GENOVA DIAGNOSTICS

3425 Corporate Way
Duluth, GA 30096

GI fx GI Effects Stool Profiles

Patient:

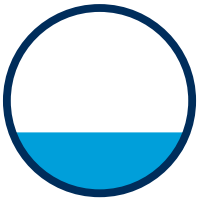
DOB:
Sex:
MRN:

2200 GI Effects™ Comprehensive Profile - Stool

Interpretation At-a-Glance

INFECTION

INFLAMMATION



INSUFFICIENCY

Pancreatic Elastase 1 ▼

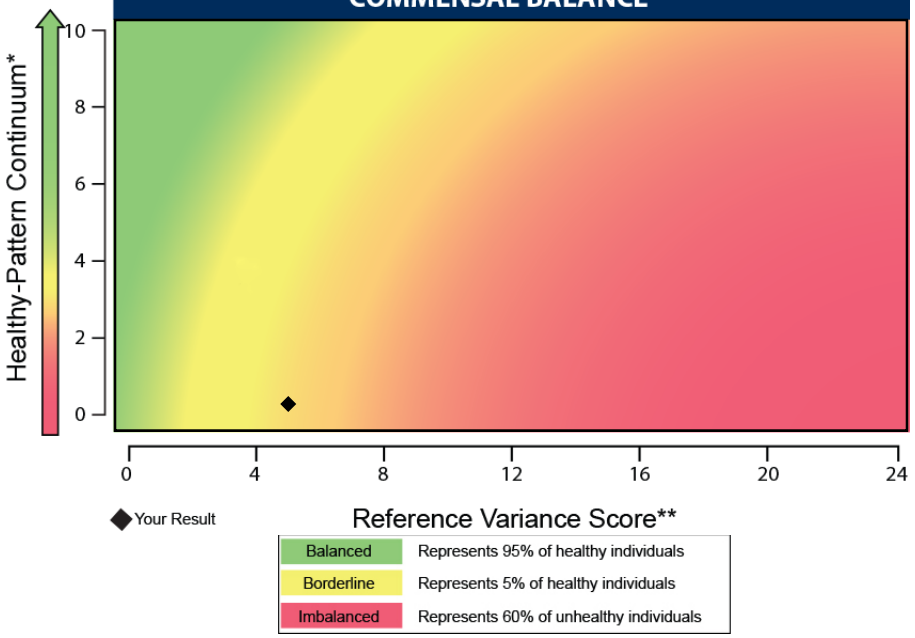
IMBALANCE

Beneficial Bacteria ▼

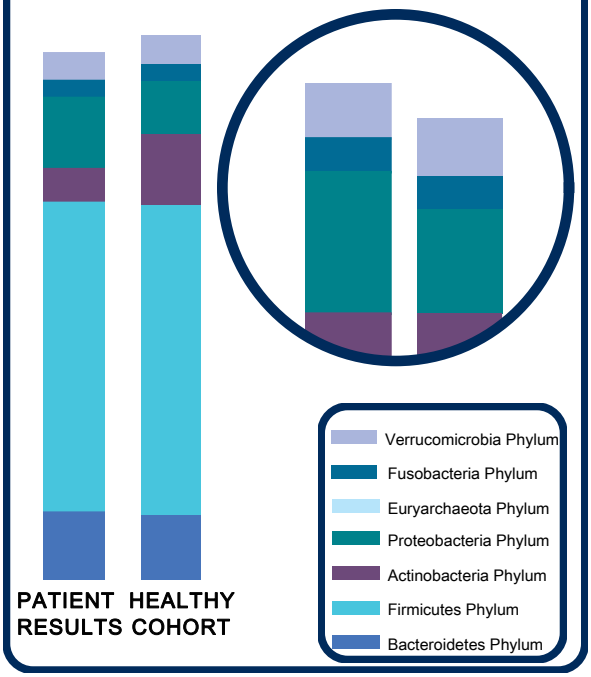
PP Bacteria ▲

PP Yeast/Fungi ▲

COMMENSAL BALANCE



RELATIVE ABUNDANCE



*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.

2200 GI Effects™ Comprehensive Profile - Stool

Interpretation At-a-Glance

Commensal Bacteria	Patient Results Out of Reference Range	Genova Diagnostics Commensal Bacteria Clinical Associations*							
		IBS	IBD	Metabolic Syndrome	Chronic Fatigue	Auto-immune	Type 2 Diabetes	High Blood Pressure	Mood Disorders
Bacteroidetes Phylum									
Bacteroides-Prevotella group		↑	↑	↑	↑	↑	↑	↑	↑
Bacteroides vulgatus	H	↑			↑	↑		↑	↑
Barnesiella spp.									
Odoribacter spp.	H								
Prevotella spp.	L	↑		↑	↑	↑		↑	↑
Firmicutes Phylum									
Anaerotruncus colihominis		↑	↑	↑	↑	↑	↑	↑	↑
Butyrivibrio crossotus									
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	L	**↓↑**	**↓↑**	↓	**↓↑**	**↓↑**	**↓↑**	**↓↑**	**↓↑**
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 clincial 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 clincial 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.

2200 GI Effects™ Comprehensive Profile - Stool

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	L	↓	↓	↓	↓	↓	↓	↓	↓
Products of Protein Breakdown (Total)							↑↓		
Fecal Fat (Total*)		↑		↑	↑	↑	↓↑	↑	↑
Triglycerides		↑			↑	↑	↑	↑	↑
Long-Chain Fatty Acids		↑			↑	↑	↓↑	↑	↑
Cholesterol							↓↑	↑	
Phospholipids		↑	↑	↑	↑	↑	↑	↑	↑
Calprotectin			↑					↑	
Eosinophil Protein X (EPX)			↑						
Fecal secretory IgA		↑	↑	↑	↑	↑	↑	↑	↑
Short-Chain Fatty Acids (SCFA) (Total)					↓	↓			
n-Butyrate Concentration				↓					
n-Butyrate %									
Actetate %					↑↓		↓↑		
Propionate %				↑			↑	↑	
Beta-glucuronidase						↑↓			↑↓

***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 clincial 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 clincial 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.

GI Effects™ Comprehensive Profile - Stool

Methodology: GC/MS, Automated Chemistry, EIA

	Results	QUINTILE DISTRIBUTION (1st 2nd 3rd 4th 5th)	Reference Range
Digestion and Absorption			
Pancreatic Elastase 1 †	158 L	100 200	>200 mcg/g
Products of Protein Breakdown (Total*) (Valerate, Isobutyrate, Isovalerate)	2.6		1.8-9.9 micromol/g
Fecal Fat (Total*)	19.5		3.2-38.6 mg/g
Triglycerides	1.1		0.3-2.8 mg/g
Long-Chain Fatty Acids	12.9		1.2-29.1 mg/g
Cholesterol	0.5		0.4-4.8 mg/g
Phospholipids	5.0		0.2-6.9 mg/g
Inflammation and Immunology			
Calprotectin †	<16	50 120	<=50 mcg/g
Eosinophil Protein X (EPX)†	0.6	1.1 4.6	<=4.6 mcg/g
Fecal secretory IgA	206		<=885 mcg/g
Gastrointestinal Microbiome			
Metabolic			
Short-Chain Fatty Acids (SCFA) (Total*) (Acetate, n-Butyrate, Propionate)	47.5		>=23.3 micromol/g
n-Butyrate Concentration	10.6		>=3.6 micromol/g
n-Butyrate %	22.3		11.8-33.3 %
Acetate %	62.8		48.1-69.2 %
Propionate %	14.7		<=29.3 %
Beta-glucuronidase	2,297		368-6,266 U/g

**Total value is equal to the sum of all measurable parts.*

†These results are not represented by quintile values.

A. L. Peace-Brewer, PhD, D(ABMLI), Lab Director · CLIA Lic. #34D0655571 · Medicare Lic. #34-8475

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

Commensal Bacteria (PCR)	Result CFU/g stool		QUINTILE DISTRIBUTION 1st 2nd 3rd 4th 5th	Reference Range CFU/g stool
Bacteroidetes Phylum				
Bacteroides-Prevotella group	6.1**E8**			3.4**E6**-1.5**E9**
Bacteroides vulgatus	2.6**E9**	H		<=2.2**E9**
Barnesiella spp.	<DL			<=1.6**E8**
Odoribacter spp.	8.2**E7**	H		<=8.0**E7**
Prevotella spp.	<DL	L		1.4**E5**-1.6**E7**
Firmicutes Phylum				
Anaerotruncus colihominis	4.7**E6**			<=3.2**E7**
Butyrivibrio crossotus	7.2**E4**			5.5**E3**-5.9**E5**
Clostridium spp.	1.8**E9**			1.7**E8**-1.5**E10**
Coprococcus eutactus	7.0**E5**			<=1.2**E8**
Faecalibacterium prausnitzii	2.5**E9**			5.8**E7**-4.7**E9**
Lactobacillus spp.	1.4**E8**			8.3**E6**-5.2**E9**
Pseudoflavonifractor spp.	1.9**E8**	H		4.2**E5**-1.3**E8**
Roseburia spp.	2.0**E9**			1.3**E8**-1.2**E10**
Ruminococcus spp.	3.0**E8**			9.5**E7**-1.6**E9**
Veillonella spp.	1.5**E7**			1.2**E5**-5.5**E7**
Actinobacteria Phylum				
Bifidobacterium spp.	2.8**E8**			<=6.4**E9**
Bifidobacterium longum	3.1**E7**			<=7.2**E8**
Collinsella aerofaciens	<DL	L		1.4**E7**-1.9**E9**
Proteobacteria Phylum				
Desulfovibrio piger	6.6**E4**			<=1.8**E7**
Escherichia coli	5.2**E6**			9.0**E4**-4.6**E7**
Oxalobacter formigenes	1.8**E6**			<=1.5**E7**
Euryarchaeota Phylum				
Methanobrevibacter smithii	<DL			<=8.6**E7**
Fusobacteria Phylum				
Fusobacterium spp.	1.7**E4**			<=2.4**E5**
Verrucomicrobia Phylum				
Akkermansia muciniphila	7.8**E6**			>=1.2**E6**
Firmicutes/Bacteroidetes Ratio				
Firmicutes/Bacteroidetes (F/B Ratio)	10	L		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 10^6 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

Bacteriology (Culture)

			1+	2+	3+	4+
Lactobacillus spp.		NG				
Escherichia coli	4+	NP				◆
Bifidobacterium	4+	NP				◆

Additional Bacteria

			1+	2+	3+	4+
alpha haemolytic Streptococcus	3+	NP			◆	
Klebsiella oxytoca	4+	PP				◆
Bacillus species	2+	NP		◆		
gamma haemolytic Streptococcus	4+	NP				◆

Mycology (Culture)

			1+	2+	3+	4+
Candida species	3+	PP			◆	
Rhodotorula species	1+	NP	◆			

** Microbiology culture 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

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

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

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.

Methodology: Direct Microscopic Examination, EIA

Parasitology

Microscopic Exam Results**

No Ova or Parasites seen

Parasitology

Parasite Recovery: Literature suggests that >90% of enteric parasitic infections may be detected in a sample from a single stool collection. Increased sensitivity results from the collection of additional specimens on separate days.

Parasitology EIA Tests:

	In Range	Out of Range
Cryptosporidium◆	Negative	
Giardia lamblia◆	Negative	
Entamoeba histolytica◆	Negative	

*** 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

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: EIA, Fecal Immunochemical Testing (FIT)

Additional Results

	Result	Expected Value
Fecal Occult Blood◆	Negative	Negative
Color††	Brown	
Consistency††	Formed/Normal	

Lab Comments (if applicable)

††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.

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

Mycology Sensitivity

Azole Antifungals

Candida species	R	I	S-DD	S	NI
Fluconazole					<=0.25
Voriconazole					0.015

Non-absorbed Antifungals

Candida species	LOW INHIBITION	HIGH INHIBITION
Nystatin		

Natural Agents

Candida species	LOW INHIBITION	HIGH INHIBITION
Berberine		
Caprylic Acid		
Garlic		
Undecylenic Acid		
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.

Nystatin and Natural Agents:
Results for Nystatin are being reported with natural antifungals in this category in accordance with laboratory guidelines for reporting sensitivities. In this assay, inhibition is defined as the reduction level on organism growth as a direct result of inhibition by a natural 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.

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

Bacteria Sensitivity

Prescriptive Agents

Klebsiella oxytoca	R	I	S-DD	S	NI
Ampicillin	R				
Amox./Clavulanic Acid				S	
Cephalothin				S	
Ciprofloxacin				S	
Tetracycline				S	
Trimethoprim/Sulfa				S	

Natural Agents

Klebsiella oxytoca	LOW INHIBITION	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.

Methodology: EIA

Stool Zonulin

	Result	Reference Range
Zonulin, Stool	50.0	22.3-161.1 ng/mL

Zonulin

Zonulin is a protein modulator of intestinal tight junctions and is used to assess intestinal permeability. It can be used for assessing impaired gut barrier function for various conditions.[1]

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

References:

1. Malickova K, Francova I, Lukas M, et al. Fecal Zonulin is Elevated in Crohn's Disease and in Cigarette Smokers. Pract Lab Med. 2017;9:39-44