



Order: SAMPLE REPORT



Client #: 12345

Doctor: Sample Doctor

Doctor's Data, Inc.

3755 Illinois Ave.

St. Charles, IL 60174

Patient: Sample Patient

Age: 35

Sex: Female

Sample Collection

Date/Time

Date Collected

08/12/2021

Date Received

08/13/2021

Date Reported

08/14/2021

Specimens Collected

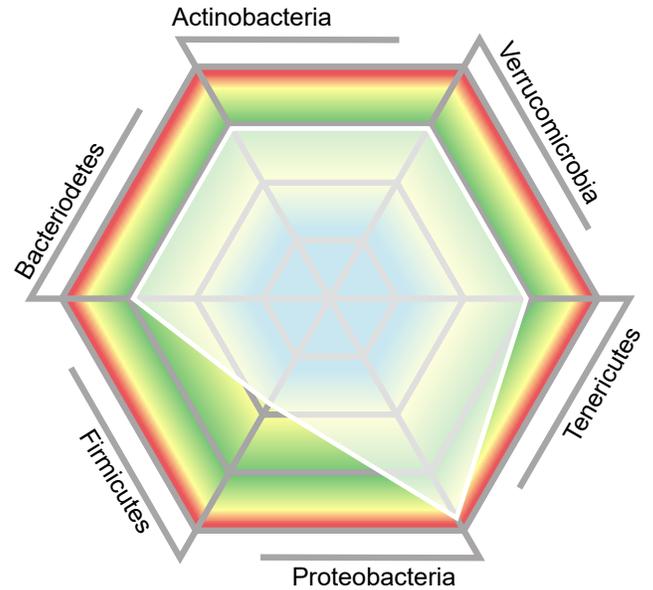
3

Microbiome Abundance and Diversity Summary

The abundance and diversity of gastrointestinal bacteria provide an indication of gastrointestinal health, and gut microbial imbalances can contribute to dysbiosis and other chronic disease states. The GI360™ Microbiome Profile is a gut microbiota DNA analysis tool that identifies and characterizes more than 45 targeted analytes across six Phyla using PCR and compares the patient results to a characterized normobiotic reference population. The web chart illustrates the degree to which an individual's microbiome profile deviates from normobiosis.

LEGEND

The web image shows the relative diversity and balance among bacteria belonging to the six primary Phyla. The white shaded area represents the patient's results compared to a normobiotic reference population. The center of the web represents less abundance while the outer edges represent more than normobiotic.



Dysbiosis Index

The Dysbiosis Index (DI) is calculated strictly from the results of the Microbiome Profile, with scores from 1 to 5. A DI score above 2 indicates dysbiosis; a microbiota profile that differs from the defined normobiotic reference population. The higher the DI above 2, the more the sample deviates from the normobiotic profile. The dysbiosis test and DI does not include consideration of dysbiotic and pathogenic bacteria, yeast, parasites and viruses that may be reported in subsequent sections of the GI360™ test.

DI Score

5



Key Findings

Proteobacteria, Very High	↑	
<i>Escherichia</i> spp., Very High	↑	
Clostridia Class, Very Low	↓	
<i>Eubacterium hallii</i> , Very Low	↓	
<i>Faecalibacterium prausnitzii</i> , Very Low	↓	
Lachnospiraceae, Very Low	↓	



Microbiome Bacterial Abundance; Multiplex PCR



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LEGEND



Results are graphed as deviations from a normobiotic population. Normobiosis or a normobiotic state characterizes a composition of the microbiota profile in which microorganisms with potential health benefits predominate in abundance and diversity over potentially harmful ones.

Actinobacteria	Result	-3	-2	-1	0	+1	+2	+3	Reference Interval
Actinobacteria	0				▲				0
Actinomycetales	0				▲				0
Bifidobacterium spp.	0				▲				0
Bacteroidetes	Result	-3	-2	-1	0	+1	+2	+3	Reference Interval
Alistipes spp.	+1					▲			0
Alistipes onderdonkii	0				▲				0
Bacteroides fragilis	0				▲				0
Bacteroides spp. & Prevotella spp.	0				▲				0
Bacteroides spp.	-1			▲					0
Bacteroides pectinophilus	-1			▲					0
Bacteroides stercoris	+1					▲			0
Bacteroides zooglyphiformans	0				▲				0
Parabacteroides johnsonii	0				▲				0
Parabacteroides spp.	0				▲				0
Firmicutes	Result	-3	-2	-1	0	+1	+2	+3	Reference Interval
Firmicutes	0				▲				0
Bacilli Class	0				▲				0
Catenibacterium mitsuokai	0				▲				0

Notes:

The gray-shaded area of the bar graph represents reference values outside the reporting limits for this test.

*This test was developed and its performance characteristics determined by Doctor's Data Laboratories in a manner consistent with CLIA requirements. The U. S. Food and Drug Administration (FDA) has not approved or cleared this test; however, FDA clearance is not currently required for clinical use. The results are not intended to be used as a sole means for clinical diagnosis or patient management decisions.

Methodology: Multiplex PCR

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Firmicutes	Result	-3	-2	-1	0	+1	+2	+3	Reference Interval
<i>Streptococcus salivarius</i> ssp. <i>thermophilus</i>	-1			▲					0
<i>Streptococcus</i> spp.	0				▲				0
<i>Veillonella</i> spp.	-1			▲					0
Proteobacteria	Result	-3	-2	-1	0	+1	+2	+3	Reference Interval
Proteobacteria	+3							▲	0
<i>Enterobacteriaceae</i>	0				▲				0
<i>Escherichia</i> spp.	+3							▲	0
<i>Acinetobacter junii</i>	0				▲				0
Tenericutes	Result	-3	-2	-1	0	+1	+2	+3	Reference Interval
<i>Mycoplasma hominis</i>	0				▲				0
Verrucomicrobia	Result	-3	-2	-1	0	+1	+2	+3	Reference Interval
<i>Akkermansia muciniphila</i>	0				▲				0

**Microbiome Abundance Information:**

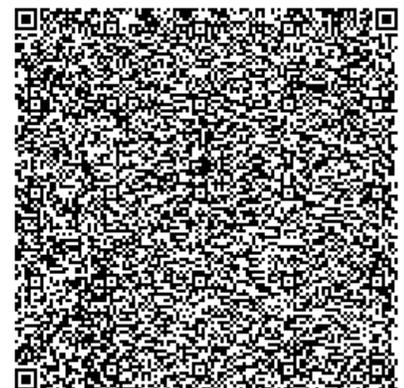
- The GI360™ Microbiome Profile is a focused gut microbiota DNA analysis tool that identifies more than 45 targeted analytes across six phyla using a CE-marked multiplex PCR system. Patient results are compared to a highly defined normobiotic reference population (n > 1,100). The white shadowed web plot within the hexagonal diagram illustrates the degree to which an individual's microbiome profile deviates from normobiosis. The center of the diagram represents less bacterial abundance while the outer edges represent greater than normobiosis. Deviation from a hexagon-shaped plot indicates variant diversity of the microbial community. Key findings for patient's microbiome profile are summarized in the table below the diagram, and detailed results for all of the analytes are presented on the next 3 pages of the report. Detailed results for the specific bacteria are reported as -3 to +3 standard deviations, as compared to the normobiotic reference population.

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Introduction

This analysis of the stool specimen provides fundamental information about the overall gastrointestinal health of the patient. When abnormal microflora or significant aberrations in intestinal health markers are detected, specific commentaries are presented. If no significant abnormalities are found, commentaries are not presented.

Microbiome Abundance Information

Actinobacteria (phylum)

Actinobacteria is one of the largest bacterial phyla, comprised of Gram-positive bacteria. This phylum includes a wide range of species, with different morphological and physiological characteristics. Significant groups in the human colon include Actinomycetales and Bifidobacteriales. Actinomycetales were inversely associated with clinically significant depression in IBS patients, suggesting these bacteria may be depleted in depressed IBS patients. A strict vegetarian diet may increase the total count of *Actinomyces* spp. compared to following a Western diet.

Bacteroidetes (phylum)

Bacteroidetes make up approximately 28% of the gut microbiota in healthy human adults. They are early colonizers of the infant gut and are amongst the most stable, at a species and strain level, in the host. A low preponderance of Bacteroidetes in relation to Firmicutes has been associated with obesity, though this can increase with weight loss and restricted calorie intake.

↑ *Alistipes* (genus)

Alistipes does not contribute significantly to short chain fatty acid production. A diet rich in animal protein and fat increases the abundance of *Alistipes*. High abundance of *Alistipes* was identified as a possible predictor of successful weight loss. Increased abundance of *Alistipes* has been correlated with a greater frequency of pain in pediatric irritable bowel syndrome patients. In contrast, *Alistipes onderdonkii* was shown to be decreased in patients diagnosed with ulcerative colitis. Lower abundance of the *Alistipes* genus has been observed in patients with psoriatic arthritis and pediatric Crohn's disease. *Alistipes* may positively correlate with depression.

↓ *Bacteroides pectinophilus* (species)

Bacteroides pectinophilus contributes to breakdown of dietary pectins which are prebiotics. Pectins are complex, plant-derived carbohydrates that are indigestible by human enzymes, but can be easily degraded by certain commensal bacteria in the gut. Subsequent microbial fermentation of constituent sugar moieties yields important short chain fatty acids and other metabolites. The pectin-derived microbial fermentation products have important functions including reduction of ammonia, delay of gastric emptying and postprandial glucose regulation, induction of gut immunity, and maintenance of the mucosal barrier. Adequate intake and microbial metabolism of pectins appears to stimulate growth of various beneficial bacteria, including *Lachnospiraceae*, *Dorea* species, *Bifidobacterium*, *Lactobacillus* species, *Faecalibacterium prausnitzii*, and *Eubacterium rectale*. The abundance of *B. pectinophilus* has been positively correlated with a healthy fasting serum lipid profile, and negatively correlated with biomarkers of insulin resistance and dyslipidemia. *B. pectinophilus* was less abundant for IBS patients compared to healthy controls. High consumption of kimchi (fermented cabbage) may be associated with lower than normal levels of *B. pectinophilus*.

↑ *Bacteroides* (species)

Species in the genus *Bacteroides* carry out broad metabolic functions, including degradation of complex plant polysaccharides, proteolytic activities, de-conjugation of bile acids, mucosal barrier integrity, short chain fatty acid production, fatty acid storage and glucose metabolism. *Bacteroides* spp. are maintained at a higher abundance in breastfed individuals into adulthood. *Bacteroides fragilis* plays an important role in the prevention of intestinal inflammation. An energy-restricted diet has been shown to increase *B. fragilis* in overweight adolescents. An increase in *B. stercoris* has been associated with higher risk of colon cancer. Decreased levels of *Bacteroides* spp. have been reported in association with multiple sclerosis, rheumatoid arthritis and Parkinson's disease.

Firmicutes (phylum)

The phylum Firmicutes constitutes the most diverse and abundant group of gastrointestinal microbiota which are grouped into four classes, Bacilli, Clostridia, Erysipelotrichia, and Negativicutes. They constitute about 39% of gut bacteria in healthy adults, but may increase to as high as 80% in an imbalanced microbial community.



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Microbiome Abundance Information continued...

↓ **Clostridium (genus)**

Clostridium spp. represents an extremely heterogeneous class of organisms that are still actively undergoing taxonomic revision. *Clostridium* spp. are strict anaerobic, spore-forming bacteria. Decreased abundance of the genus *Clostridium* was found to be associated with prediabetes. Some *Clostridium* spp. are transferred to infants from breast milk within the first months of life. Increased levels of some *Clostridium* spp. were observed in irritable bowel syndrome patients. Many species, some of them related to diarrhea, were decreased after consumption of inulin combined with maltodextrin.

↓ **Clostridium methylpentosum (species)**

Appropriate digestion and metabolism of complex dietary carbohydrates from plants drives healthy diversity in the gut microbiota. *Clostridium methylpentosum* ferments the naturally occurring sugar L-rhamnose that is released by microbial breakdown of plant-derived pectin. Rhamnose is fermented to propionate and acetate which are short chain fatty acids that have pivotal regulatory roles in the maintenance of mucosal barrier integrity, gut microbiota balance, post-prandial appetite suppression and normoglycemia. Lower levels of *C. methylpentosum* were reported for children with autism and pervasive developmental disorder compared to neurotypicals controls. Consumption of probiotic yogurt LKM512 containing *Bifidobacterium animalis* (subspecies lactis LKM512) increased the levels of *C. methylpentosum*.

↓ **Dorea (genus)**

Dorea is a genus within the *Lachnospiraceae* family that is in the Firmicutes phylum. *Dorea* species are known to produce hydrogen and carbon dioxide as end-products of glucose fermentation and may be associated with bloating. Decreased levels of *Dorea* spp. were observed in patients with Parkinson's disease. Recent studies have identified increased levels of *Dorea* spp. in patients diagnosed with IBS, nonalcoholic fatty liver disease and non-alcoholic steatohepatitis, multiple sclerosis and colorectal cancer.

↓ **Eubacterium hallii (species)**

Eubacterium hallii and *Eubacterium rectale* are both part of the *Lachnospiraceae* family that is in the Firmicutes phylum. *E. hallii* and *E. rectale* produce butyrate that is a key regulator of mucosal barrier integrity and function. Decreased levels of *Eubacterium* spp. have been associated with very high protein diets. *Eubacterium hallii* is capable of metabolizing glucose into products with antimicrobial properties.

↓ **Faecalibacterium prausnitzii (species)**

Faecalibacterium prausnitzii is one of the most abundant butyrate producing bacteria in a healthy gastrointestinal tract. As such, *F. prausnitzii* is a protective factor for the intestinal mucosa and supports very important intestinal barrier functions. *F. prausnitzii* exerts anti-inflammatory effects via metabolites such as short-chain fatty acids. *F. prausnitzii* is reduced in inflammatory bowel disease, irritable bowel syndrome, celiac disease and gastrointestinal inflammation in general. It is reduced in patients diagnosed with Parkinson's disease, bipolar disorder, colorectal cancer, diabetes and chronic idiopathic diarrhea. Diminished levels of *F. prausnitzii* were found in patients with major depressive disorder. The abundance of *F. prausnitzii* together with *E. coli* has been proposed as a discrimination tool between ulcerative colitis and Crohn's disease. *F. prausnitzii* has been correlated with pediatric obesity in instances of high consumption of foods that are rich in unabsorbed carbohydrate (banana, maize, rice). The prebiotic inulin has been shown to increase the proportion of *F. prausnitzii* in the human intestinal microbiota. Low FODMAP diets are associated with diminished *F. prausnitzii* and butyrate production.

↓ **Lachnospiraceae (family)**

The *Lachnospiraceae* family is a diverse group of butyric acid producers, which have been associated with beneficial microbial and epithelial cell growth. Consumption of a Mediterranean diet decreased levels of species belonging to *Lachnospiraceae*. *Lachnospiraceae* are known to increase with intake of cruciferous vegetables and wheat bran, and decrease with a resistant starch diet.

↓ **Streptococcus (genus)**

Higher abundance of *S. salivarius* and *S. thermophilus* (Firmicutes phylum) have been associated with a moderate to severe disease course in newly diagnosed ulcerative colitis (UC) patients. These findings are in accordance with a study that showed that UC patients have significantly increased *Streptococcus* spp. and depletion of *Bifidobacterium* spp. Higher levels of *Streptococcus* spp. were also observed in patients with colorectal cancer compared to healthy controls. Administration of *S. salivarius* together with *Bifidobacterium bifidum* was shown to reduce the incidence of acute diarrhea and rotavirus shedding in infants. *S. salivarius* and *S. thermophilus* are also widely used in dairy products like yogurt and cheese.



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Microbiome Abundance Information continued...

↓ **Veillonella (genus)**

Veillonella (Firmicutes phylum) are known for their ability to ferment lactate, producing the short chain fatty acids propionate and acetate. *Veillonella* spp. were shown to be significantly increased in patients with Crohn's disease, type 1 diabetes, and patients diagnosed with liver cirrhosis. Increased amounts of *Veillonella* have been found in patients with constipation dominant irritable bowel syndrome (IBS-C). It is hypothesized that the relationship between *Veillonella* strains and IBS stems from its robust production of organic acids (propionate and acetate) which contribute to bloating, anxiety and abdominal pain. Higher levels of *Veillonella* were found in formula-fed infants compared to breast-fed infants.

Proteobacteria (phylum)

Proteobacteria include a wide variety of pathogens, including species within the *Escherichia*, *Shigella*, *Salmonella*, *Vibrio*, and *Helicobacter* genera. The phylum includes a number of species that are permanent residents of the microbiota and capable of inducing nonspecific inflammation and diarrhea when their presence is increased. Proteobacteria make up approximately 2% of the gut microbiota in healthy adults.

↑ **Proteobacteria**

A high-fat diet is positively associated with an abundance of Proteobacteria. Slightly increased abundance of Proteobacteria may be associated with low-grade inflammation. Proteobacteria are increased in inflammatory bowel disease and irritable bowel syndrome. Higher abundance of Proteobacteria has been associated with a moderate to severe disease course in newly discovered ulcerative colitis patients. They are associated with diarrhea in IBS.

↑ **Escherichia (genus)**

Clinically, *Escherichia* has been reported to contribute to irritable bowel syndrome. *Escherichia* spp. are commonly recovered from inflamed tissues of both Crohn's disease and ulcerative colitis patients. Untreated inflammatory bowel disease patients were shown to have higher abundance of *Escherichia* and lower abundance of *Faecalibacterium prausnitzii*. Increased levels of *Escherichia* were observed in colorectal cancer patients. Patients diagnosed with nonalcoholic steatohepatitis have higher abundance of *Escherichia*. Consumption of a Western diet is positively associated with *Escherichia* levels. Increased levels of *E. coli* were observed in people on a gluten-free diet. A non-pathogenic strain of *Escherichia*, *Escherichia nissle*, is a widely used probiotic for treating gut related diseases such as chronic constipation.

Tenericutes (phylum)

Tenericutes are cell wall-less bacteria that do not synthesize precursors of peptidoglycan. Tenericutes consist of four main clades designated as the *Acholeplasma*, *Spiroplasma*, *Pneumoniae* and *Hominis* clusters. Tenericutes are typically parasites or commensals of eukaryotic hosts.

Verrucomicrobia (phylum)

Verrucomicrobia is a less common phylum in the human gut microbiota, but one with increasing recognition with regards to health. Verrucomicrobia includes *Akkermansia muciniphila*. The obligate anaerobe *A. muciniphila* constitutes 3-5% of total bacteria in a healthy microbiome, and has a protective or anti-inflammatory role in the intestinal mucosa.

GI Pathogens

Introduction

The GI Pathogen profile is performed using an FDA-cleared multiplex PCR system. It should be noted that PCR testing is much more sensitive than traditional techniques and allows for the detection of extremely low numbers of pathogens. PCR testing does not differentiate between viable and non-viable pathogens and should not be repeated until 21 days after completion of treatment or resolution to prevent false positives due to lingering traces of DNA. PCR testing can detect multiple pathogens in the patient's stool but does not differentiate the causative pathogen. All decisions regarding the need for treatment should take the patient's complete clinical history and presentation into account.