GENOVA DIAGNOSTICS

63 Zillicoa Street
Asheville, NC 28801
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GI fx GI Effects Stool Profiles

Patient: KELLY BURRIS

Order Number: R3290211
Reported: October 10, 2022
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Collected: September 27, 2022

Sayana Medical Spa & Wellness Center
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2200 GI Effects™ Comprehensive Profile - Stool

Powered by Genova AI

Results Overview

MALDIGESTION — INFLAMMATION — INFECTION — DYSBIOSIS — METABOLITE IMBALANCE

DIGESTION · INFLAMMATION · GUT MICROBIOME
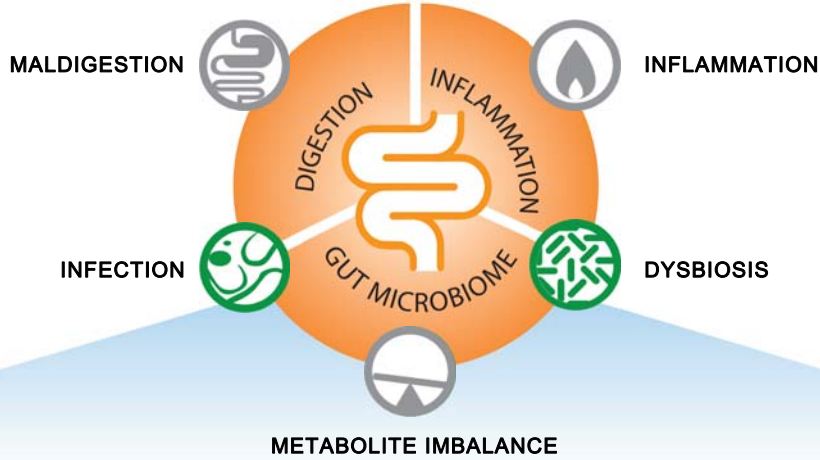
Functional Imbalance Scores

Key (< 2): Low Need for Support   (2-3): Optional Need for Support   (4-6): Moderate Need for Support   (7-10): High Need for Support
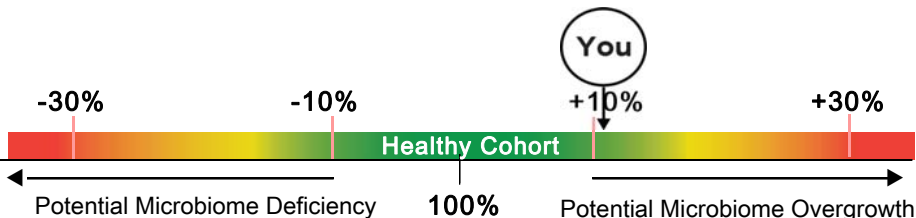
Need for Digestive Support	Need for Inflammation Modulation	Need for Microbiome Support	Need for Prebiotic Support	Need for Antimicrobial Support
MALDIGESTION	**INFLAMMATION**	**DYSBIOSIS**	**METABOLIC IMBALANCE**	**INFECTION**
3	2	0	2	0

Biomarkers

Maldigestion		Inflammation		Dysbiosis		Metabolic Imbalance		Infection	
Fecal Fats	▲	Secretory IgA	△	Total Abundance	△	Total SCFA's	▽	Total Abundance	△
Pancreatic Elastase	●	Calprotectin	●	IAD/Methane Score	●	n-Butyrate Conc.	▽	Parasitic Infection	●
Products of Protein Breakdown	●	Eosinophil Protein X	●	PP Bacteria/Yeast	●	SCFA (%)	●	Pathogenic Bacteria	●
		Occult Blood	●	Reference Variance	●	Beta-glucuronidase	●	PP Bacteria/Yeast	●

Therapeutic Support Options

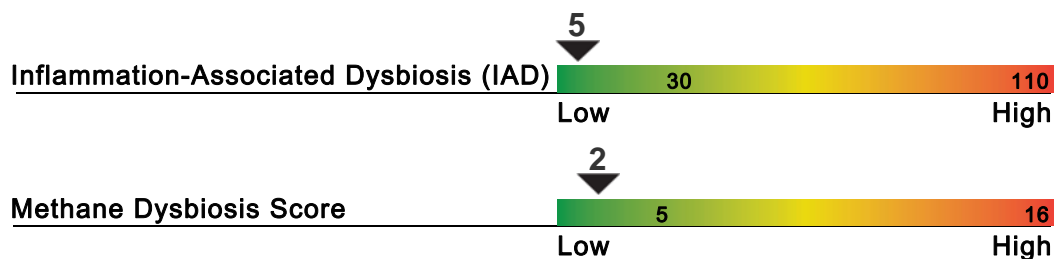|				
• Digestive Enzymes • Betaine HCl • Bile Salts • Apple Cider Vinegar • Mindful Eating Habits • Digestive Bitters	• Elimination Diet/ Food Sensitivity Testing • Mucosa Support: Slippery Elm, Althea, Aloe, DGL, etc. • Zinc Carnosine • L-Glutamine • Quercetin • Turmeric • Omega-3's • GI Referral (If Calpro is Elevated)	• Pre-/Probiotics • Increase Dietary Fiber Intake • Consider SIBO Testing • Increase Resistant Starches • Increase Fermented Foods • Meal Timing	• Pre-/Probiotics • Increased Dietary Fiber Intake • Increase Resistant Starches • Increase Fermented Foods • Calcium D-Glucarate (for high beta-glucuronidase)	• Antibiotics (if warranted) • Antimicrobial Herbal Therapy • Antiparasitic Herbal Therapy (if warranted) • *Saccharomyces boulardii*

Commensal Microbiome Analysis

Commensal Abundance

Patient Total Commensal Abundance

You

-30%   -10%   +10%   +30%

Healthy Cohort

Potential Microbiome Deficiency   100%   Potential Microbiome Overgrowth

Total Commenal Balance: The total commensal abundance is a sum-total of the reported commensal bacteria compared to a healthy cohort. Low levels of commensal bacteria are often observed after antimicrobial therapy, or in diets lacking fiber and/or prebiotic-rich foods and may indicate the need for microbiome support. Conversely, higher total commensal abundance may indicate potential bacteria overgrowth or probiotic supplementation.

Dysbiosis Patterns

Inflammation-Associated Dysbiosis (IAD)

5

30   110
Low   High

Methane Dysbiosis Score

2

5   16
Low   High

Dysbiosis Patterns: Genova's data analysis has led to the development of unique dysbiosis patterns, related to key physiologic disruptions, such as immunosuppression and inflammation. These patterns may represent dysbiotic changes that could pose clinical significance. Please see Genova's published literature for more details: https://rdcu.be/bRhzv
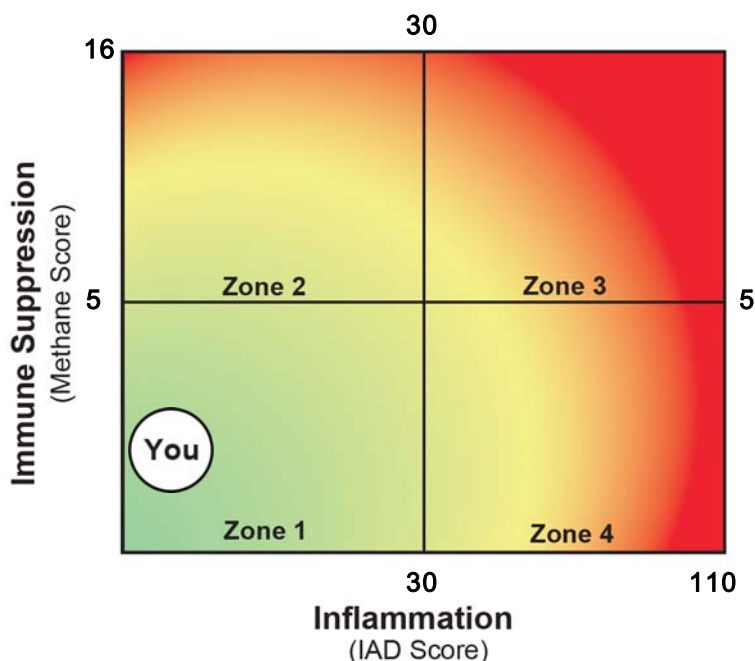
Zone 1: The commensal profile in this zone does not align with profiles associated with intestinal inflammation or immunosuppression. If inflammatory biomarkers are present, other causes need to be excluded, such as infection, food allergy, or more serious pathology.

Zone 2: This pattern of bacteria is associated with impaired intestinal barrier function (low fecal sIgA and EPX). Patients in this zone have higher rates of opportunistic infections (e.g. *Blastocystis spp.* & *Dientamoeba fragilis*) as well as fecal fat malabsorption. Commensal abundance is higher in this group suggesting potential bacterial overgrowth.

Zone 3: Patients in this zone may have more inflammation compared to those in zone 4. However, commensal abundance is usually higher making use of antimicrobial therapy relatively safer. Patients in this zone may have higher rates of pathogenic infections.

Zone 4: This commensal profile is associated with increased intestinal inflammation. IBD patients are more likely to have this pattern of bacteria. Commensal abundance is lower in this zone; therefore, antibiotic use for GI potential pathogens should be used with caution. In addition to standard treatment for intestinal inflammation, modulation of the commensal gut profile is encouraged.
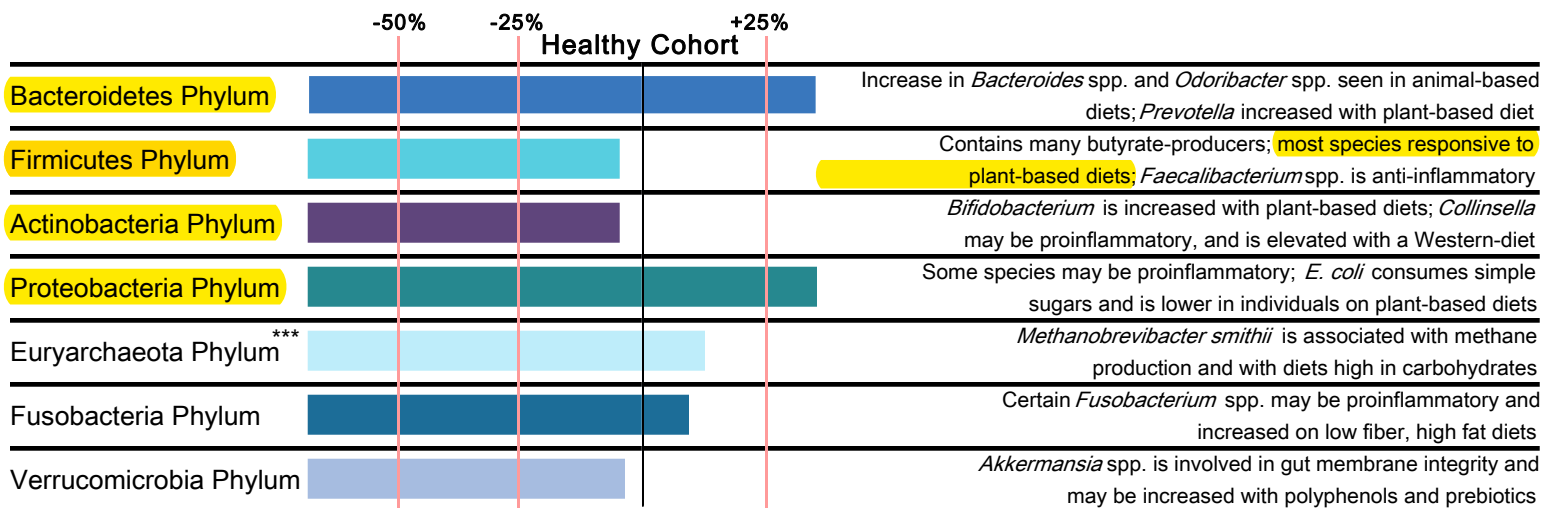
Commensal Microbiome Analysis

Commensal Balance
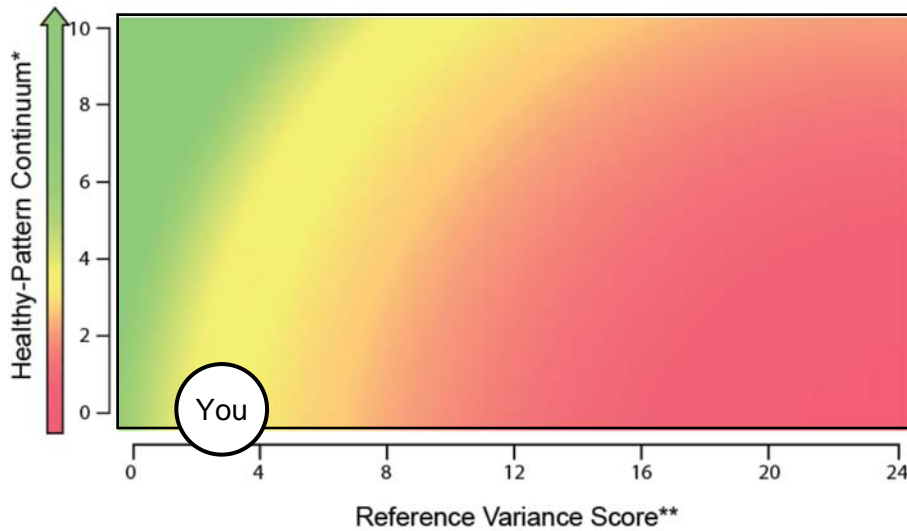
Balanced	Represents 95% of healthy individuals
Borderline	Represents 5% of healthy individuals
Imbalanced	Represents 60% of unhealthy individuals

*A progressive ranking scale based on a Genova proprietary algorithm that differentiates healthy and unhealthy commensal patterns.

**The total number of Commensal Bacteria (PCR) that are out of reference ranges for this individual.

Relative Commensal Abundance

Phylum	Description
Bacteroidetes Phylum	Increase in *Bacteroides* spp. and *Odoribacter* spp. seen in animal-based diets; *Prevotella* increased with plant-based diet
Firmicutes Phylum	Contains many butyrate-producers; most species responsive to plant-based diets; *Faecalibacterium* spp. is anti-inflammatory
Actinobacteria Phylum	*Bifidobacterium* is increased with plant-based diets; *Collinsella* may be proinflammatory, and is elevated with a Western-diet
Proteobacteria Phylum	Some species may be proinflammatory; *E. coli* consumes simple sugars and is lower in individuals on plant-based diets
Euryarchaeota Phylum ***	*Methanobrevibacter smithii* is associated with methane production and with diets high in carbohydrates
Fusobacteria Phylum	Certain *Fusobacterium* spp. may be proinflammatory and increased on low fiber, high fat diets
Verrucomicrobia Phylum	*Akkermansia* spp. is involved in gut membrane integrity and may be increased with polyphenols and prebiotics

Relative Abundance: The relative abundance compares the quantity of each of 7 major bacterial phyla to a healthy cohort. This can indicate broader variances in the patient's gut microbiome profile. Certain interventions may promote or limit individual phyla when clinically appropriate. Please refer to Genova's Stool Testing Support Guide for more information on modulation of commensal bacteria through diet & nutrient interventions. ***Approximately 75% of the healthy cohort had below detectable levels of *Methanobrevibacter smithii.*

Physician Notes/Recommendations
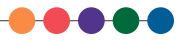
2200 GI Effects™ Comprehensive Profile - Stool

Methodology: GC-FID, Automated Chemistry, EIA

	Result	QUINTILE DISTRIBUTION (1st, 2nd, 3rd, 4th, 5th)	Reference Range

Digestion and Absorption

	Result		Reference Range
Pancreatic Elastase 1 †	>500		>200 mcg/g
Products of Protein Breakdown (Total*) (Valerate, Isobutyrate, Isovalerate)	3.2		1.8-9.9 micromol/g
Fecal Fat (Total*)	57.0 H		3.2-38.6 mg/g
Triglycerides	2.0		0.3-2.8 mg/g
Long-Chain Fatty Acids	35.8 H		1.2-29.1 mg/g
Cholesterol	14.3 H		0.4-4.8 mg/g
Phospholipids	4.9		0.2-6.9 mg/g

Inflammation and Immunology

	Result		Reference Range
Calprotectin †	<16		<=50 mcg/g
Eosinophil Protein X (EPX)†	<DL		<=2.7 mcg/g
Fecal secretory IgA	1,781		<=2,040 mcg/mL

Gut Microbiome Metabolites

Metabolic

	Result		Reference Range
Short-Chain Fatty Acids (SCFA) (Total*) (Acetate, n-Butyrate, Propionate)	28.7		>=23.3 micromol/g
n-Butyrate Concentration	6.0		>=3.6 micromol/g
n-Butyrate %	20.9		11.8-33.3 %
Acetate %	58.6		48.1-69.2 %
Propionate %	20.4		<=29.3 %
Beta-glucuronidase	1,592		368-6,266 U/g

Total value is equal to the sum of all measurable parts.
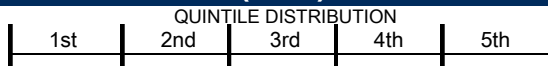*†These results are not represented by quintile values.*
Tests were developed and their performance characteristics determined by Genova Diagnostics. Unless otherwise noted with ♦, the assays have not been cleared by the U.S. Food and Drug Administration.

Methodology: DNA by PCR

Gastrointestinal Microbiome (PCR)**

Commensal Bacteria (PCR)	Result CFU/g stool	QUINTILE DISTRIBUTION	Reference Range CFU/g stool
Bacteroidetes Phylum			
Bacteroides-Prevotella group	2.8E8		3.4E6 -1.5E9
Bacteroides vulgatus	3.0E9 H		<=2.2E9
Barnesiella spp.	2.0E7		<=1.6E8
Odoribacter spp.	4.5E7		<=8.0E7
Prevotella spp.	4.4E6		1.4E5 -1.6E7
Firmicutes Phylum			
Anaerotruncus colihominis	1.3E7		<=3.2E7
Butyrivibrio crossotus	<DL L		5.5E3 -5.9E5
Clostridium spp.	1.2E9		1.7E8 -1.5E10
Coprococcus eutactus	5.6E6		<=1.2E8
Faecalibacterium prausnitzii	1.5E9		5.8E7 -4.7E9
Lactobacillus spp.	2.8E9		8.3E6 -5.2E9
Pseudoflavonifractor spp.	1.5E8 H		4.2E5 -1.3E8
Roseburia spp.	1.9E9		1.3E8 -1.2E10
Ruminococcus spp.	1.1E8		9.5E7 -1.6E9
Veillonella spp.	6.0E6		1.2E5 -5.5E7
Actinobacteria Phylum			
Bifidobacterium spp.	1.3E9		<=6.4E9
Bifidobacterium longum	1.1E7		<=7.2E8
Collinsella aerofaciens	9.1E7		1.4E7 -1.9E9
Proteobacteria Phylum			
Desulfovibrio piger	1.5E5		<=1.8E7
Escherichia coli	3.9E6		9.0E4 -4.6E7
Oxalobacter formigenes	2.4E6		<=1.5E7
Euryarchaeota Phylum			
Methanobrevibacter smithii	4.7E6		<=8.6E7
Fusobacteria Phylum			
Fusobacterium spp.	2.8E4		<=2.4E5
Verrucomicrobia Phylum			
Akkermansia muciniphila	1.1E7		>=1.2E6
Firmicutes/Bacteroidetes Ratio			
Firmicutes/Bacteroidetes (F/B Ratio)	22		12-620

The gray-shaded portion of a quintile reporting bar represents the proportion of the reference population with results below detection limit.

Commensal results and reference range values are displayed in a computer version of scientific notation, where the capital letter "E" indicates the exponent value (e.g., 7.3E6 equates to 7.3 x 10⁶ or 7,300,000).

The Firmicutes/Bacteroidetes ratio (F/B Ratio) is estimated by utilizing the lowest and highest values of the reference range for individual organisms when patient results are reported as <DL or >UL.

Methodology: Culture/MALDI-TOF MS, Automated and Manual Biochemical Methods, Vitek® 2 System Microbial identification and Antibiotic susceptibility

Gastrointestinal Microbiome (Culture)

Human microflora is influenced by environmental factors and the competitive ecosystem of the organisms in the GI tract. Pathogenic significance should be based upon clinical symptoms.

Additional Bacteria

Non-Pathogen: Organisms that fall under this category are those that constitute normal, commensal flora, or have not been recognized as etiological agents of disease.

Potential Pathogen: Organisms that fall under this category are considered potential or opportunistic pathogens when present in heavy growth.

Pathogen: The organisms that fall under this category have a well-recognized mechanism of pathogenicity in clinical literature and are considered significant regardless of the quantity that appears in the culture.

Microbiology Legend

NG	NP	PP	P
No Growth	Non-Pathogen	Potential Pathogen	Pathogen

Bacteriology (Culture)

Organism	Quantity	Category
Lactobacillus spp.		NG
Escherichia coli	4+	NP
Bifidobacterium (Anaerobic Culture)	2+	NP

Additional Bacteria
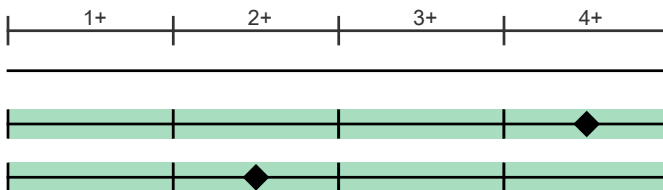
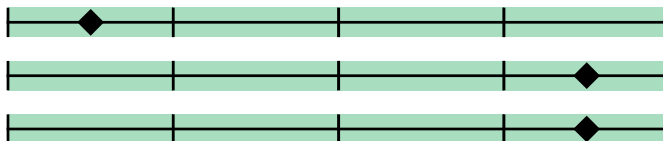| Organism	Quantity	Category
alpha haemolytic Streptococcus	1+	NP
Mucoid Escherichia coli	4+	NP
Enterococcus faecalis	4+	NP

Mycology (Culture) — NG

Parasitology

Microscopic O&P Results

Microscopic O&P is capable of detecting all described gastrointestinal parasites. The organisms listed in the box represent those commonly found in microscopic stool analysis. Should an organism be detected that is not included in the list below, it will be reported in the Additional Results section. These results were obtained using wet preparation(s) and trichrome stained smear. For an extensive reference of all potentially detectable organisms, please visit　　www.gdx.net/product/gi-effects-comprehensive-stool-test

Genus/species	Result
Nematodes - roundworms	
Ancylostoma/Necator (Hookworm)	Not Detected
Ascaris lumbricoides	Not Detected
Capillaria philippinensis	Not Detected
Enterobius vermicularis	Not Detected
Strongyloides stercoralis	Not Detected
Trichuris trichiura	Not Detected
Cestodes - tapeworms	
Diphyllobothrium latum	Not Detected
Dipylidium caninum	Not Detected
Hymenolepis diminuta	Not Detected
Hymenolepis nana	Not Detected
Taenia spp.	Not Detected
Trematodes - flukes	
Clonorchis/Opisthorchis spp.	Not Detected
Fasciola spp./ *Fasciolopsis buski*	Not Detected
Heterophyes/Metagonimus	Not Detected
Paragonimus spp.	Not Detected
Schistosoma spp.	Not Detected
Protozoa	
Balantidium coli	Not Detected
Blastocystis spp.	Not Detected
Chilomastix mesnili	Not Detected
Cryptosporidium spp.	Not Detected
Cyclospora cayetanensis	Not Detected
Dientamoeba fragilis	Not Detected
Entamoeba coli	Not Detected
Entamoeba histolytica/dispar	Not Detected
Entamoeba hartmanii	Not Detected
Entamoeba polecki	Not Detected
Endolimax nana	Not Detected
Giardia	Not Detected
Iodamoeba buetschlii	Not Detected
Cystoisospora spp.	Not Detected
Trichomonads (e.g. *Pentatrichomonas*)	Not Detected
Additional Findings	
White Blood Cells	Not Detected
Charcot-Leyden Crystals	Not Detected
Other Infectious Findings	

One negative specimen does not rule out the possibility of a parasitic infection.

Parasitology

PCR Parasitology - Protozoa

Methodologies: DNA by PCR, Next Generation Sequencing

Organism	Result	Units		Expected Result
Blastocystis spp.	<2.14e2	femtograms/microliter C&S stool	Not Detected	Not Detected
Cryptosporidium parvum/hominis	<1.76e2	genome copies/microliter C&S stool	Not Detected	Not Detected
Cyclospora cayetanensis	<2.65e2	genome copies/microliter C&S stool	Not Detected	Not Detected
Dientamoeba fragilis	<1.84e2	genome copies/microliter C&S stool	Not Detected	Not Detected
Entamoeba histolytica	<9.64e1	genome copies/microliter C&S stool	Not Detected	Not Detected
Giardia	<1.36e1	genome copies/microliter C&S stool	Not Detected	Not Detected

Additional Results

Methodology: Fecal Immunochemical Testing (FIT)

	Result	Expected Value
Fecal Occult Blood◆	Negative	Negative
Consistency††	Not Given	

††Results provided from patient input.

Tests were developed and their performance characteristics determined by Genova Diagnostics. Unless otherwise noted with ◆, the assays have not been cleared by the U.S. Food and Drug Administration.

Commentary

** Indicates testing performed at Genova Diagnostics 3425 Corporate Way, Duluth GA 30096
  Lab Director = Robert M. David, PhD, Lab Director · CLIA Lic. #11D0255349 · Medicare Lic. #34-8475
 · Georgia Lab Lic. Code #067-007 · New York Clinical Lab PFI #4578 · Florida Clinical Lab Lic. #800008124

Commentary is provided to the practitioner for educational purposes and should not be interpreted as diagnostic or as treatment recommendations. Diagnosis and treatment decisions are the practitioner's responsibility.

For more information regarding GI Effects clinical interpretation, please refer to the GI Effects Support Guide at **www.gdx.net/gieffectsguide.**

Patient: KELLY BURRIS

2200 GI Effects™ Comprehensive Profile - Stool

Commensal Bacteria	Patient Results Out of Reference Range	IBS	IBD	Metabolic Syndrome	Chronic Fatigue	Auto-immune	Type 2 Diabetes	High Blood Pressure	Mood Disorders
Interpretation At-a-Glance									
		Genova Diagnostics Commensal Bacteria Clinical Associations*							
Bacteroidetes Phylum									
Bacteroides-Prevotella group		↑	↑	↑	↑	↑	↑	↑	↑
Bacteroides vulgatus	H	↑			↑	↑		↑	↑
Barnesiella spp.									
Odoribacter spp.									
Prevotella spp.		↑		↑	↑	↑		↑	↑
Firmicutes Phylum									
Anaerotruncus colihominis		↑	↑	↑	↑	↑	↑	↑	↑
Butyrivibrio crossotus	L								
Clostridium spp.									
Coprococcus eutactus		↑			↑	↑		↑	↑
Faecalibacterium prausnitzii		↑				↑			↑
Lactobacillus spp.									
Pseudoflavonifractor spp.	H	↑	↑	↑	↑	↑	↑	↑	↑
Roseburia spp.			↓						
Ruminococcus spp.		↓↑	↓	↓	↓	↓↑	↓↑	↓↑	↓↑
Veillonella spp.		↑	↑	↑	↑	↑	↑		
Actinobacteria Phylum									
Bifidobacterium spp.									
Bifidobacterium longum									
Collinsella aerofaciens		↓↑	↓↑	↓	↓↑	↓↑	↓↑	↓↑	↓↑
Proteobacteria Phylum									
Desulfovibrio piger									↑
Escherichia coli		↑	↑	↑	↑	↑	↑	↑	↑
Oxalobacter formigenes		↑		↑	↑				↑
Euryarchaeota Phylum									
Methanobrevibacter smithii		↑				↑			↑
Fusobacteria Phylum									
Fusobacterium spp.		↑	↑	↑	↑	↑	↑	↑	↑
Verrucomicrobia Phylum									
Akkermansia muciniphila		↓	↓	↓	↓	↓	↓	↓	↓

*Information derived from GDX results data comparing a healthy cohort to various clinical condition cohorts. The chart above showing a comparison of patient results to clinical conditions is meant for informational purposes only; it is not diagnostic, nor does it imply that the patient has a specific clinical diagnosis or condition.

The arrows indicate Genova's clinical condition cohort test results falling below ↓ or above ↑ the reference range that is greater than that of Genova's healthy cohort.

↓↑ Indicates Genova's clinical condition cohort test results falling below and above the reference range that are greater than that of Genova's healthy cohort.

Cells with bolded arrows indicate Genova's clinical condition cohort had more test results falling above versus below ↓↑ or more below versus above ↓↑ the reference range compared to that of Genova's healthy cohort.

GIECA

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Interpretation At-a-Glance										
Biomarker	**Patient Results Out of Reference Range**	**Genova Diagnostics Biomarker Clinical Associations***								
		IBS	**IBD**	**Metabolic Syndrome**	**Chronic Fatigue**	**Auto-immune**	**Type 2 Diabetes**	**High Blood Pressure**	**Mood Disorders**	
Pancreatic Elastase		↓	↓	↓	↓	↓	↓	↓	↓	
Products of Protein Breakdown (Total)							↑↓			
Fecal Fat (Total*)	H	↑		↑	↑	↑	↓↑	↑	↑	
Triglycerides		↑			↑	↑	↑	↑	↑	
Long-Chain Fatty Acids	H	↑			↑	↑	↓↑	↑	↑	
Cholesterol	H						↓↑	↑		
Phospholipids		↑	↑	↑	↑	↑	↑	↑	↑	
Calprotectin			↑					↑		
Eosinophil Protein X (EPX)			↑							
Fecal secretory IgA		↑	↑	↑	↑	↑	↑	↑	↑	
Short-Chain Fatty Acids (SCFA) (Total)					↓	↓				
n-Butyrate Concentration				↓						
n-Butyrate %										
Acetate %					↑↓		↓↑			
Propionate %				↑			↑	↑		
Beta-glucuronidase						↑↓			↑↓	

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