GENOVA DIAGNOSTICS

3425 Corporate Way
Duluth, GA 30096

GI fx GI Effects Stool Profiles

Patient: **SAMPLE PATIENT**
DOB:
Sex:
MRN:

Order Number:
Completed:
Received:
Collected:

GI Effects™ Comprehensive Profile - Stool

Interpretation At-a-Glance

INFECTION

INFLAMMATION

- Calprotectin ▲
- Fecal Lactoferrin ▲
- EPX ▲
- Fecal secretory IgA ▲

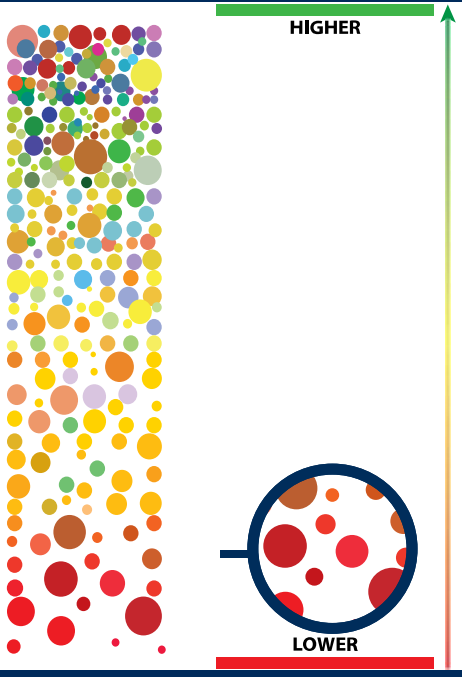
INSUFFICIENCY

- Fecal Fats (Total) ▲

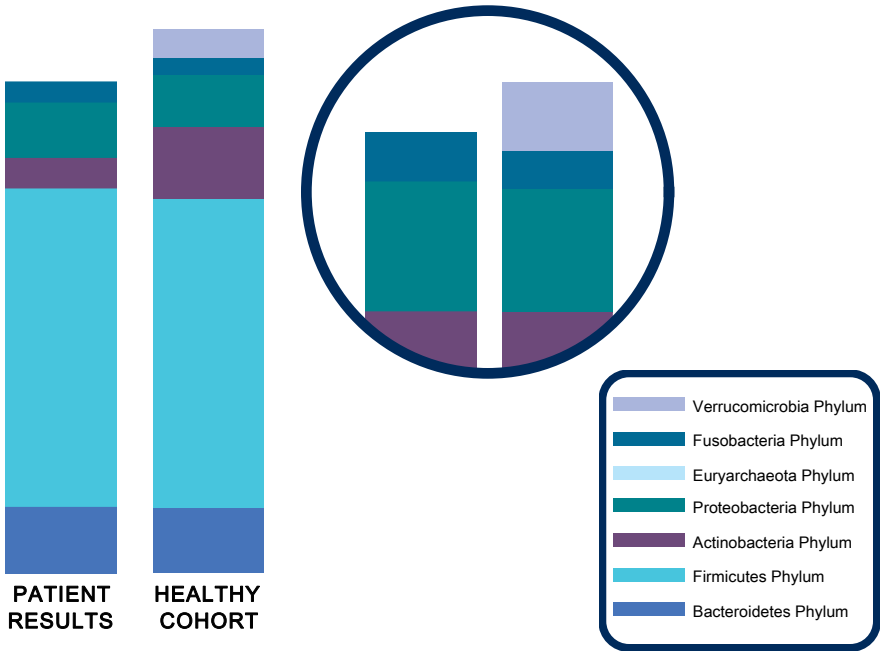
IMBALANCE

- PP Bacteria ▲
- Beneficial Bacteria ▼
- n-Butyrate ▼
- Beta-glucuronidase ▲

DIVERSITY ASSOCIATION



RELATIVE ABUNDANCE



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)	6.6		1.8-9.9 micromol/g
Fecal Fat (Total*)	41.8 H		3.2-38.6 mg/g
Triglycerides	3.5 H		0.3-2.8 mg/g
Long-Chain Fatty Acids	26.3		1.2-29.1 mg/g
Cholesterol	7.7 H		0.4-4.8 mg/g
Phospholipids	4.3		0.2-6.9 mg/g
Inflammation and Immunology			
Calprotectin †	693 H	50 120	<=50 mcg/g
Eosinophil Protein X (EPX)†	10.3 H	1.1 4.6	<=4.6 mcg/g
Fecal secretory IgA	>UL H		<=885 mcg/g
Gastrointestinal Microbiome			
Metabolic			
Short-Chain Fatty Acids (SCFA) (Total*) (Acetate, n-Butyrate, Propionate)	45.6		>=23.3 micromol/g
n-Butyrate Concentration	6.6		>=3.6 micromol/g
n-Butyrate %	14.5		11.8-33.3 %
Acetate %	62.4		48.1-69.2 %
Propionate %	23.0		<=29.3 %
Beta-glucuronidase	6,237		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 or approved by the U.S. Food and Drug Administration.

Methodology: DNA by PCR

Gastrointestinal Microbiome

Commensal Bacteria (PCR)

	Result CFU/g stool		Reference Range CFU/g stool
Bacteroidetes Phylum			
Bacteroides-Prevotella group	2.9E9	H	3.4E6-1.5E9
Bacteroides vulgatus	3.8E9	H	<=2.2E9
Barnesiella spp.	<DL		<=1.6E8
Odoribacter spp.	6.6E6		<=8.0E7
Prevotella spp.	1.8E7	H	1.4E5-1.6E7
Firmicutes Phylum			
Anaerotruncus colihominis	7.2E7	H	<=3.2E7
Butyrivibrio crossotus	3.2E4		5.5E3-5.9E5
Clostridium spp.	7.0E9		1.7E8-1.5E10
Coprococcus eutactus	7.0E5		<=1.2E8
Faecalibacterium prausnitzii	1.2E10	H	5.8E7-4.7E9
Lactobacillus spp.	3.7E8		8.3E6-5.2E9
Pseudoflavonifractor spp.	3.2E8	H	4.2E5-1.3E8
Roseburia spp.	1.0E9		1.3E8-1.2E10
Ruminococcus spp.	8.9E7	L	9.5E7-1.6E9
Veillonella spp.	2.4E7		1.2E5-5.5E7
Actinobacteria Phylum			
Bifidobacterium spp.	4.1E7		<=6.4E9
Bifidobacterium longum	8.7E6		<=7.2E8
Collinsella aerofaciens	<DL	L	1.4E7-1.9E9
Proteobacteria Phylum			
Desulfovibrio piger	<DL		<=1.8E7
Escherichia coli	8.7E7	H	9.0E4-4.6E7
Oxalobacter formigenes	8.2E5		<=1.5E7
Euryarchaeota Phylum			
Methanobrevibacter smithii	<DL		<=8.6E7
Fusobacteria Phylum			
Fusobacterium spp.	1.8E5		<=2.4E5
Verrucomicrobia Phylum			
Akkermansia muciniphila	<DL		>=1.2E6

Firmicutes/Bacteroidetes Ratio			
Firmicutes/Bacteroidetes (F/B Ratio)	7	L	12-620

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

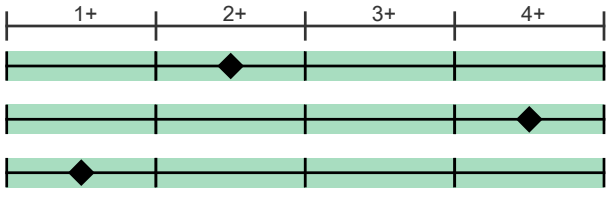
Commensal results and reference range values are displayed in a computer version of scientific notation, where the capital letter “E” indicates the exponent value (e.g., 7.3E6 equates to 7.3 x 10^6 or 7,300,000).

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)



Lactobacillus spp.	2+	NP
Escherichia coli	4+	NP
Bifidobacterium	1+	NP

Additional Bacteria

alpha haemolytic Streptococcus	3+	NP
Streptococcus agalactiae gp B	4+	NP
gamma haemolytic Streptococcus	4+	NP
Pseudomonas aeruginosa	4+	PP
Proteus mirabilis	4+	PP

Mycology (Culture)

Candida albicans/dubliniensis	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*
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Methodology: EIA, Fecal Immunochemical Testing (FIT)

Additional Results

	Result	Expected Value
Fecal Occult Blood◆	Negative	Negative
Consistency††	Not Given	
HpSA - *H. pylori*	Negative	Negative
Campylobacter spp◆	Negative	Negative
Clostridium difficile◆**	Negative	Negative
Shiga toxin *E. coli*◆**	Negative	Negative
Fecal Lactoferrin◆**	Positive	Negative

Lab Comments (if applicable)

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.

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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 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

Bacteria Sensitivity

Prescriptive Agents

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

Natural Agents

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

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