SmartGut™ Test Report

Report Date November 14, 2017
Report Type Final

Ordering Provider		Patient		Sample	
Physician	[redacted]	Patient	[redacted]	Type	Swab
City, State		DOB		Source	Fecal
Phone		Age		Collected	
NPI		Gender		Received	
		Patient ID		Report ID	[redacted]

Summary & Interpretation

Please Note: Detecting a microorganism by this test does not imply having a disease. Similarly, not detecting a microorganism by this test does not exclude the presence of a disease-causing microorganism. Further, other organisms may be present that are not detected by this test. This test is not a substitute for established methods for identifying microorganisms or their antimicrobial susceptibility profile. Please consult your medical professional.

Comments

No comments for this report.

Diversity Score	Compared to a healthy reference range, your diversity score is	Normal

Pathogens	Positive: 0 of 3 species, 0 of 2 genera	
Pathogenic Species	*Clostridium difficile*	Negative
	Salmonella enterica	Negative
	Vibrio cholerae	Negative
Pathogenic Genera	*Campylobacter*	Negative
	Escherichia-Shigella	Negative

Organisms Outside Healthy Reference Range	
Akkermansia muciniphila	Low
Anaerotruncus colihominis	Low
Butyrivibrio crossotus	Low
Ruminococcus albus	Low

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Definitions

The reference range for each organism and the microbial diversity score was established using 897 samples from self-reported healthy individuals. For more information about the healthy cohort, go to http://ubiome.com/gutpaper for the publication explaining uBiome's methods underlying this test. The microbial diversity score is a measure of the microorganism richness, evenness and distinctness in the sample.

For these conditions:

- Diarrhea
- Irritable Bowel Syndrome
- Inflammatory Bowel Disease
- Crohn's Disease
- Ulcerative Colitis
- Constipation
- Abdominal Tenderness
- Bloating
- Flatulence
- Obesity
- Type II Diabetes
- Prediabetes
- Kidney Stones

A microorganism is either:

Associated	These microorganisms have an observed association with the condition in the scientific literature
Inversely Associated	These microorganisms are found to be less abundant in people who have this condition in the scientific literature

For these microorganisms:

- *Bacteroides fragilis*
- *Campylobacter*
- *Clostridium*
- *Clostridium difficile*
- *Desulfovibrio piger*
- *Escherichia-Shigella*
- *Fusobacterium*
- *Ruminococcus*
- *Salmonella enterica*
- *Veillonella*
- *Vibrio cholerae*

Results are displayed as:

● Positive	Microorganism in the sample exceeds the upper 99th percentile of the reference range
○ Negative	Microorganism in the sample is within the 99th percentile of the reference range

For the diversity score and the following microorganisms:

- *Akkermansia muciniphila*
- *Alistipes*
- *Anaerotruncus colihominis*
- *Barnesiella*
- *Bifidobacterium*
- *Butyrivibrio crossotus*
- *Collinsella aerofaciens*
- *Dialister invisus*
- *Lactobacillus*
- *Methanobrevibacter smithii*
- *Odoribacter*
- *Oxalobacter formigenes*
- *Prevotella*
- *Roseburia*
- *Ruminococcus albus*

Results are displayed as:

High	Microorganism in the sample exceeds the upper 99th* percentile of the reference range
Normal	Microorganism in the sample is within the 99th* percentile of the reference range
Low	Microorganism in the sample below the lower 99th* percentile of the reference range

*95th percentile for the diversity score

Results outside of the healthy reference range are highlighted with an alert symbol:	⚠
Organisms linked to disease and health risk are highlighted with a pathogen symbol:	⚙
References to scientific publications associating organisms with conditions are listed in brackets:	[1]

Infections

Pathogenic microorganisms included in the uBiome SmartGut test are microorganisms that have been linked to disease and health risk. As noted above, a positive result in your sample is not a diagnosis, nor does it imply you have a disease. Similary, a negative result does not preclude disease. Consult your medical professional regarding any positive test results.

Diarrhea

Associated	*Clostridium difficile* [1-3]	Negative
	Campylobacter [4,5]	Negative
	Escherichia-Shigella [6-10]	Negative
	Salmonella enterica [11-15]	Negative
	Vibrio cholerae [16,17]	Negative
	Clostridium [18,19]	Negative
	Bacteroides fragilis [20,21]	Negative
Inversely associated	*Lactobacillus* [22]	Normal
	Microbial Diversity [23,24]	Normal

Gut Conditions

Your microbiome might include microorganisms associated with conditions such as irritable bowel syndrome, flatulence, or bloating. Use the section below to find out more about the relationship between your gut conditions and your microbiome.

Irritable Bowel Syndrome

Associated	*Salmonella enterica* [25]	○	Negative
	Campylobacter [25]	○	Negative
	Escherichia-Shigella [25]	○	Negative
	Veillonella [26]	○	Negative
Inversely associated	*Alistipes* [27]	⋮	Normal
	Bifidobacterium [28]	⋮	Normal
	Collinsella aerofaciens [28-30]	⋮	Normal
	Lactobacillus [26,28]	⋮	Normal

Inflammatory Bowel Disease

Associated	*Desulfovibrio piger* [31]	○	Negative
	Fusobacterium [32]	○	Negative
Inversely associated	*Roseburia* [33]	⋮	Normal

Crohn's Disease

Associated	*Escherichia-Shigella* [33-35]	○	Negative
	Ruminococcus [36,38]	○	Negative
Inversely associated	*Akkermansia muciniphila* [36]	⋮	Low ⚠
	Bifidobacterium [37]	⋮	Normal
	Dialister invisus [37]	⋮	Normal
	Odoribacter [33]	⋮	Normal
	Roseburia [38,39]	⋮	Normal
	Microbial Diversity [40]	⋮	Normal

Gut Conditions (continued)

Ulcerative Colitis

Associated	*Ruminococcus* [36]	Negative	
Inversely associated	*Akkermansia muciniphila* [36]	Low	⚠
	Odoribacter [33]	Normal	
	Prevotella [38,39,41]	Normal	
	Roseburia [42]	Normal	
	Ruminococcus albus [43]	Low	⚠
	Microbial Diversity [41]	Normal	

Constipation

Associated	*Methanobrevibacter smithii* [44]	Normal	
Inversely associated	*Bifidobacterium* [45]	Normal	

Abdominal Tenderness

Associated	*Methanobrevibacter smithii* [46]	Normal	

Bloating

Associated	*Anaerotruncus colihominis* [47]	Low	

Flatulence

Associated	*Bacteroides fragilis* [48]	Negative	

Lifestyle & Diet

SmartGut provides information on how your lifestyle and diet affect the microorganisms in your microbiome, including probiotics in your gut and associations between your microbiome and weight.

Obesity

Associated	*Lactobacillus* [49-51]	Normal	
Inversely associated	*Akkermansia muciniphila* [52,53]	Low	⚠
	Alistipes [27]	Normal	
	Anaerotruncus colihominis [27,54]	Low	⚠
	Barnesiella [27]	Normal	
	Butyrivibrio crossotus [55,56]	Low	⚠
	Lactobacillus [51]	Normal	
	Methanobrevibacter smithii [50,57]	Normal	
	Microbial Diversity [55,56,58]	Normal	

Type II Diabetes

Associated	*Akkermansia muciniphila* [59]	Low	
Inversely associated	*Lactobacillus* [60,61]	Normal	
	Roseburia [59,62,63]	Normal	

Prediabetes

Inversely associated	Microbial Diversity [55]	Normal	

Kidney Stones

Inversely associated	*Oxalobacter formigenes* [64,65]	Normal	

Methods & Limitations

Microbial DNA is extracted and marker genes are amplified by polymerase chain reaction (PCR) and then sequenced using the Illumina® NextSeq 500 sequencer. The sequence data is processed using a proprietary phylogenetic analysis algorithm.

This test detects the presence of the following microorganisms with 99% sensitivity and specificity: *Akkermansia muciniphila, Alistipes, Anaerotruncus colihominis, Bacteroides fragilis, Barnesiella, Bifidobacterium, Butyrivibrio crossotus, Campylobacter, Clostridium, Clostridium difficile, Collinsella aerofaciens, Desulfovibrio piger, Dialister invisus, Escherichia-Shigella, Fusobacterium, Lactobacillus, Methanobrevibacter smithii, Odoribacter, Oxalobacter formigenes, Prevotella, Roseburia, Ruminococcus, Ruminococcus albus, Salmonella enterica, Veillonella,* and *Vibrio cholerae*.

Some of these microorganisms may not be considered pathogenic, but are included as they reflect the state of the patients microbiome. The microbiome and its clinical relevance is an area of active investigation. This sample has 94.2 Mb of sequenced DNA, in 313,839 reads, exceeding our 10,000 read quality control threshold.

About This Test

This test was developed and its performance characteristics were determined by uBiome, Inc. For more information go to http://ubiome.com/gutpaper for the publication explaining uBiomes methods underlying this test. This test has not been cleared or approved by the U.S. Food and Drug Administration (FDA). The FDA has determined that such clearance or approval is not necessary. This test may be used for clinical purposes and should not be regarded as investigational or for research only. uBiomes clinical reference laboratory is accredited by the internationally recognized College of American Pathologists (CAP) and is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high complexity clinical laboratory testing.

This test is a next-generation sequencing-based assay that can identify 13 species and 13 genera of gastrointestinal microbiome related microorganisms from a stool swab sample, including 5 pathogenic organisms. The detection (or lack thereof) of microorganisms, as the case may be, is reported to a patients treating medical professional in this report. The report should be considered in context with other clinical criteria (e.g. patient history, physical exam), as well as other studies (such as laboratory, pathology, and imaging) by a qualified medical professional prior to initiating or changing a patients diagnostic work-up or treatment plan.

This test is not a substitute for established methods for identifying microorganisms or their antimicrobial susceptibility profile. Patient management decisions must be based on the independent medical judgment of the treating medical professional. The test and accompanying report are not intended to be used as the sole means for clinical diagnosis or patient management decisions.

The report may include information on the relevance of reported microorganisms. This information is derived from peer-reviewed studies and other publicly available databases and may include associations between the microorganism and a health condition. Careful consideration must be made by the medical professional when using this information, as it may or may not be relevant to this patient. Organisms not included in this test may also have an effect on the mentioned health conditions. The organisms on this test may affect additional health conditions not mentioned on this report.

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