

Order
Report Date
Provider
Provider NPI
Order Date
QA Review Date

Patient
Patient
DOB
Age
Gender
Patient ID

Sample	
Type	Swab
Source	Fecal
Collected	
Received	

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.

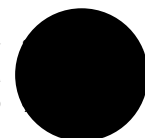
Diversity Score Compared to a healthy reference range, your diversity score is Normal

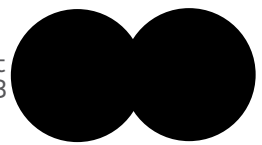
Pathogens Positive: 0 of 3 species, 0 of 2 genera

Pathogenic Species	<i>Clostridium difficile</i>	Negative
	<i>Salmonella enterica</i>	Negative
	<i>Vibrio cholerae</i>	Negative
Pathogenic Genera	<i>Campylobacter</i>	Negative
	<i>Escherichia-Shigella</i>	Negative

Organisms Outside Healthy Reference Range

<i>Akkermansia muciniphila</i>	Low
<i>Anaerotruncus colihominis</i>	Low
<i>Butyrivibrio crossotus</i>	Low
<i>Ruminococcus albus</i>	Low





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



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:

<i>Bacteroides fragilis</i>	<i>Fusobacterium</i>
<i>Campylobacter</i>	<i>Ruminococcus</i>
<i>Clostridium</i>	<i>Salmonella enterica</i>
<i>Clostridium difficile</i>	<i>Veillonella</i>
<i>Desulfovibrio piger</i>	<i>Vibrio cholerae</i>
<i>Escherichia-Shigella</i>	




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:

<i>Akkermansia muciniphila</i>	<i>Lactobacillus</i>
<i>Alistipes</i>	<i>Methanobrevibacter smithii</i>
<i>Anaerotruncus colihominis</i>	<i>Odoribacter</i>
<i>Barnesiella</i>	<i>Oxalobacter formigenes</i>
<i>Bifidobacterium</i>	<i>Prevotella</i>
<i>Butyrivibrio crossotus</i>	<i>Roseburia</i>
<i>Collinsella aerofaciens</i>	<i>Ruminococcus albus</i>
<i>Dialister invisus</i>	

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 is absent or 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:

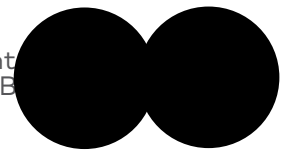


Organisms linked to disease and health risk are highlighted with a pathogen symbol:



References to scientific publications associating organisms with conditions are listed in brackets:

[1]

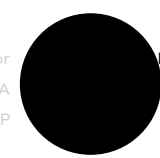


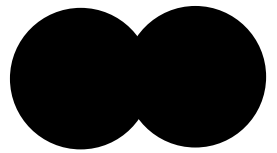
Infections

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. Similarly, a negative result does not preclude disease. Consult your medical professional regarding any positive test results.

Diarrhea

Associated	<i>Clostridium difficile</i> [1-3]	Negative
	<i>Campylobacter</i> [4,5]	Negative
	<i>Escherichia-Shigella</i> [6-10]	Negative
	<i>Salmonella enterica</i> [11-15]	Negative
	<i>Vibrio cholerae</i> [16,17]	Negative
	<i>Clostridium</i> [18,19]	Negative
	<i>Bacteroides fragilis</i> [20,21]	Negative
Inversely associated	<i>Lactobacillus</i> [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

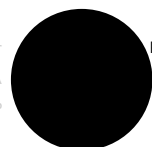
Associated	<i>Salmonella enterica</i> [25]	Negative
	<i>Campylobacter</i> [25]	Negative
	<i>Escherichia-Shigella</i> [25]	Negative
	<i>Veillonella</i> [26]	Negative
Inversely associated	<i>Alistipes</i> [27]	Normal
	<i>Bifidobacterium</i> [28]	Normal
	<i>Collinsella aerofaciens</i> [28-30]	Normal
	<i>Lactobacillus</i> [26,28]	Normal

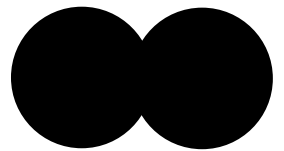
Inflammatory Bowel Disease

Associated	<i>Desulfovibrio piger</i> [31]	Negative
	<i>Fusobacterium</i> [32]	Negative
Inversely associated	<i>Roseburia</i> [33]	Normal

Crohn's Disease

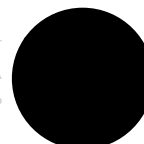
Associated	<i>Escherichia-Shigella</i> [33-35]	Negative
	<i>Ruminococcus</i> [36,38]	Negative
Inversely associated	<i>Akkermansia muciniphila</i> [36]	Low
	<i>Bifidobacterium</i> [37]	Normal
	<i>Dialister invisus</i> [37]	Normal
	<i>Odoribacter</i> [33]	Normal
	<i>Roseburia</i> [38,39]	Normal
	Microbial Diversity [40]	Normal

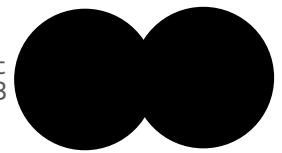




Gut Conditions (continued)

Ulcerative Colitis			
Associated	<i>Ruminococcus</i> [36]		Negative
Inversely associated	<i>Akkermansia muciniphila</i> [36]		Low
	<i>Odoribacter</i> [33]		Normal
	<i>Prevotella</i> [38,39,41]		Normal
	<i>Roseburia</i> [42]		Normal
	<i>Ruminococcus albus</i> [43]		Low
	Microbial Diversity [41]		Normal
Constipation			
Associated	<i>Methanobrevibacter smithii</i> [44]		Normal
Inversely associated	<i>Bifidobacterium</i> [45]		Normal
Abdominal Tenderness			
Associated	<i>Methanobrevibacter smithii</i> [46]		Normal
Bloating			
Associated	<i>Anaerotruncus colihominis</i> [47]		Low
Flatulence			
Associated	<i>Bacteroides fragilis</i> [48]		Negative





Lifestyle & Diet

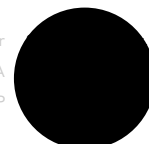
SmartGut provides information on how your lifestyle and diet affect the microorganisms in your microbiome, including probiotics in your gut and associations between your microbiome and weight.

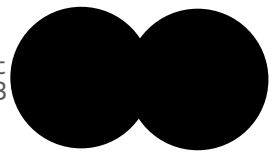
Obesity			
Associated	<i>Lactobacillus</i> [49-51]		Normal
Inversely associated	<i>Akkermansia muciniphila</i> [52,53]		Low
	<i>Alistipes</i> [27]		Normal
	<i>Anaerotruncus colihominis</i> [27,54]		Low
	<i>Barnesiella</i> [27]		Normal
	<i>Butyrivibrio crossotus</i> [55,56]		Low
	<i>Lactobacillus</i>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

Type II Diabetes			
Associated	<i>Akkermansia muciniphila</i> [59]		Low
Inversely associated	<i>Lactobacillus</i> [60,61]		Normal
	<i>Roseburia</i> [59,62,63]		Normal

Prediabetes			
Inversely associated	Microbial Diversity [55]		Normal

Kidney Stones			
Inversely associated	<i>Oxalobacter formigenes</i> [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 51.8 Mb of sequenced DNA, in 172,804 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.

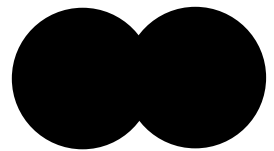
This test is not a substitute for established methods for identifying microorganisms or their antimicrobial susceptibility profile. Patient management decisions must be based on the independent medical judgment of the treating medical professional. The test and accompanying report are not intended to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

SmartGut is a clinical test, successfully validated using samples collected from individuals of mainly adult age, with a subset of minors. When ordered for minors, the results may still provide valuable information about the minor's health; however, the accuracy of the results will differ from what was validated for the adult age range.

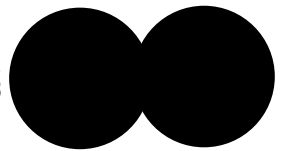
QA Review Date is defined as 90 days from release of final report and identifies a timeframe where test reports will undergo quality surveillance processes utilizing a selected subset of samples to assess quality assurance.





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