GENOVA DIAGNOSTICS EUROPE
46-50 Coombe Road
New Malden
Surrey
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GI fx GI Effects Stool Profiles

Patient: Jane Doe
DOB: September 16, 1960
Sex: F
MRN:

Order Number:
Completed: October 05, 2017
Received: September 21, 2017
Collected: September 20, 2017

2200 GI Effects™ Comprehensive Profile – Stool

Interpretation At-a-Glance

INFECTION

INFLAMMATION

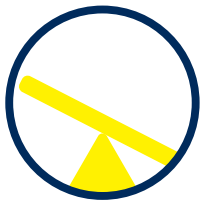
EPX ▲
Fecal secretory IgA ▲

INSUFFICIENCY

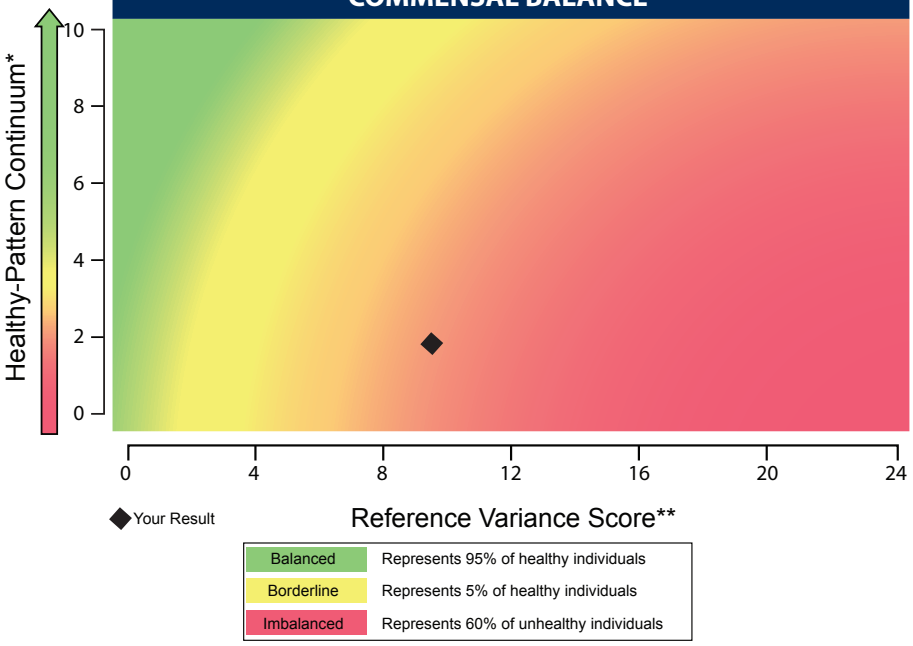
Fecal Fats (Total) ▲

IMBALANCE

PP Bacteria ▲
Beneficial Bacteria ▼
Beta-glucuronidase ▲

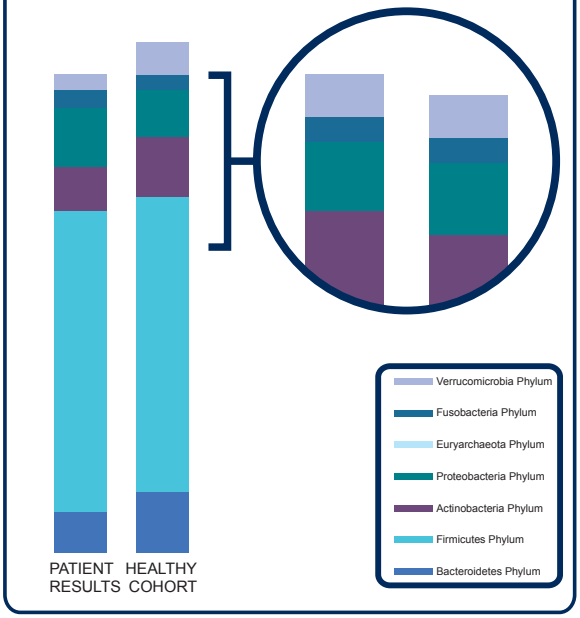


COMMENSAL BALANCE



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 range 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		↑			↑	↑		↑	↑
Barnesiella spp.									
Odoribacter spp.									
Prevotella spp.	H	↑		↑	↑	↑		↑	↑
Firmicutes Phylum									
Anaerotruncus colihominis	H	↑	↑	↑	↑	↑	↑	↑	↑
Butyrivibrio crossotus									
Clostridium spp.									
Coprococcus eutactus		↑			↑	↑		↑	↑
Faecalibacterium prausnitzii	H	↑				↑			↑
Lactobacillus spp.									
Pseudoflavonifractor spp.	H	↑	↑	↑	↑	↑	↑	↑	↑
Roseburia spp.			↓						
Ruminococcus spp.	L	**↓↑**	↓	↓	↓	**↓↑**	**↓↑**	**↓↑**	**↓↑**
Veillonella spp.		↑	↑	↑	↑	↑	↑		↑
Actinobacteria Phylum									
Bifidobacterium spp.	H								
Bifidobacterium longum									
Collinsella aerofaciens	L	**↓↑**	**↓↑**	↓	**↓↑**	**↓↑**	**↓↑**	**↓↑**	**↓↑**
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 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		↓	↓	↓	↓	↓	↓	↓	↓
Products of Protein Breakdown (Total)							↓↑		
Fecal Fat (Total)		↑		↑	↑	↑	**↓↑**	↑	↑
Triglycerides	H	↑			↑	↑	↑	↑	↑
Long Chain Fatty Acids		↑			↑	↑	**↓↑**	↑	↑
Cholesterol							**↓↑**	↑	
Phospholipids		↑	↑	↑	↑	↑	↑	↑	↑
Calprotectin			↑					↑	
Eosinophil Protein X (EPX)			↑						
Fecal sIgA	H	↑	↑	↑	↑	↑	↑	↑	↑
Short Chain Fatty Acids (SCFA) (Total)					↓	↓			
n-Butyrate Concentration				↓					
n-Butyrate %									
Acetate%					↓↑		**↓**↑		
Propionate %				↑			↑	↑	
Beta-glucuronidase						↓↑			↓↑

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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

Methodology: GC/MS, Automated Chemistry, EIA

	Results	QUINTILE DISTRIBUTION (1st | 2nd | 3rd | 4th | 5th)	Reference Range
Digestion and Absorption			
Pancreatic Elastase 1†	>500	100 / 200	>200 mcg/g
Products of Protein Breakdown (Total) (Valerate+Isobutyrate+Isovalerate)	5.7		1.8 - 9.9 micromol/g
Fecal Fat (Total*)	34.0		3.2 - 38.6 mg/g
Triglycerides	3.2 H		0.3 - 2.8 mg/g
Long Chain Fatty Acids	23.3		1.2 - 29.1 mg/g
Cholesterol	1.2		0.4 - 4.8 mg/g
Phospholipids	6.3		0.2 - 6.9 mg/g
Inflammation and Immunology			
Calprotectin†	<16	50 / 120	<= 50 mcg/g
Eosinophil Protein X (EPX)†	1.7	2 / 7	<=4.6 mcg/g
Fecal sIgA	2,033 H		<=885 mcg/g
Gastrointestinal Microbiome			
Metabolic			
SCFA (Total*) (Acetate, n-Butyrate, Propionate)	52.3		> = 23.3 micromol/g
n-Butyrate Concentration	9.1		> = 3.6 micromol/g
n-Butyrate %	17.4		11.8 - 33.3 %
Acetate%	59.7		48.1 - 69.2 %
Propionate%	22.8		<=29.3 %
Beta-Glucuronidase	4,592		368 - 6266 U/g

**Total Value equals 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

Commensal Bacteria (PCR)	Result CFU/g stool	QUINTILE DISTRIBUTION 1st 2nd 3rd 4th 5th	Reference Range CFU/g stool
Bacteroidetes Phylum			
Bacteroides-Prevotella group	1.1E9		3.4**E6** - 1.5**E9**
Bacteroides vulgatus	2.2E9		<=2.2**E9**
Barnesiella spp.	<DL		<=1.6**E8**
Odoribacter spp.	<DL		<=8.0**E7**
Prevotella spp.	1.7E7 **H**		1.4**E5** - 1.6**E7**
Firmicutes Phylum			
Anaerotruncus colihominis	7.0E7 **H**		<=3.2**E7**
Butyrivibrio crossotus	5.9E4		5.5**E3** - 5.9**E5**
Clostridium spp.	5.5E9		1.7**E8** - 1.5**E10**
Coprococcus eutactus	1.2E7		<=1.2**E8**
Faecalibacterium prausnitzii	1.2E10 **H**		5.8**E7** - 4.7**E9**
Lactobacillus spp.	1.0E8		8.3**E6** - 5.2**E9**
Pseudoflavonifractor spp.	2.7E8 **H**		4.2**E5** - 1.3**E8**
Roseburia spp.	3.3E9		1.3**E8** - 1.2**E10**
Ruminococcus spp.	7.1E7 **L**		9.5**E7** - 1.6**E9**
Veillonella spp.	9.1E6		1.2**E5** - 5.5**E7**
Actinobacteria Phylum			
Bifidobacterium spp.	6.7E9 **H**		<=6.4**E9**
Bifidobacterium longum	2.0E8		<=7.2**E8**
Collinsella aerofaciens	<DL **L**		1.4**E7** - 1.9**E9**
Proteobacteria Phylum			
Desulfovibrio piger	<DL		<=1.8**E7**
Escherichia coli	7.4E7 **H**		9.0**E4** - 4.6**E7**
Oxalobacter formigenes	1.6E7 **H**		<=1.5**E7**
Euryarchaeota Phylum			
Methanobrevibacter smithii	<DL		<=8.6**E7**
Fusobacteria Phylum			
Fusobacterium spp.	6.0E4		<=2.4**E5**
Verrucomicrobia Phylum			
Akkermansia muciniphila	3.6E6		>=1.2**E6**
Firmicutes/Bateriodetes Ratio			
Firmicutes/Bacteroidetes (F/B Ratio)	19		12 - 620

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

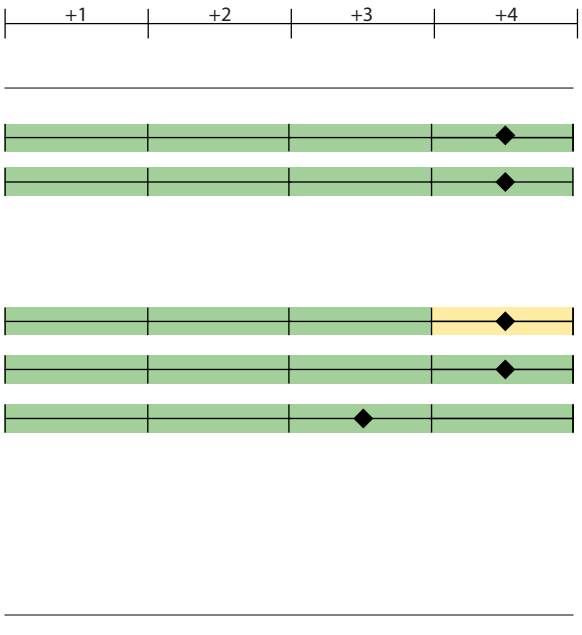
Commensal results and reference range values are displayed in a computer version of scientific notation, where the capital letter "E" indicates the exponent value (e.g., 7.3E6 equates to 7.3 x 10^6 or 7,300,000).

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)



Mycology (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.

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 are well-recognized pathogens in clinical literature that have a clearly recognized mechanism of pathogenicity and are considered significant regardless of the quantity that appears in 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	

Methodology: EIA, Fecal Immunochemical Testing (FIT)

Additional Results

	Result	Expected Value
Fecal Occult Blood◆	Negative	Negative
Color††	Brown	
Consistency††	Formed/Normal	
HpSA - *H.pylori*	Negative	Negative
Campylobacter spp◆	Negative	Negative
Clostridium difficile◆**	Negative	Negative
Shiga toxin *E. coli*◆**	Negative	Negative
Fecal Lactoferrin◆**	Negative	Negative

HpSA (Helicobacter pylori stool antigen) Helicobacter pylori is a bacterium which causes peptic ulcer disease and plays a role in the development of gastric cancer. Direct stool testing of the antigen (HpSA) is highly accurate and is appropriate for diagnosis and follow-up of infection.

Campylobacter Campylobacter jejuni is the most frequent cause of bacterial-induced diarrhea. While transmission can occur 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.

Clostridium difficile is an anaerobic, spore-forming gram-positive bacterium. After a disturbance of the gut flora (usually with antibiotics), colonization with Clostridium difficile can take place. Clostridium difficile infection is much more common than once thought.

Shiga toxin E. coli Shiga toxin-producing Escherichia coli (STEC) is a group of bacterial strains that have been identified as worldwide causes of serious human gastrointestinal disease. The subgroup enterohemorrhagic E. coli 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 include alfalfa sprouts, fresh produce, beef, and unpasteurized juices.

†† Results provided from patient input.

*** 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 or approved by the U.S. Food and Drug Administration.

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

Bacteria Sensitivity

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

Natural Agents

Citrobacter braakii	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 acheived.
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 prodcuts should be considered investgational 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 albicans/dubliniensis	S	I	R
Fluconazole	=0.25		
Caspofungin		=0.25	
Voriconazole	=0.25		

Non-absorbed Antifungals

Candida albicans/dubliniensis	LOW INHIBITION	HIGH INHIBITION
Nystatin		

Natural Agents

Candida albicans/dubliniensis	LOW INHIBITION	HIGH INHIBITION
Berberine		
Caprylic Acid		
Garlic		
Undecylenic Acid		
Plant tannins		
Uva Ursi		

Prescriptive Agents:
Microbial testing has been performed in vitro to determine antibiotic sensitivity and resistance at standard dosages. Prudent use of antimicrobials requires knowledge of appropriate blood or tissue levels of those agents. Antibiotics that appear in the “S” (susceptible) column are more effective at inhibiting the growth of this organism. Antibiotics that appear in the “I” (intermediate) column are partially effective at inhibiting the growth of this organism. Antibiotics that appear in the “R” (resistant) column allow continued growth of the organism in vitro and are usually less effective clinically. Inappropriate use of antibacterials often results in the emergence of resistance.

Natural Agents:
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 natural substance was at limiting the growth of an organism in an in vitro environment. High Inhibition indicates a greater ability by the natural substance to limit growth, while Low Inhibition a lesser ability to limit growth. In accordance with laboratory guidelines for reporting sensitivities, results for Nystatin are now being reported with natural antifungals in this category.

Methodology: EIA

Stool Zonulin

	Result	Reference Range
Zonulin, Stool	75.5	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]

References

1. Ann N Y *Acad Sci*. 2012 Jul; 1258(1): 25–33.

Methodology: Microscopy

Potassium Hydroxide (KOH) Preparation for Yeast

	Result
KOH Preparation, stool	Rare 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

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.