



Patient:

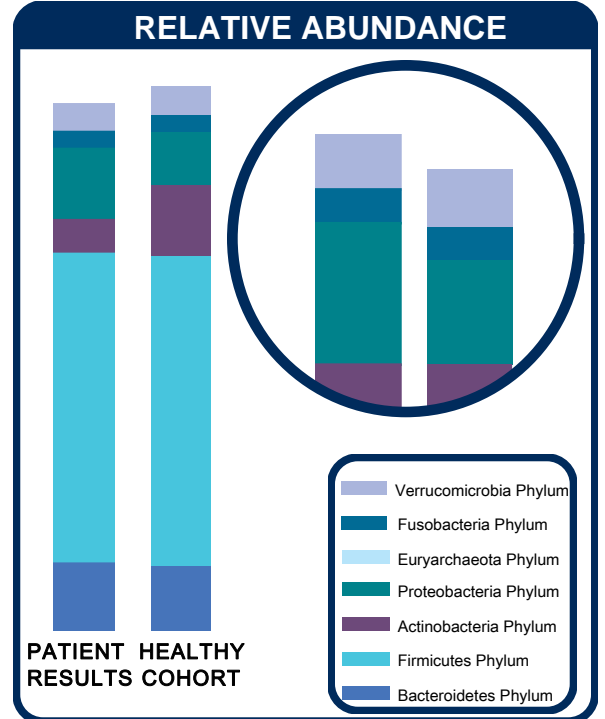
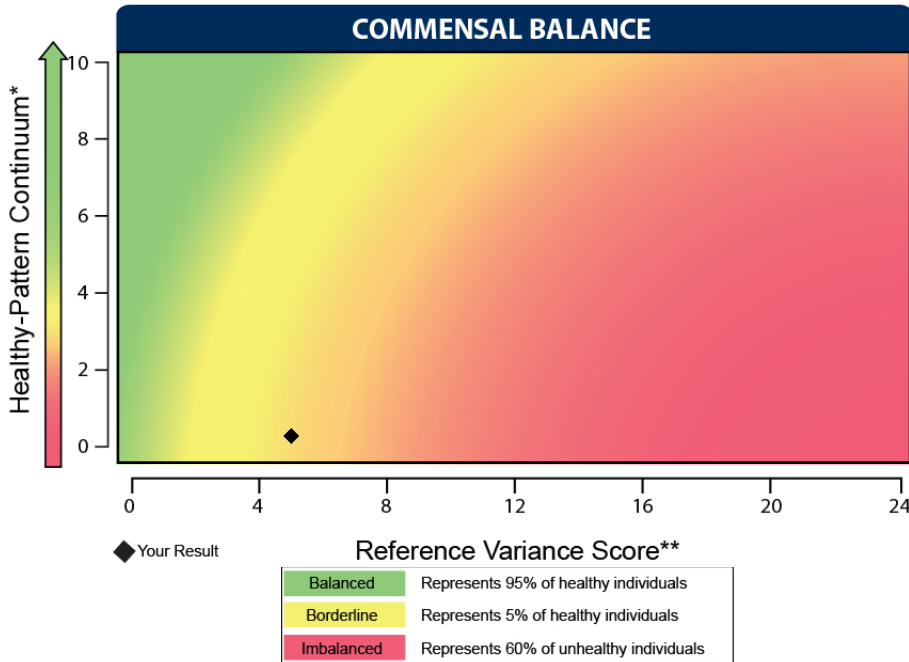
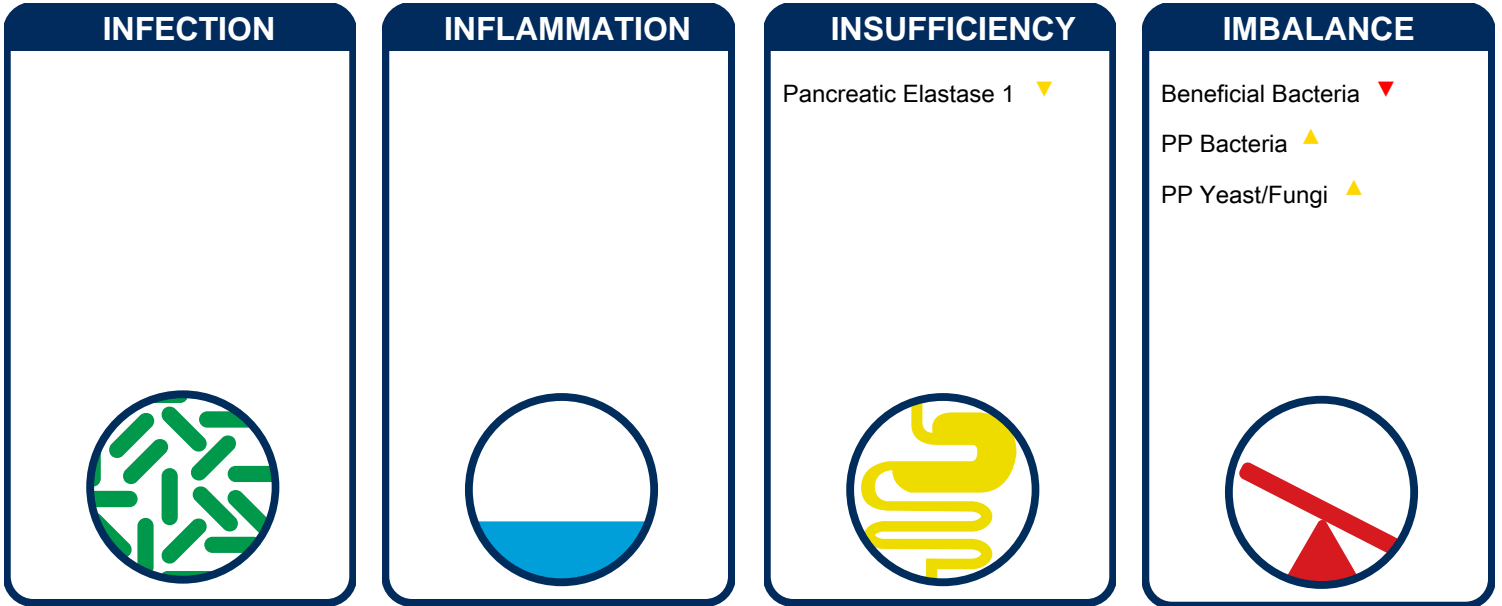
DOB:

Sex:

MRN:

2200 GI Effects™ Comprehensive Profile - Stool

Interpretation At-a-Glance



*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									
<i>Bacteroides-Prevotella</i> group		↑	↑	↑	↑	↑	↑	↑	↑
<i>Bacteroides vulgatus</i>	H	↑			↑	↑		↑	↑
<i>Barnesiella</i> spp.									
<i>Odoribacter</i> spp.	H								
<i>Prevotella</i> spp.	L	↑		↑	↑	↑		↑	↑
Firmicutes Phylum									
<i>Anaerotruncus colihominis</i>		↑	↑	↑	↑	↑	↑	↑	↑
<i>Butyrivibrio crossotus</i>									
<i>Clostridium</i> spp.									
<i>Coprococcus eutactus</i>		↑			↑	↑		↑	↑
<i>Faecalibacterium prausnitzii</i>		↑				↑			↑
<i>Lactobacillus</i> spp.									
<i>Pseudoflavonifractor</i> spp.	H	↑	↑	↑	↑	↑	↑	↑	↑
<i>Roseburia</i> spp.			↓						
<i>Ruminococcus</i> spp.		↕	↓	↓	↓	↕	↕	↕	↕
<i>Veillonella</i> spp.		↑	↑	↑	↑	↑	↑		↑
Actinobacteria Phylum									
<i>Bifidobacterium</i> spp.									
<i>Bifidobacterium longum</i>									
<i>Collinsella aerofaciens</i>	L	↕	↕	↓	↕	↕	↕	↕	↕
Proteobacteria Phylum									
<i>Desulfovibrio piger</i>									↑
<i>Escherichia coli</i>		↑	↑	↑	↑	↑	↑	↑	↑
<i>Oxalobacter formigenes</i>		↑		↑	↑				↑
Euryarchaeota Phylum									
<i>Methanobrevibacter smithii</i>		↑				↑			↑
Fusobacteria Phylum									
<i>Fusobacterium</i> spp.		↑	↑	↑	↑	↑	↑	↑	↑
Verrucomicrobia Phylum									
<i>Akkermansia muciniphila</i>		↓	↓	↓	↓	↓	↓	↓	↓

*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.



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 %									
Acetate %					↕		↕		
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 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.

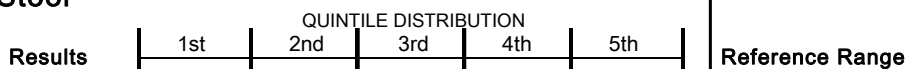
↕ Indicates Genova's clinical condition cohort test results falling below and above the reference range that are greater than that of Genova's healthy cohort.

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.



GI Effects™ Comprehensive Profile - Stool

Methodology: GC/MS, Automated Chemistry, EIA



Digestion and Absorption

Parameter	Result	Quintile Distribution	Reference Range
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

Parameter	Result	Quintile Distribution	Reference Range
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

Parameter	Result	Quintile Distribution	Reference Range
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.



Gastrointestinal Microbiome

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



Gastrointestinal Microbiome

Bacteriology (Culture)

Lactobacillus spp.

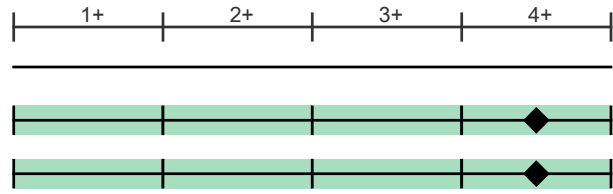
NG

Escherichia coli

4+ NP

Bifidobacterium

4+ NP



Additional Bacteria

alpha haemolytic Streptococcus

3+ NP

Klebsiella oxytoca

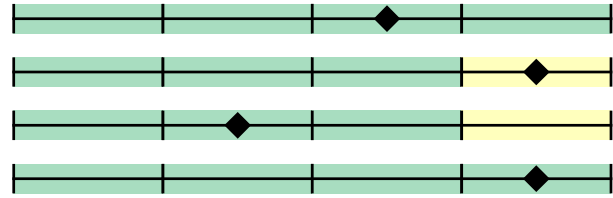
4+ PP

Bacillus species

2+ NP

gamma haemolytic Streptococcus

4+ NP



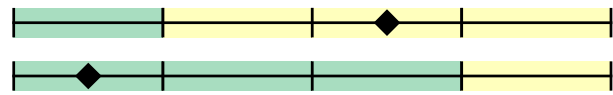
Mycology (Culture)

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.

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



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
<i>Cryptosporidium</i> ♦	Negative	
<i>Giardia lamblia</i> ♦	Negative	
<i>Entamoeba histolytica</i> ♦	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.



Mycology Sensitivity

Azole Antifungals

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

Non-absorbed Antifungals

<i>Candida species</i>	LOW INHIBITION	HIGH INHIBITION
Nystatin		

Natural Agents

<i>Candida species</i>	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.



Bacteria Sensitivity

Prescriptive Agents

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

Natural Agents

	LOW INHIBITION	HIGH INHIBITION
<i>Klebsiella oxytoca</i>		
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	33.0	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 several autoimmune and metabolic conditions including celiac disease, type 1 diabetes and insulin resistance.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. Ann N Y Acad Sci 2012 Jul;1258(1): 25–33.