SEND OUTS Please Note: Not all test codes assigned to each assay are listed in the table of contents. Please refer to the complete listing on the page numbers indicated.				
Test Code	**Former Test Code**	**Test Name**	**Effective Date**	**Page #**
A52588		Corticosteroid Binding Globulin (CBG)	12/31/2013	1
S52567		**Prometheus® IBD sgi Diagnostic**	1/3/2014	1

Due to these assays being performed by outside vendors, we are unable to use our normal method of communication. Some of the changes listed in this document may be effective in less than 30 days. Please note the individual effective dates below, as these changes may require **IMMEDIATE ACTION.**

Test Send Out (Referrals)

The following test changes will be effective on the dates indicated below. **Please note that only the information that is changing appears in this update.** *Former test names and test codes have been italicized*.

Corticosteroid Binding Globulin (CBG)	
Effective Date	**12/31/2013**
Test Code	A52588
Additional Information	This test is discontinued. The recommended alternative is S51344 -Cortisol Binding Globulin (Transcortin) performed at Quest Diagnostics Nichols Institute, San Juan Capistrano.

Prometheus® IBD sgi Diagnostic	
Message	***This test is **now available** for New York patient testing***
Effective Date	**1/3/2014**
Former Test Name	*IBD SGI Diagnostic*
Test Code	S52567
Specimen Requirements	**2 mL (1 mL minimum) serum collected in red-top (no gel) tube AND whole blood collected in an EDTA (lavender-top) tube**
Specimen Stability	**Room temperature: 7 days** **Refrigerated: 21 days** **Frozen: Unacceptable**
Set-up/Analytic Time	**Set up: Mon-Fri; Report available: 3-4 days**
Reference Range	

Draw Date:	
Draw Time:	
IBD:	No Reference Range available
Crohn's Disease:	No Reference Range available
Ulcerative Colitis:	No Reference Range available
Inconclusive for CDvsUC(a):	No Reference Range available
ASCA IgA ELISA:	<8.5 EU/ml
ASCA IgG ELISA:	<17.8 EU/ml

Anti-OmpC IgA ELISA:	<10.9 EU/ml
Anti-CBir1 IgG ELISA:	<78.4 EU/ml
Anti-A4-Fla2 IgG ELISA:	<44.8 EU/ml
Anti-FlaX IgG ELISA:	<33.4 EU/ml
IBD-spec pANCA AutoAbELISA:	<19.8 EU/ml
IFA Perinuclear Pattern:	Not Detected
DNAse Sensitivity:	Not Detected
ATG16L1 SNP (rs2241880):	**Variant Not Detected: rs2241880(A;A)**
ECM1 SNP (rs3737240):	**Variant Not Detected: rs3737240(C;C)**
NKX2-3 SNP (rs10883365):	**Variant Not Detected: rs10883365(A;A)**
STAT3 SNP (rs744166):	**Variant Detected: rs744166(G;G)**
ICAM-1:	<0.54 ug/ml
VCAM-1:	<0.68 ug/ml
VEGF:	<345 pg/ml
CRP:	<13.2 mg/L
SAA:	<10.9 mg/L

Always Message

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.

Overall performance of PROMETHEUS IBD sgi Diagnostic Sensitivity IBD 74%, CD 89%, UC 98%; Specificity IBD 90%, CD 81%, **UC 84%**. Smart Diagnostic Algorithm technology was trained (n=1083; 39% CD, 21% UC, 29% disease controls, and 11% healthy controls) and validated (n=437; 35% CD, 23% 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.

(a) Patient samples exhibiting a pattern consistent with IBD but not conclusive for a Crohn's Disease or Ulcerative Colitis pattern determination.
References available upon 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. **Prometheus recommends that patients seek appropriate genetic counseling to explain the implications of genetic test results.** This test may be covered by one or more US pending or issued patents - see prometheuslabs.com for details.