GENOVA DIAGNOSTICS
3425 Corporate Way
Duluth, GA. 30096

GI fx GI Effects Stool Profiles

Patient:

DOB:
Sex:
MRN:

GI Effects™ Microbial Ecology Profile - Stool

Interpretation At-a-Glance

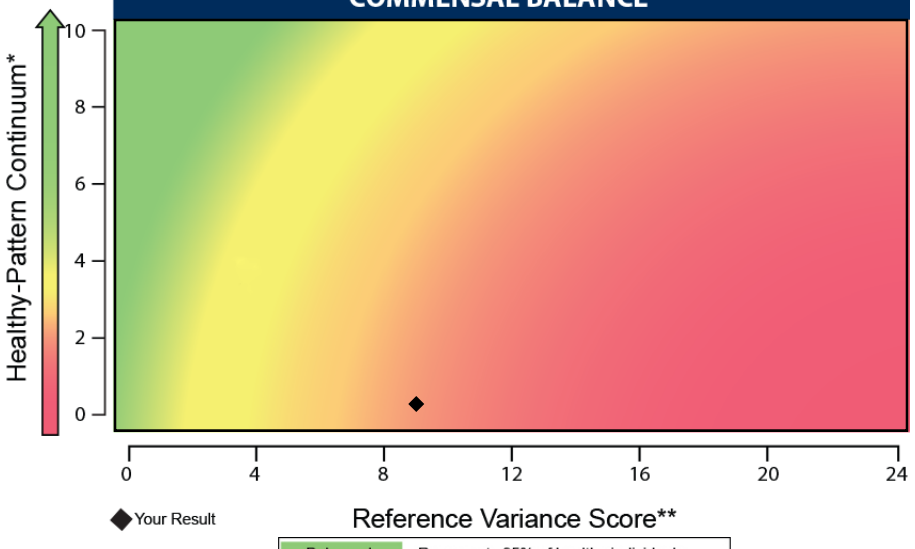
INFECTION

IMBALANCE

PP Bacteria ▲

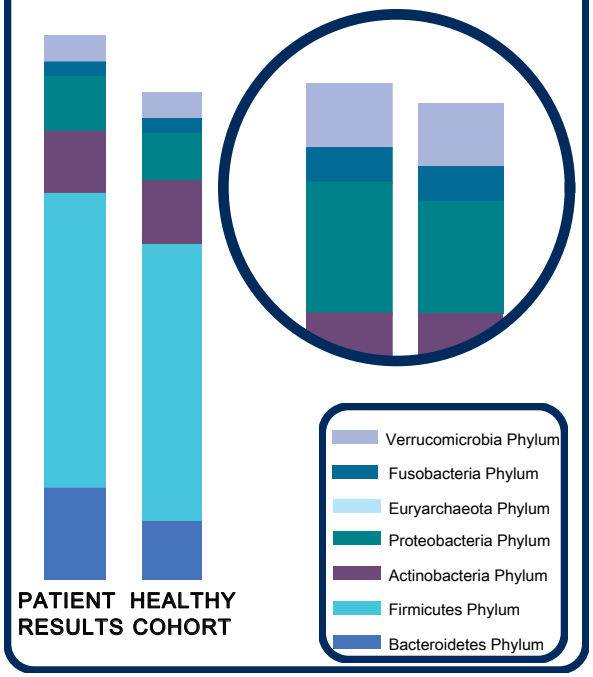
PP Yeast/Fungi ▲

COMMENSAL BALANCE



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

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.

GI Effects™ Microbial Ecology 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	H	↑	↑	↑	↑	↑	↑	↑	↑
Bacteroides vulgatus	H	↑			↑	↑		↑	↑
Barnesiella spp.									
Odoribacter spp.	H								
Prevotella spp.	H	↑		↑	↑	↑		↑	↑
Firmicutes Phylum									
Anaerotruncus colihominis		↑	↑	↑	↑	↑	↑	↑	↑
Butyrivibrio crossotus									
Clostridium spp.	H								
Coprococcus eutactus		↑			↑	↑		↑	↑
Faecalibacterium prausnitzii	H	↑				↑			↑
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	H	↑	↑	↑	↑	↑	↑	↑	↑
Oxalobacter formigenes	H	↑		↑	↑				↑
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 faiing 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.

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GI Effects Stool Profiles

Patient:

DOB:
Sex:
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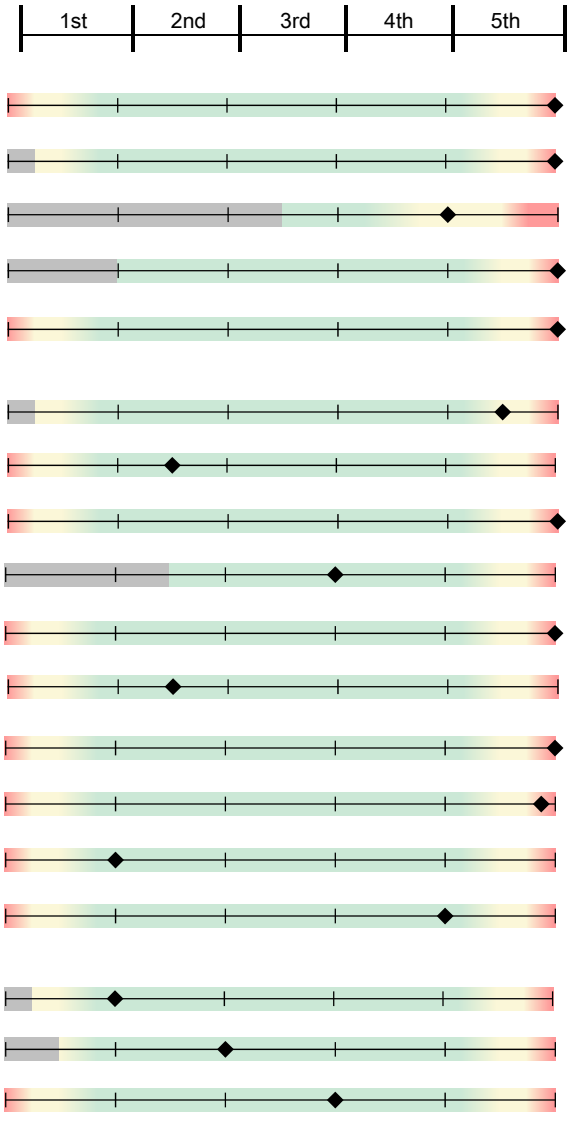
GI Effects™ Microbial Ecology Profile - Stool

Methodology: DNA by PCR

Gastrointestinal Microbiome

Commensal Bacteria (PCR)

	Result CFU/g stool		Reference Range CFU/g stool
Bacteroidetes Phylum			
Bacteroides-Prevotella group	2.1E9	H	3.4E6-1.5E9
Bacteroides vulgatus	1.4E10	H	<=2.2E9
Barnesiella spp.	4.8E7		<=1.6E8
Odoribacter spp.	1.9E8	H	<=8.0E7
Prevotella spp.	1.8E7	H	1.4E5-1.6E7
Firmicutes Phylum			
Anaerotruncus colihominis	2.1E7		<=3.2E7
Butyrivibrio crossotus	4.8E4		5.5E3-5.9E5
Clostridium spp.	1.7E10	H	1.7E8-1.5E10
Coprococcus eutactus	7.5E6		<=1.2E8
Faecalibacterium prausnitzii	9.9E9	H	5.8E7-4.7E9
Lactobacillus spp.	3.1E8		8.3E6-5.2E9
Pseudoflavonifractor spp.	4.3E8	H	4.2E5-1.3E8
Roseburia spp.	1.2E10		1.3E8-1.2E10
Ruminococcus spp.	3.2E8		9.5E7-1.6E9
Veillonella spp.	2.7E7		1.2E5-5.5E7
Actinobacteria Phylum			
Bifidobacterium spp.	3.5E8		<=6.4E9
Bifidobacterium longum	6.4E7		<=7.2E8
Collinsella aerofaciens	6.3E8		1.4E7-1.9E9



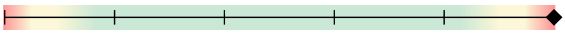
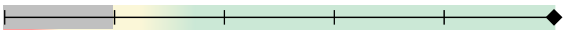
The gray-shaded portion of a quintile reporting bar represents the proportion of the reference population with results below detection limit.

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).

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
Proteobacteria Phylum			
Desulfovibrio piger	<DL		<=1.8**E7**
Escherichia coli	5.0**E7** H		9.0**E4** -4.6**E7**
Oxalobacter formigenes	3.7**E7** H		<=1.5**E7**
Euryarchaeota Phylum			
Methanobrevibacter smithii	<DL		<=8.6**E7**
Fusobacteria Phylum			
Fusobacterium spp.	1.1**E4**		<=2.4**E5**
Verrucomicrobia Phylum			
Akkermansia muciniphila	3.6**E7**		>=1.2**E6**
Firmicutes/Bacteroidetes Ratio			
Firmicutes/Bacteroidetes (F/B Ratio)	17		12-620

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

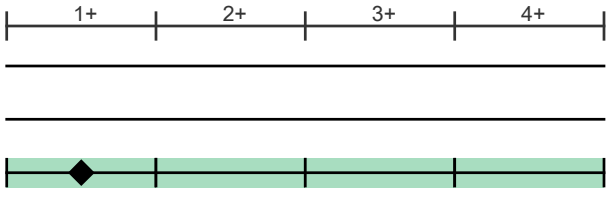
Commensal results and reference range values are displayed in a computer version of scientific notation, where the capital letter “E” indicates the exponent value (e.g., 7.3E6 equates to 7.3 x 10^6 or 7,300,000).

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)



Lactobacillus spp.		NG
Escherichia coli		NG
Bifidobacterium	1+	NP

Additional Bacteria

alpha haemolytic Streptococcus	2+	NP
Citrobacter freundii	4+	PP
Klebsiella oxytoca	4+	PP
gamma haemolytic Streptococcus	2+	NP
Pseudomonas aeruginosa	4+	PP

Mycology (Culture)

Candida kruseii	2+	PP

** 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
Consistency††	Formed/Normal	

Lab Comments (if applicable)

Lab Comments
SENSI'S: All yeast, add'l bacteria

††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

Bacteria Sensitivity

Prescriptive Agents

Pseudomonas aeruginosa	R	I	S-DD	S	NI
Ciprofloxacin				S	
Tetracycline	R				
Trimethoprim/Sulfa	R				

Natural Agents

Pseudomonas aeruginosa	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: 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		

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

Bacteria Sensitivity

Prescriptive Agents

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

Natural Agents

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

Mycology Sensitivity

Azole Antifungals

Candida kruseii	R	I	S-DD	S	NI
Fluconazole					32
Voriconazole				0.25	

Non-absorbed Antifungals

Candida kruseii	LOW INHIBITION	HIGH INHIBITION
Nystatin		

Natural Agents

Candida kruseii	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: EIA

Stool Zonulin

	Result	Reference Range
Zonulin, Stool	112.5	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.