

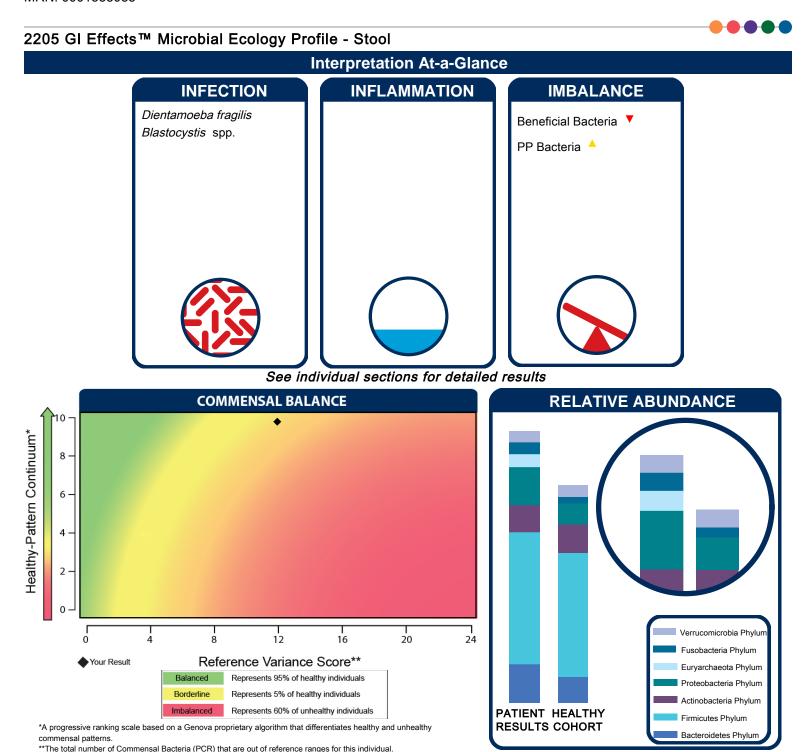


Patient: MALE TEST DOB: February 02, 1956 Sex: M MRN: 0001558085 3425 Corporate Way Duluth, GA 30096

Order Number: M9300998

Completed: January 31, 2019 Received: January 30, 2019 Collected: January 30, 2019 Test Doctor 84 Peachtree Rd Asheville, NC 28803

GI Effects X Stool Profiles



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2205 GI Effects™ Microbial Ecology Profile - Stool

3425 Corporate Way Duluth, GA 30096

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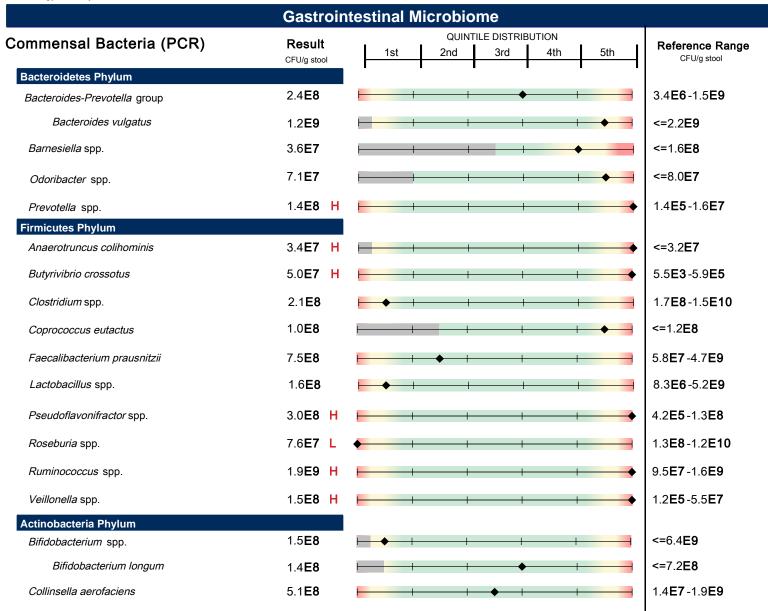
Received: January 30, 2019

Collected: January 30, 2019

Methodology: DNA by PCR

GI Effects Stool Profiles

Test Doctor 84 Peachtree Rd Asheville, NC 28803



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).

Patient: MALE TEST

ID: M9300998

Methodology: DNA by PCR		
	Gastroin	testinal Microbiome
Commensal Bacteria (PCR)	Result CFU/g stool	QUINTILE DISTRIBUTION 1st 2nd 3rd 4th 5th CFU/g stool
Proteobacteria Phylum		
Desulfovibrio piger	8.7 E7 H	<=1.8 E7
Escherichia coli	1.3 E8 H	9.0 E4 -4.6 E7
Oxalobacter formigenes	5.0 E7 H	<=1.5 E7
Euryarchaeota Phylum		
Methanobrevibacter smithii	1.4 E8 H	<=8.6E7
Fusobacteria Phylum		
<i>Fusobacterium</i> spp.	2.3 E7 H	<=2.4E5
Verrucomicrobia Phylum		
Akkermansia muciniphila	3.1 E7	>=1.2 E 6
Firmicutes/Bacteroidetes Ratio		
Firmicutes/Bacteroidetes (F/B Ratio)	11 L	↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓

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.

NG

No Growth

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

Ρ

Pathogen

Gastrointestinal Microbiome**

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.

Microbiology Legend

PP

Potential

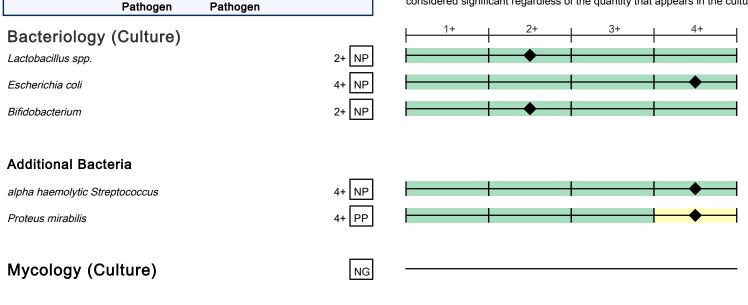
NP

Non-

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.



KOH Preparation for Yeast

Methodology: Potassium Hydroxide (KOH) Preparation for Yeast

Potassium Hydroxide (KOH) Preparation for Yeast

These yeast usually represent the organisms isolated by culture. In the presence of a negative yeast culture, microscopic yeast may reflect organisms not viable enough to grow in culture. The presence of yeast on KOH prep should be correlated with the patient's symptoms. However, moderate to many yeast suggests yeast overgrowth.

Results

KOH Preparation, stool

No Yeast Present

The result is reported as the amount of yeast seen microscopically: Rare: 1-2 per slide Few: 2-5 per high power field (HPF) Moderate: 5-10 per HPF Many: >10 per HPF

** Indicates testing performed by Genova Diagnostics, Inc. 63 Zillicoa St., Asheville, NC 28801-0174 A. L. Peace-Brewer, PhD, D(ABMLI), Lab Director - CLIA Lic. #34D0655571 - Medicare Lic. #34-8475



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. 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.	Moderate Detected	
Chilomastix mesnili	Not Detected	
Cryptosporidium spp.	Not Detected	
Cyclospora cayetanensis	Not Detected	
Dientamoeba fragilis	Few 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	
odamoeba buetschlii	Not Detected	
Cystoisospora spp.	Not Detected	
Trichomonads (e.g. Pentatrichomonas)	Not Detected	
Additional Findings		
White Blood Cells	Not Detected	
Charcot-Levden Crystals	Not Detected	

Charcot-Leyden Crystals **Other Infectious Findings** Not Detected

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Parasitology

PCR Parasitology - Protozoa**

Methodologies: DNA by PCR, Next Generation Sequencing

Organism	Result	Units		Expected Result		
Blastocystis spp.	2.00e3	femtograms/microliter C&S stool	Detected	Not Detected		
Cryptosporidium spp.	<4.87e2	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	2.96e3	genome copies/microliter C&S stool	Detected	Not Detected		
Entamoeba histolytica	<1.14e3	genome copies/microliter C&S stool	Not Detected	Not Detected		
Giardia	<1.57e2	genome copies/microliter C&S stool	Not Detected	Not Detected		
Blastocystis spp. Reflex S	Subtyping					
Type 1: Not Detected	Туре 4	: Not Detected Type 7	7: Not Detected)		
Type 2: Detected	Туре 5	: Not Detected Type 8	3: Not Detected)		
Type 3: Not Detected	Туре 6	: Not Detected Type 9	: Not Detected)		

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Additional Results

	Result
Color††	Brown
Consistency ⁺⁺	Formed/Normal

††Results provided from patient input.

	Z	onulin Family Peptide	
Methodology: EIA	Result	Reference Range	Zonulin Family Peptide
Zonulin Family Peptide, Stool	100.0	22.3-161.1 ng/mL	This test is for research use only. Genova will not provide support on interpreting the test results. This test does not
			detect zonulin. ¹ The Scheffler paper suggests that the IDK kit may detect a zonulin family peptide, such as properdin Genova's unpublished data demonstrated that the current IDK kit results were associated with stool inflammation biomarkers and an inflammation-associated dysbiosis
			profile. The performance characteristics of Zonulin Family Peptide have been verified by Genova Diagnostics. Inc. The assa

have been verified by Genova Diagnostics, Inc. The assay has not been cleared by the U.S. Food and Drug Administration.

Reference:

1. Scheffler L, et al. Widely Used Commercial ELISA Does Not Detect Precursor of Haptoglobin2, but Recognizes Properdin as a Potential Second Member of the Zonulin Family. *Front Endocrinol.* 2018;9:22.

Page 7

Macroscopic Exam for Worms **

Methodology: Macroscopic Evaluation

No larvae seen macroscopically.

Add-on Testing								
lethodology: EIA	Result	Expected Value	HpSA (<i>Helicobacter pylori</i> stool antigen)					
HpSA - <i>H. pylori</i>	Negative	Negative	Helicobacter pylori is a bacterium which causes peptic ulcer disease and plays a role in the development of					
<i>Campylobacter</i> spp. •**	Negative	Negative	gastric cancer. Direct stool testing of the antigen (HpSA is highly accurate and is appropriate for diagnosis and					
Clostridium difficile+**	Negative	Negative	follow-up of infection.					
Shiga toxin <i>E. coli</i> ∙**	Negative	Negative	<i>Campylobacter</i> spp. <i>Campylobacter jejuni</i> is the most frequent cause of					
Fecal Lactoferrin◆**	Negative	Negative	bacterial-induced diarrhea. While transmission can occu via the fecal-oral route, infection is primarily associated with the ingestion of contaminated and poorly cooked foods of animal origin, notably, red meat and milk.					
			<i>Clostridium difficile</i> <i>Clostridium difficile</i> is an anaerobic, spore-forming gram-positive bacterium. After a disturbance of the gut flora (usually with antibiotics), colonization with <i>Clostridium difficile</i> can take place. <i>Clostridium difficile</i> infection is much more common than once thought.					
			Shiga toxin <i>E. coli</i> Shiga toxin-producing <i>Escherichia coli</i> (STEC) is a grou of bacterial strains that have been identified as worldwid causes of serious human gastrointestinal disease. The subgroup enterohemorrhagic <i>E. coli</i> includes over 100 different serotypes, with 0157:H7 being the most significant, as it occurs in over 80% of all cases. Contaminated food continues to be the principal vehicle for transmission; foods associated with outbreaks includ alfalfa sprouts, fresh produce, beef, and unpasteurized					

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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.

juices.

ID: M9300998

Methodology: Vitek 2® System Microbial Antibiotic susceptibility, Manual Minimum Inhibition Concentration

Bacteria Sensitivity

Prescriptive Agents

R	1	S-DD	S	NI
R				
			S	
			S	
			S	
R				
			S	
	R	R	R	R IIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIII

Natural Agents

Proteus mirabilis	LOW INHIBITION	I	HIGH INHIBITION
Berberine			
Oregano			
Plant Tannins			
Uva-Ursi			

Prescriptive Agents:

The R (Resistant) category implies isolate is not inhibited by obtainable levels of pharmaceutical agent.

The I (Intermediate) category includes isolates for which the minimum inhibition concentration (MIC) values usually approach obtainable pharmaceutical agent levels and for which response rates may be lower than for susceptible isolates.

The S-DD (Susceptible-Dose Dependent) category implies clinical efficacy when higher than normal dosage of a drug can be used and maximal concentration achieved.

The S (Susceptible) column implies that isolates are inhibited by the usually achievable concentrations of the pharmaceutical agent.

NI (No Interpretive guidelines established) category is used for organisms that currently do not have established guidelines for MIC interpretation.

Refer to published pharmaceutical guidelines for appropriate dosage therapy.

Natural Agents:

In this assay, inhibition is defined as the reduction level on organism growth as a direct result of inhibition by a substance. The level of inhibition is an indicator of how effective the substance was at limiting the growth of an organism in an in vitro environment. High inhibition indicates a greater ability by the substance to limit growth, while Low Inhibition a lesser ability to limit growth. The designated natural products should be considered investigational in nature and not be viewed as standard clinical treatment substances.



2205 GI Effects™ Microbial Ecology Profile - Stool

Interpretation At-a-Glance										
Commensal Bacteria Out Refer	Patient Results Out of									
	Out of Reference Range	IBS	IBD	Metabolic Syndrome	Chronic Fatigue	Auto- immune	Type 2 Diabetes	High Blood Pressure	Mood Disorder	
Bacteroidetes Phylum							1			
Bacteroides-Prevotella group		1	1	1	1	1	1	1	1	
Bacteroides vulgatus		1			1	1		1	1	
<i>Barnesiella</i> spp.										
<i>Odoribacter</i> spp.										
<i>Prevotella</i> spp.	н	1		1	1	1		1	1	
Firmicutes Phylum										
Anaerotruncus colihominis	н	1	1	1	1	1	1	1	1	
Butyrivibrio crossotus	н									
<i>Clostridium</i> spp.										
Coprococcus eutactus		1			1	1		1	1	
Faecalibacterium prausnitzii		1				1			1	
Lactobacillus spp.										
Pseudoflavonifractor spp.	н	1	1	1	1	1	1	1	1	
<i>Roseburia</i> spp.	L		+							
Ruminococcus spp.	Н		+	•	4		₹↑	↓ ↑	↓ ↑	
<i>Veillonella</i> spp.	Н	1	1	1	1	1	1		1	
Actinobacteria Phylum										
<i>Bifidobacterium</i> spp.										
Bifidobacterium longum										
Collinsella aerofaciens			↓ ↑	↓	↓ ↑			♦	♦ ↑	
Proteobacteria Phylum										
Desulfovibrio piger	н								1	
Escherichia coli	н	1	1	1	1	1	1	1	1	
Oxalobacter formigenes	н	1		1	1				1	
Euryarchaeota Phylum										
Methanobrevibacter smithii	н	1				1			1	
Fusobacteria Phylum										
Fusobacterium spp.	н	1	1	1	1	1	1	1	1	
Verrucomicrobia Phylum										
Akkermansia muciniphila		¥	1	4	4	4	4	4	Ļ	
Information derived from GDX re- esults to clinical conditions is me										
*Information derived from GDX re- results to clinical conditions is me condition. The arrows indicate Genova's clir cohort.	ant for informati	onal purpose	s only; it is no	ot diagnostic, no	or does it impl	y that the patio	ent has a spec	ific clinical diag	gnosis o	

Noticates 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 4 or more below versus above 4 the reference range compared to that of Genova's healthy cohort.