of ASCA and pANCA has a specificity of as high as 99% for differentiation of CD from UC.[3] Nevertheless, there are a substantial number of patients with IBD who are negative for both. The addition of novel serological markers improves the sensitivity of the conventional ASCA/pANCA combination.[3]

About two-thirds of patients with CD develop either a stricturing or penetrating disease course within 10 years after diagnosis. As many as 80% of all CD patients undergo surgery at least once during the course of their disease. Consequently, the identification of individuals susceptible to the development of more complicated disease behavior would allow for earlier and more aggressive treatment.[4]

This profile offers three novel markers: antichitobioside IgA (ACCA), antilaminaribioside IgG (ALCA), antimannobioside IgG (AMCA), together with anti-*Saccharomyces cerevisiae* IgG (gASCA) and pANCA. These markers provide additional diagnostic and prognostic information

depending on the combination of results.[3-6]

The antibodies included in the panel are ASCA (anti-*Saccharomyces cerevisiae* antibodies), ALCA (antilaminaribioside carbohydrate antibodies), ACCA (antichitobioside carbohydrate antibodies), and AMCA (antimannobioside carbohydrate antibodies).[3,5,6] Numerous studies of CD have demonstrated an association between ileal disease and the presence of ACCA,[3] ALCA,[3,6] AMCA,[6] and ASCA.[3,5-10] Among these antibodies, the association with localization to the small intestine increased with the number of positive antibodies and with the concentration of individual antibodies.[3,5,6,9,11] A more aggressive or complicated disease course in CD (as indicated by stricturing or perforation of the intestine or need for surgery), has also been associated with the presence of ACCA,[3,5] ALCA,[3,5,6] AMCA,[3,5] and ASCA.[3,5,6,8-10] Among these antibodies, the association with complicated disease behavior or surgery increased with the number and concentration of antibodies.[3,5,9,11]

Footnotes

1. Carter M, Lobo AJ, Travis SP; IBD Section, British Society of Gastroenterology. Guidelines for the management of inflammatory bowel disease in adults. *Gut.* 2004; 53(Suppl 5):V1-16. PubMed 15306569

2. Jaskowski TD, Litwin CM, Hill HR. Analysis of serum antibodies in patients suspected of having inflammatory bowel disease. *Clin Vaccine Immunol.* 2006; 13(6):655-660. PubMed 16760323

3. Ferrante M, Henckaerts L, Joossens M, et al. New serological markers in inflammatory bowel disease are associated with complicated disease behavior. *Gut.* 2007; 56(10):1394-1403. PubMed 17456509

4. Rieder F, Schleder S, Wolf A, et al. Serum anti-glycan antibodies predict complicated Crohn's disease behavior: A cohort study. *Inflamm Bowel Dis.* 2010; 16(8):1367-1375.

5. Papp M, Altorjay I, Dotan N, et 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(3):665-681. PubMed 17478404

6. Dotan I, Fishman S, Dgani Y, et al. Antibodies against laminaribioside and chitobioside are novel serologic markers in Crohn's disease. *Gastroenterology.* 2006; 131(2):366-378. PubMed 16890590

7. Vasiliauskas EA, Plevy SE, Landers CJ, et al. Perinuclear antineutrophil cytoplasmic antibodies in patients with Crohn's disease define a clinical subgroup. *Gastroenterology.* 1996; 110(6):1810-1819. PubMed 8964407

8. Vasiliauskas EA, Kam LY, Karp LC, et al. Marker antibody expression stratifies Crohn's disease into immunologically homogeneous subgroups with distinct clinical characteristics. *Gut.* 2000; 47(4):487-496. PubMed 10986208

9. Arnott ID, Landers CJ, Nimmo EJ, et al. Sero-reactivity to microbial components in Crohn's disease Is associated with disease severity and progression, but not NOD2/CARD15 genotype. *Am J Gastroenterol.* 2004; 99(12):2376-2384. PubMed 15571586

10. Walker LJ, Aldhous MC, Drummond HE, et al. Anti-*Saccharomyces cerevisiae* antibodies (ASCA), in Crohn's disease are associated with disease severity but not NOD2/CARD15 mutations. *Clin Exp Immuno.* 2004; 135(3):490-496. PubMed 15008984
11. Mow WS, Vasiliauskas EA, Lin YC, et al. Association of antibody responses to microbial antigens and complications of small bowel Crohn's disease. *Gastroenterology.* 2004; 126(2):414-424. PubMed 14762777

LabCorp
Laboratory Corporation of America

Patient Report

Specimen ID: 052-988-3235-0
Control ID:

SAMPLE REPORT, 162045

Acct #: 90000999 **Phone:** (336) 436-8645 **Rte:** 00
LabCorp Test Master
Test Account
3060 South Church Street
Burlington NC 27215

Patient Details
DOB: 01/10/1980
Age(y/m/d): 037/01/11
Gender: F **SSN:**
Patient ID:

Specimen Details
Date collected: 02/21/2017 0000 Local
Date entered: 02/21/2017
Date reported: 00/00/0000 0000 ET

Physician Details
Ordering:
Referring:
ID:
NPI:

General Comments & Additional Information
Clinical Info: NORMAL REPORT

Ordered Items
IBD Expanded Panel

TESTS	RESULT	FLAG	UNITS	REFERENCE INTERVAL	LAB
IBD Expanded Panel					
gASCA	10		units	0 - 50	01
			Negative	<45	
			Equivocal	45 - 50	
			Positive	>50	
ACCA	32		units	0 - 90	01
			Negative	<80	
			Equivocal	80 - 90	
			Positive	>90	
ALCA	23		units	0 - 60	01
			Negative	<55	
			Equivocal	55 - 60	
			Positive	>60	
AMCA	23		units	0 - 100	01
			Negative	< 90	
			Equivocal	90 - 100	
			Positive	>100	
	This test was developed and its performance characteristics determined by LabCorp. It has not been cleared or approved by the Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary.				
Atypical pANCA	Negative		Negative		01
Comments					
Pattern is not suggestive of Inflammatory Bowel Disease					

01 BN LabCorp Burlington
1447 York Court, Burlington, NC 27215-3361
Dir: William F Hancock, MD

For inquiries, the physician may contact **Branch: 800-222-7566 Lab: 336-436-2762**

LabCorp
Laboratory Corporation of America

Patient Report

Specimen ID: 052-988-3236-0
Control ID:

SAMPLE REPORT, 162045

Acct #: 90000999 **Phone:** (336) 436-8645 **Rte:** 00
LabCorp Test Master
Test Account
3060 South Church Street
Burlington NC 27215

Patient Details
DOB: 01/10/1980
Age(y/m/d): 037/01/11
Gender: F **SSN:**
Patient ID:

Specimen Details
Date collected: 02/21/2017 0000 Local
Date entered: 02/21/2017
Date reported: 00/00/0000 0000 ET

Physician Details
Ordering:
Referring:
ID:
NPI:

General Comments & Additional Information
Clinical Info: ABNORMAL REPORT

Ordered Items
IBD Expanded Panel

TESTS	RESULT	FLAG	UNITS	REFERENCE INTERVAL	LAB
IBD Expanded Panel					
gASCA	**87**	**High**	units	0 - 50	01
			Negative	**<45**	
			Equivocal	**45 - 50**	
			Positive	**>50**	
ACCA	**112**	**High**	units	0 - 90	01
			Negative	**<80**	
			Equivocal	**80 - 90**	
			Positive	**>90**	
ALCA	**88**	**High**	units	0 - 60	01
			Negative	**<55**	
			Equivocal	**55 - 60**	
			Positive	**>60**	
AMCA	**284**	**High**	units	0 - 100	01
			Negative	**< 90**	
			Equivocal	**90 - 100**	
			Positive	**>100**	
This test was developed and its performance characteristics determined by LabCorp. It has not been cleared or approved by the Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary.					
Atypical pANCA	1:160			Negative	01
Comments	Performed				

01 BN LabCorp Burlington
1447 York Court, Burlington, NC 27215-3361
Dir: William F Hancock, MD

For inquiries, the physician may contact **Branch: 800-222-7566 Lab: 336-436-2762**