

| Ordering Provider | | Patient | | Sample | |
|-------------------|-----------------|------------|------------------|-----------|---------------|
| Physician | Alan Greene, MD | Patient | Jane Doe | Type | Swab |
| City, State | Danville, CA | DOB | January 01, 1970 | Source | Fecal |
| Phone | 925-964-1793 | Age | 47 | Collected | June 19, 2017 |
| NPI | 1699822304 | Gender | Female | Received | June 22, 2017 |
| | | Patient ID | 589A5376DF12E | Report ID | R11235813 |

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 **Low**

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>Bifidobacterium</i> | Low |
| <i>Desulfovibrio piger</i> | Positive |
| <i>Fusobacterium</i> | Positive |
| <i>Lactobacillus</i> | Low |
| <i>Roseburia</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>Butyvirbio 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 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] |  | Low  |
| | Microbial Diversity [23,24] |  | Low  |







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>Veilonella</i> [26] |  Negative | |
| Inversely associated | <i>Alistipes</i> [27] |  Normal | |
| | <i>Bifidobacterium</i> [28] |  Low  | |
| | <i>Collinsella aerofaciens</i> [28-30] |  Normal | |
| | <i>Lactobacillus</i> [26,28] |  Low  | |

















Inflammatory Bowel Disease

| | | | |
|----------------------|---------------------------------|--|--|
| Associated | <i>Desulfovibrio piger</i> [31] |  Positive  | |
| | <i>Fusobacterium</i> [32] |  Positive  | |
| Inversely associated | <i>Roseburia</i> [33] |  Low  | |

Crohn's Disease

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

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] |  Low |  |
| | <i>Ruminococcus albus</i> [43] |  Normal | |
| | Microbial Diversity [41] |  Low |  |
| Constipation | | | |
| Associated | <i>Methanobrevibacter smithii</i> [44] |  Normal | |
| Inversely associated | <i>Bifidobacterium</i> [45] |  Low |  |
| Abdominal Tenderness | | | |
| Associated | <i>Methanobrevibacter smithii</i> [46] |  Normal | |
| Bloating | | | |
| Associated | <i>Anaerotruncus colihominis</i> [47] |  Normal | |
| 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] | | Low |
| Inversely associated | <i>Akkermansia muciniphila</i> [52,53] | | Low |
| | <i>Alistipes</i> [27] | | Normal |
| | <i>Anaerotruncus colihominis</i> [27,54] | | Normal |
| | <i>Barnesiella</i> [27] | | Normal |
| | <i>Butyvirbio crossotus</i> [55,56] | | Normal |
| | <i>Lactobacillus</i> [51] | | Low |
| | <i>Methanobrevibacter smithii</i> [50,57] | | Normal |
| | Microbial Diversity [55,56,58] | | Low |

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

| Prediabetes | | | |
|----------------------|--------------------------|--|-----|
| Inversely associated | Microbial Diversity [55] | | Low |

| 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 bacteria 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 bacteria may not be considered pathogenic, but are included as they reflect the state of the patient's microbiome. The microbiome and its clinical relevance is an area of active investigation. This sample has 32.5 Mb of sequenced DNA, in 108,305 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 uBiome's 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. uBiome's 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 patient's 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 patient's 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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