



## Fecal ASCA Measurements in the Assessment of Pediatric Patients with Crohn's Disease (CD) or Suspected Inflammatory Bowel Disease (IBD)

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### Introduction

- Non-invasive biomarkers are being explored for use in the diagnosis and interval assessment of patients with Inflammatory Bowel Disease (IBD).
- Previous studies have demonstrated that serum anti-*Saccharomyces cerevisiae* antibodies (ASCA) can be measured in 40-60% of adult and pediatric patients with Crohn's disease (CD).
- Elevated serum ASCA titers are found in less than 5% of patients with ulcerative colitis (UC).
- Antibodies are secreted into the gastrointestinal tract via biliary excretion or receptor mediated transport.
- The development of reliable and validated surrogate markers of intestinal inflammation will minimize the need for invasive, uncomfortable, and costly procedures for use in evaluating pediatric and adult patients suspected of having IBD.

Figure 1: Diagnosing IBD in Children: Serologic Markers

Antibody	Antigen	Non-IBD (%)	CD (%)	UC (%)
ASCA	Anti- <i>Saccharomyces cerevisiae</i> antibody	5%	55-65%	5%
DNase Sensitive ANCA	Histone H1, bacterial antigen	<5%	10-25%	50-65%

### Hypothesis

- Measurement of fecal IgG and IgA ASCA antibody levels are useful in the assessment of pediatric patients with symptoms of IBD.

### Goals

- Assess for the presence of elevated fecal ASCA titers in pediatric patients with known CD or suspected IBD.

### Methods

- The study population included 104 subjects (72 male and 32 female) ages 2-18 years (mean = 12.9 years)
- 87 Subjects had CD, and 17 had UC.
- 16 healthy pediatric controls also provided samples.
- Patients were identified and recruited from ambulatory clinics, the endoscopy suite, and inpatient units.
- Fecal samples were collected at the time of enrollment or sent by overnight courier. Matched serum samples were collected at the next clinical blood draw.
- Fecal samples were diluted 1:10 and analyzed using a qualitative ASCA ELISA immunoassay ASCA-CHEK® (TechLab, Blacksburg, VA). A spectrophotometer using an optical density of 450 nm was employed and results  $\geq 0.150$  were considered positive.
- All results were reported blinded to a subject's diagnosis.

### Study Design

- Inpatient Criteria**
  - Pediatric patients (age  $\leq 18$  years of age) with an existing diagnosis of Crohn's disease
  - Newly presenting pediatric patients with a clinical history that suggests a diagnosis of IBD
- Exclusion Criteria**
  - Hepatitis B, C, or HIV
  - Recent documented enteric infection

### Preliminary Results

Figure 2: Study Population

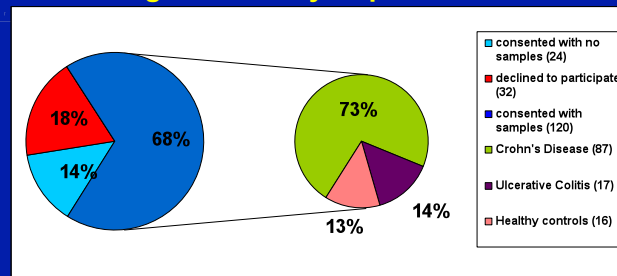


Figure 3: Sensitivity and Specificity of Fecal ASCA in Pediatric Patients with Crohn's Disease

		Crohn's Disease	
		Present	Absent
ASCA	Pos	45	8
	Neg	42	25

- Sensitivity for CD:  $45/87 = 52\%$
- Specificity for CD:  $25/33 = 76\%$

Figure 4: Fecal ASCA When Assessed by Disease Location

	Ileum Only/Normal Colon	Colon Only/Normal Ileum	Ileum & Cecum/Normal Colon	Ileal & Colonic Disease
Sensitivity	71%	54%	71%	43%
Specificity	58%	58%	58%	55%

### Preliminary Conclusions

- ASCA antibodies can be detected in the stool of pediatric patients with Crohn's disease.
- Fecal ASCA positivity appears to be more sensitive in individuals with ileal disease.
- Fecal ASCA testing offers the advantage of being inexpensive and noninvasive.
- When coupled with other diagnostic assays, such as those for fecal lactoferrin, fecal ASCA may prove clinically useful for the assessment of pediatric patients suspected of having IBD.

