

Proteobacteria

Dysbiosis and Diversity Index

These indexes are calculated from the results of the Microbiome Profile, with scores ranging from 1 to 5, and do not include consideration of dysbiotic and pathogenic bacteria, yeast, parasites and viruses that may be reported in subsequent sections of the GI360[™] test.

The Dysbiosis Index the (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 GI360TM test.

A diversity score of 3 indicates an expected amount of diversity, with 4 & 5 indicating an increased distribution of bacteria based on the number of different species and their abundance in the sample, calculated based on Shannon's diversity index. Scores of 1 or 2 indicate less diversity than the defined normobiotic reference population.



GI Health Markers	
Butyrate producing bacteria	
Gut barrier protective bacteria	
Gut intestinal health marker	
Pro-inflammatory bacteria	
Gut barrier protective bacteria vs. opportunistic bacteria	
= Expected = Imb	alanced

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Date/Time

04/15/2024

04/25/2024

05/02/2024

Order: 999999-9999 Client #: 999999

Doctor: Sample Doctor, MD Doctors Data Inc 123 Main St. St. Charles, 60174 USA

-2

-3

Very Low

-1

Low

0

Within Reference Interval

 Patient: Sample Patient

 Id: 999999

 Age: 55
 DOB: 01/01/1968

 Sex: Female

+2

+1

High

LEGEND

Very High

+3

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.

Sample Collection

Date Collected

Date Received

Date Reported

Actinobacteria	Result	-3	-2	-1	0	+1	+2	+3	Reference Interval
Actinobacteria	0								0
Actinomycetales	-1			\triangle					0
Bifidobacterium family	0								0
Bacteroidetes	Result	-3	-2	-1	0	+1	+2	+3	Reference Interval
Alistipes spp.	-2								0
Alistipes onderdonkii	0								0
Bacteroides fragilis	0								0
Bacteroides spp. & Prevotella spp.	+1					\triangle			0
Bacteroides spp.	+3								0
Bacteroides pectinophilus	0								0
Bacteroides stercoris	0								0
Bacteroides zoogleoformans	-1			\wedge					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





Order: 999999-9999 Patient: Sample Patient **Sample Collection** Date/Time ld:999999 Date Collected 04/15/2024 Age: 55 DOB: 01/01/1968 Date Received 04/25/2024 Client #: 999999 Sex: Female **Date Reported** 05/02/2024 Doctor: Sample Doctor, MD **Doctors Data Inc** 123 Main St. St. Charles, 60174 USA **Firmicutes** Result **Reference Interval** -3 -2 -1 0 +1 +2 +3 0 Clostridia Class 0 0 0 Clostridium methylpentosum Clostridium L2-50 0 0 Coprobacillus cateniformis 0 0 Dialister invisus 0 0 Dialister invisus & Megasphaera 0 0 micronuciformis 0 Dorea spp. -1 Holdemanella biformis 0 0 Anaerobutyricum hallii 0 0 0 0 Agathobacter rectalis Eubacterium siraeum 0 0 -2 0 Faecalibacterium prausnitzii Lachnospiraceae 0 0 Ligilactobacillus ruminis & Pediococcus 0 0 acidilactici Lactobacillus family 0 0 Phascolarctobacterium spp. 0 +1 Ruminococcus albus & R. bromii 0 0 +3 0 Mediterraneibacter gnavus Streptococcus agalactiae & Agathobacter 0 0 rectalis Streptococcus salivarius ssp. +1 0 thermophilus & S. sanguinis

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Methodology: Multiplex PCR





Order: 9999999-9999 Client #: 999999 Doctor: Sample Doctor, MD Doctors Data Inc 123 Main St. St. Charles, 60174 USA	Patier Id:999 Age:5 Sex:F	Patient: Sample Patient Id: 999999 Age: 55 DOB: 01/01/1968 Sex: Female						collection ected eived orted	Date/Time 04/15/2024 04/25/2024 05/02/2024
Firmicutes	Result	-3	-2	-1	0	+1	+2	+3	Reference Interval
Streptococcus salivarius ssp. thermophilus	0								0
Streptococcus spp.	0								0
<i>Veillonella</i> spp.	0								0
Proteobacteria	Result	-3	-2	-1	0	+1	+2	+3	Reference Interval
Proteobacteria	+2								0
Enterobacteriaceae	0								0
Escherichia spp.	+2								0
Acinetobacter junii	0								0
Mycoplasmatota	Result	-3	-2	-1	0	+1	+2	+3	Reference Interval
Metamycoplasma hominis	0								0
Verrucomicrobiota	Result	-3	-2	-1	0	+1	+2	+3	Reference Interval
Akkermansia muciniphila	0								0



Microbiome Abundance Information:

• The Gl360[™] 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.



Notes:

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Order: 999999-9999 Client #: 999999

Doctor: Sample Doctor, MD Doctors Data Inc 123 Main St. St. Charles, 60174 USA Patient: Sample Patient Id: 999999 Age: 55 DOB: 01/01/1968 Sex: Female Sample Collection Date Collected Date Received Date Reported Date/Time 04/15/2024 04/25/2024 05/02/2024

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.

The majority of reference intervals are established from adult populations. Results may differ in pediatric populations and care should be taken when interpreting these values.

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.

Actinomycetales (order)

Actinomycetales are considered low abundance colonizers of the gastrointestinal tract with primary residence on the skin. Intake of proton-pump inhibitor drugs has been shown to increase the abundance of Actinomycetales in the gut, possibly by reducing gastric acidity and enabling intestinal colonization by oral microbes. Actinomycetales may be depleted in depressed irritable bowel syndrome patients. The abundance of *Actinomyces* spp. was shown to be higher with a strict vegetarian diet compared to a common 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.

Prevotella (genus)

Prevotella-rich dysbiosis has been associated with insulin-resistance, obesity and hypertension. *Prevotella* have been shown to be significantly decreased in Crohn's disease and Parkinson's disease. High levels of fiber and carbohydrates from fruits and vegetables in a Mediterranean diet have been shown to increase the relative abundance of *Prevotella*.

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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 Patient: Sample Patient

 Id: 999999

 Age: 55
 DOB: 01/01/1968

 Sex: Female

Sample Collection Date Collected Date Received Date Reported Date/Time 04/15/2024 04/25/2024 05/02/2024

Microbiome Abundance Information continued...

Uorea (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.

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.

Phascolarctobacterium (genus)

Phascolarctobacterium are in the Firmicutes phylum. *Phascolarctobacterium* can produce short chain fatty acids, including acetate and propionate, and may be associated with metabolic effects and mental state of the host. Patients diagnosed with major depressive disorder had increased levels of these species. Decreased levels of *Phascolarctobacterium* were found to be associated with Crohn's disease, ulcerative colitis and Alzheimer's disease. Consumption of cruciferous vegetables, such as broccoli, increases the abundance of *Phascolarctobacterium* in the gut.

Ruminococcus/Mediterraneibacter (genus)

Members of the *Ruminococcus* and the new genus *Mediterraneibacter* sensu produce acetate, but not butyrate. *Mediterraneibacter* (*Ruminococcus*) gnavus, like *Akkermansia muciniphila* is a mucin degrading specialist. Higher levels of *Ruminococcus*/*Mediterraneibacter* were associated with non-alcoholic fatty liver disease and non-alcoholic steatohepatitis. Reduced levels of *Ruminococcus bromii* were observed in patients with primary biliary cirrhosis. Increased abundance of *Ruminococcus*/*Mediterraneibacter* spp. has been reported in irritable bowel syndrome (IBS), whereas *Ruminococcus*/*Mediterraneibacter* spp. are reportedly decreased in abundance with Chrohn's disease and ulcerative colitis. *Mediterraneibacter gnavus* has been found to be in higher abundance in diarrhea predominant IBS. Intake of resistant starch has been associated with increased levels of *R. bromii*, whereas a diet rich in animal protein and fat was found to reduce the abundance of this species in the human gut.

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.

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.





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Microbiome Abundance Information continued...

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.

Mycoplasmatota (Tenericutes) (phylum)

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

Verrucomicrobiota (Verrucomicrobia) (phylum)

Verrucomicrobiota is a less common phylum in the human microbiota, but one with increasing recognition with regards to health. Verrucomicrobiota 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.