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PROMETHEUS
 Therapeutics & Diagnostics

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PROMETHEUS[®] IBD sgi Diagnostic



Sample ID: SN10310718 Collection Date: 10/30/2012 10:30AM (Serum) Institution Sample ID:
 Sample ID: SN10310719 Collection Date: 10/30/2012 10:30AM (Whole Blood) Institution Sample ID:

- Pattern Consistent with IBD**
 - Crohn's Disease**
 - Ulcerative Colitis
 - Inconclusive for Crohn's Disease vs. Ulcerative Colitis^a
- Pattern Not Consistent with IBD

General Test Information

- Patient test results are based on the Smart Diagnostic Algorithm which interprets complex patterns among assay values from a combination of serologic, genetic, and inflammatory markers
- The test was developed using 1,520 samples from well-characterized IBD patients and non-IBD disease and healthy controls

Serology Results

Genetics Results

Inflammation Results

Assay	Result	Reference	Assay	Result	Reference	Assay	Result	Reference
ASCA IgA ELISA	4.9 EU/ml	< 8.5 EU/ml	ATG16L1 SNP (rs2241880)	No Mutation Detected	No Mutation Detected	ICAM-1	0.40 ug/ml	< 0.54 ug/ml
ASCA IgG ELISA	< 3.1 EU/ml	< 17.8 EU/ml	ECM1 SNP (rs3737240)	No Mutation Detected	No Mutation Detected	VCAM-1	0.54 ug/ml	< 0.68 ug/ml
Anti-OmpC IgA ELISA	55.8 EU/ml	< 10.9 EU/ml	NOD2-3 SNP (rs10863365)	Mutation Detected - Heterozygous A/G	No Mutation Detected	VEGF	215 pg/ml	< 345 pg/ml
Anti-CEI1 IgG ELISA	88.3 EU/ml	< 78.4 EU/ml	STAT3 SNP (rs744166)	No Mutation Detected	Mutation Detected	CRP	82.9 mg/L	< 13.2 mg/L
Anti-A4-Fla2 IgG ELISA	> 100.0 EU/ml	< 44.8 EU/ml				SAA	> 181.6 mg/L	< 10.9 mg/L
Anti-FlaX IgG ELISA	83.8 EU/ml	< 33.4 EU/ml						
IBD-specific pANCA Autoantibody ELISA	37.8 EU/ml	< 19.8 EU/ml						
IFA Perinuclear Pattern	Detected	Not Detected						
DNAse Sensitivity	DNAse Sensitive	Not Detected						

Overall performance of PROMETHEUS IBD sgi Diagnostic: Sensitivity IBD 74%, CD 80%, UC 86%; Specificity IBD 90%, CD 81%, UC 84%. Smart Diagnostic Algorithm technology was trained (n=1083; 30% CD, 21% UC, 29% disease controls, and 11% healthy controls) and validated (n=437; 35% CD, 25% UC, 28% disease controls, and 14% healthy controls) from results of serology, genetic, and inflammation assays.

A test result is the product of a collective evaluation of all individual assays by a complex algorithm. From this, it is possible to produce a result of "Pattern Not Consistent with IBD" when one or more assay values are above the specified reference value. It is also possible to produce a result of "Pattern Consistent with IBD" when all individual assay values are below the specified reference value. Reference values have been calculated based on a population of non-IBD controls.

^aPatient samples exhibiting a pattern consistent with IBD but not conclusive for a Crohn's Disease or Ulcerative Colitis pattern determination.

References available on request.

Prometheus diagnostic services provide important information to aid in the diagnosis and management of certain diseases. Test results should be used with other clinical and diagnostic findings to make a diagnosis. This test was developed and its performance characteristics determined by Prometheus Laboratories Inc. It has not been cleared or approved by the U.S. Food and Drug Administration. This test may be covered by one or more US pending or issued patents - see prometheusibd.com for details.

Curtis A. McGuyer MD Medical Director

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TR155_0

EXAM

CT AP Abdomen / Pelvis W Contrast

Report

Indication: Change in bowel habits, rectal bleeding, anemia

Exam: CT Abdomen and Pelvis as per enterography protocol

Technique: Following oral administration of 1200 cc Volumen and 600 cc H₂O per rectum, contiguous axial 2.5 mm images were obtained from the lung bases through the proximal femurs with IV contrast. Coronal reformations were performed. 3-D coronal MIP images were performed on a separate workstation.

100 cc Isovue-300 nonionic contrast was administered intravenously without incident.

Comparison: CT pelvis dated 5/20/2009

Findings:

There are multiple circumscribed hypodensities scattered throughout the liver, with largest measuring 9 mm, consistent with cysts. There is a 1.2 cm hypodense cortically-based cyst in the left mid kidney laterally as well. Otherwise, the liver, kidneys, adrenal glands, spleen, and pancreas are normal. Two calcified gallstones layer dependently.

The distal esophagus is decompressed. Stomach and duodenum are normal. Anterior to the lower pole left kidney, best seen on images 166 through 188, there is jejunojejunal intussusception. Otherwise, small bowel loops are normal. Evaluation the colon is limited secondary to retained stool diffusely. There is mild diffuse colonic wall thickening, predominantly involving the transverse, descending, and sigmoid portions of the colon. Correlate clinically for colitis. There is a tiny amount of fluid in the right paracolic gutter and slight hazy induration of the fat surrounding the descending colon. There appears to be a rectal suture anastomosis, in the region of the rectal tube balloon.

Urinary bladder is normal. Several subcentimeter short axis right lower quadrant mesenteric lymph nodes are noted. No bulky adenopathy. There is mild left and moderate right SI joint sclerosis, predominately involving the right iliac bone, and subchondral erosions consistent with sacroiliitis. The patient has a history of ankylosing spondylitis.

Impression:

1. Mild diffuse colonic wall thickening suggests colitis.
2. A proximal jejunojejunal intussusception is noted. No definite lead point.
3. Multiple tiny hypodense hepatic cysts.
4. Bilateral sacroiliitis, right side worse than left.

DICTATED BY: Jason D Hamilton MD

Electronic Signature

Signed D/T: 02-NOV-2012 11:18 am

Transcribed D/T: 02-NOV-2012 11:04 am