



Patient: **SAMPLE**  
**PATIENT**

DOB:

Sex:

MRN:

**2200 GI Effects™ Comprehensive Profile - Stool**

**Interpretation At-a-Glance**


**INFECTION**

*Dientamoeba fragilis*  
*Blastocystis* spp.




**INFLAMMATION**

Calprotectin ▲  
EPX ▲




**INSUFFICIENCY**

Pancreatic Elastase 1 ▼

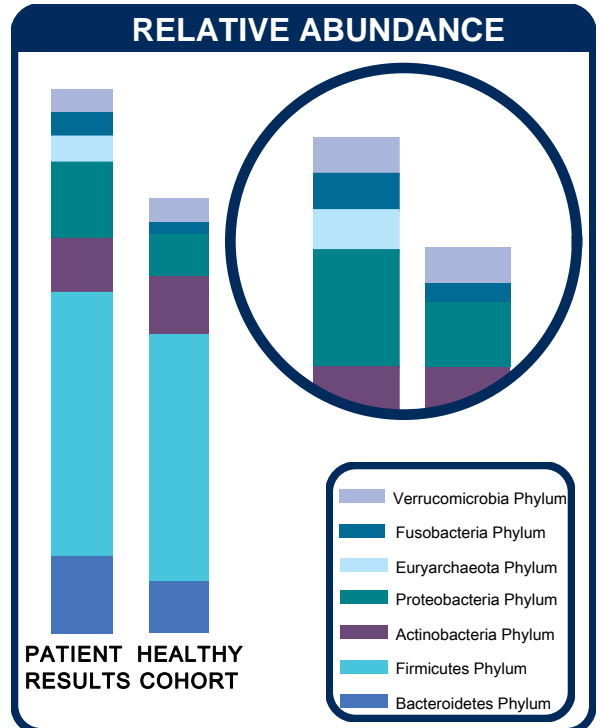
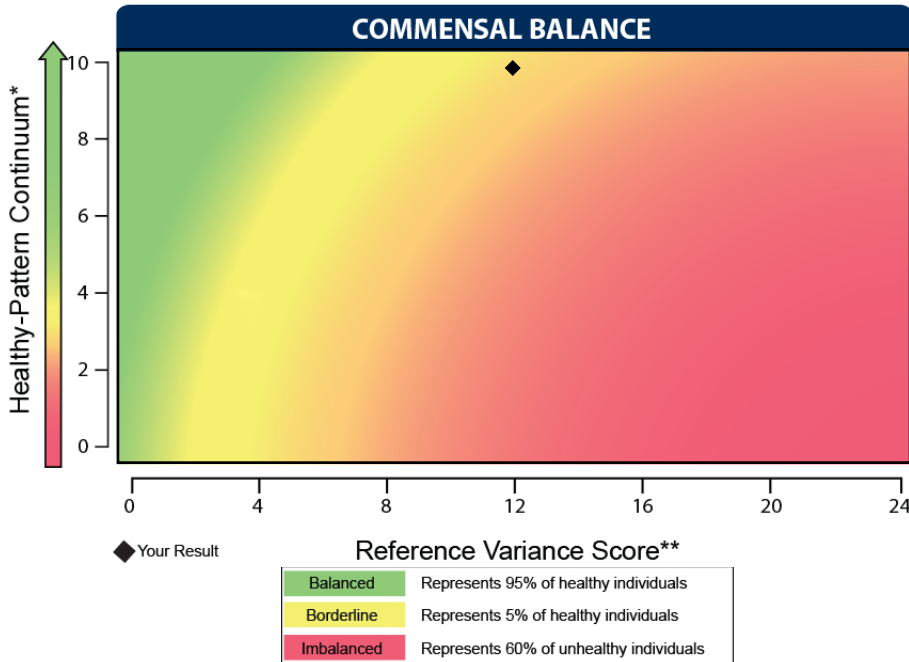


**IMBALANCE**

Beneficial Bacteria ▼  
PP Yeast/Fungi ▲



*See individual sections for detailed results*



\*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

Methodology: GC/MS, Automated Chemistry, EIA

	Result	QUINTILE DISTRIBUTION					Reference Range
		1st	2nd	3rd	4th	5th	
<b>Digestion and Absorption</b>							
Pancreatic Elastase 1 †	158 L						>200 mcg/g
Products of Protein Breakdown (Total*) (Valerate, Isobutyrate, Isovalerate)	6.0						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
<b>Inflammation and Immunology</b>							
Calprotectin †	145 H						<=50 mcg/g
Eosinophil Protein X (EPX)†	4.9 H						<=4.6 mcg/g
Fecal secretory IgA	206						<=885 mcg/g
<b>Gastrointestinal Microbiome</b>							
<b>Metabolic</b>							
Short-Chain Fatty Acids (SCFA) (Total*) (Acetate, n-Butyrate, Propionate)	81.3						>=23.3 micromol/g
n-Butyrate Concentration	18.1						>=3.6 micromol/g
n-Butyrate %	22.3						11.8-33.3 %
Acetate %	63.1						48.1-69.2 %
Propionate %	14.6						<=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.

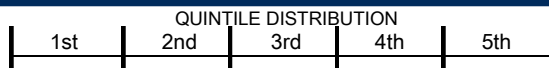
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### Gastrointestinal Microbiome

#### Commensal Bacteria (PCR)

**Result**  
CFU/g stool



**Reference Range**  
CFU/g stool

#### Bacteroidetes Phylum

<i>Bacteroides-Prevotella</i> group	2.4E8			3.4E6-1.5E9
<i>Bacteroides vulgatus</i>	1.2E9			<=2.2E9
<i>Barnesiella</i> spp.	3.6E7			<=1.6E8
<i>Odoribacter</i> spp.	7.1E7			<=8.0E7
<i>Prevotella</i> spp.	1.4E8 H			1.4E5-1.6E7

#### Firmicutes Phylum

<i>Anaerotruncus colihominis</i>	3.4E7 H			<=3.2E7
<i>Butyrivibrio crossotus</i>	5.0E7 H			5.5E3-5.9E5
<i>Clostridium</i> spp.	2.1E8			1.7E8-1.5E10
<i>Coprococcus eutactus</i>	1.0E8			<=1.2E8
<i>Faecalibacterium prausnitzii</i>	7.5E8			5.8E7-4.7E9
<i>Lactobacillus</i> spp.	1.6E8			8.3E6-5.2E9
<i>Pseudoflavonifractor</i> spp.	3.0E8 H			4.2E5-1.3E8
<i>Roseburia</i> spp.	7.6E7 L			1.3E8-1.2E10
<i>Ruminococcus</i> spp.	1.9E9 H			9.5E7-1.6E9
<i>Veillonella</i> spp.	1.5E8 H			1.2E5-5.5E7

#### Actinobacteria Phylum

<i>Bifidobacterium</i> spp.	1.5E8			<=6.4E9
<i>Bifidobacterium longum</i>	1.4E8			<=7.2E8
<i>Collinsella aerofaciens</i>	5.1E8			1.4E7-1.9E9

#### Proteobacteria Phylum

<i>Desulfovibrio piger</i>	8.7E7 H			<=1.8E7
<i>Escherichia coli</i>	1.3E8 H			9.0E4-4.6E7
<i>Oxalobacter formigenes</i>	5.0E7 H			<=1.5E7

#### Euryarchaeota Phylum

<i>Methanobrevibacter smithii</i>	1.4E8 H			<=8.6E7
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#### Fusobacteria Phylum

<i>Fusobacterium</i> spp.	2.3E7 H			<=2.4E5
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#### Verrucomicrobia Phylum

<i>Akkermansia muciniphila</i>	3.1E7			>=1.2E6
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#### Firmicutes/Bacteroidetes Ratio

<i>Firmicutes/Bacteroidetes</i> (F/B Ratio)	11 L			12-620
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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<sup>6</sup> 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\*\*

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			
<b>NG</b>	<b>NP</b>	<b>PP</b>	<b>P</b>
<b>No Growth</b>	<b>Non-Pathogen</b>	<b>Potential Pathogen</b>	<b>Pathogen</b>

### Bacteriology (Culture)

*Lactobacillus spp.*

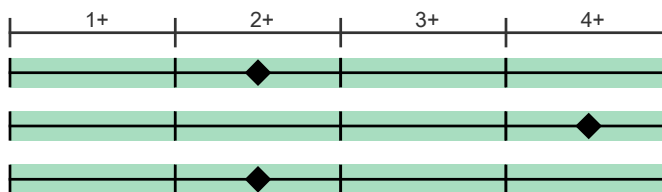
2+ NP

*Escherichia coli*

4+ NP

*Bifidobacterium*

2+ NP



### Additional Bacteria

*alpha haemolytic Streptococcus*

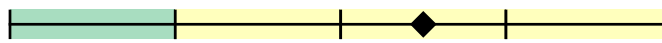
4+ NP



### Mycology (Culture)

*Candida species*

3+ PP



## KOH Preparation for Yeast

Methodology: Potassium Hydroxide (KOH) Preparation for Yeast

### 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.

#### Result

KOH Preparation, stool

Few 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

\*\* Indicates testing performed by Genova Diagnostics, Inc. 63 Zillico St., Asheville, NC 28801-0174

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



## Parasitology\*\*

### Microscopic O&P Results

Microscopic O&P is capable of detecting all described gastrointestinal parasites. The organisms listed in the box represent those commonly found in microscopic stool analysis. Should an organism be detected that is not included in the list below, it will be reported in the Additional Results section. For an extensive reference of all potentially detectable organisms, please visit [www.gdx.net/product/gi-effects-comprehensive-stool-test](http://www.gdx.net/product/gi-effects-comprehensive-stool-test)

Genus/species	Result
<b>Nematodes - roundworms</b>	
<i>Ancylostoma/Necator</i> (Hookworm)	Not Detected
<i>Ascaris lumbricoides</i>	Not Detected
<i>Capillaria philippinensis</i>	Not Detected
<i>Enterobius vermicularis</i>	Not Detected
<i>Strongyloides stercoralis</i>	Not Detected
<i>Trichuris trichiura</i>	Not Detected
<b>Cestodes - tapeworms</b>	
<i>Diphyllobothrium latum</i>	Not Detected
<i>Dipylidium caninum</i>	Not Detected
<i>Hymenolepis diminuta</i>	Not Detected
<i>Hymenolepis nana</i>	Not Detected
<i>Taenia</i> spp.	Not Detected
<b>Trematodes - flukes</b>	
<i>Clonorchis/Opisthorchis</i> spp.	Not Detected
<i>Fasciola</i> spp./ <i>Fasciolopsis buski</i>	Not Detected
<i>Heterophyes/Metagonimus</i>	Not Detected
<i>Paragonimus</i> spp.	Not Detected
<i>Schistosoma</i> spp.	Not Detected
<b>Protozoa</b>	
<i>Balantidium coli</i>	Not Detected
<i>Blastocystis</i> spp.	<b>Rare Detected</b>
<i>Chilomastix mesnili</i>	Not Detected
<i>Cryptosporidium</i> spp.	Not Detected
<i>Cyclospora cayetanensis</i>	Not Detected
<i>Dientamoeba fragilis</i>	<b>Moderate Detected</b>
<i>Entamoeba coli</i>	Not Detected
<i>Entamoeba histolytica/dispar</i>	Not Detected
<i>Entamoeba hartmanii</i>	Not Detected
<i>Entamoeba polecki</i>	Not Detected
<i>Endolimax nana</i>	Not Detected
<i>Giardia</i>	Not Detected
<i>Iodamoeba buetschlii</i>	Not Detected
<i>Cystoisospora</i> spp.	Not Detected
<i>Trichomonads</i> (e.g. <i>Pentatrichomonas</i> )	Not Detected
<b>Additional Findings</b>	
White Blood Cells	Not Detected
Charcot-Leyden Crystals	Not Detected
<b>Other Infectious Findings</b>	

One negative specimen does not rule out the possibility of a parasitic infection.

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

## Parasitology

## PCR Parasitology - Protozoa\*\*

Methodologies: DNA by PCR, Next Generation Sequencing

Organism	Result	Units		Expected Result
<i>Blastocystis</i> spp.	6.00e2	femtograms/microliter C&S stool	Detected	Not Detected
<i>Cryptosporidium</i> spp.	<4.87e2	genome copies/microliter C&S stool	Not Detected	Not Detected
<i>Cyclospora cayetanensis</i>	<2.65e2	genome copies/microliter C&S stool	Not Detected	Not Detected
<i>Dientamoeba fragilis</i>	6.40e2	genome copies/microliter C&S stool	Detected	Not Detected
<i>Entamoeba histolytica</i>	<1.14e3	genome copies/microliter C&S stool	Not Detected	Not Detected
<i>Giardia</i>	<1.57e2	genome copies/microliter C&S stool	Not Detected	Not Detected

*Blastocystis* spp. Reflex Subtyping

Type 1:	Not Detected	Type 4:	Not Detected	Type 7:	Not Detected
Type 2:	Detected	Type 5:	Not Detected	Type 8:	Not Detected
Type 3:	Not Detected	Type 6:	Not Detected	Type 9:	Not Detected

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## Additional Results

Methodology: Fecal Immunochemical Testing (FIT)

	Result	Expected Value
Fecal Occult Blood♦	Negative	Negative
Color††	Green	
Consistency††	Formed/Normal	

††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.

## Zonulin Family Peptide

Methodology: EIA

Result	Reference Range	Zonulin Family Peptide
Zonulin Family Peptide, Stool	100.0	22.3-161.1 ng/mL

This test is for research use only. Genova will not provide support on interpreting the test results. This test does not detect zonulin.<sup>1</sup> The Scheffler paper suggests that the IDK kit may detect a zonulin family peptide, such as properdin. Genova's unpublished data demonstrated that the current IDK kit results were associated with stool inflammation biomarkers and an inflammation-associated dysbiosis profile.

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

## Reference:

- Scheffler L, et al. Widely Used Commercial ELISA Does Not Detect Precursor of Haptoglobin2, but Recognizes Properdin as a Potential Second Member of the Zonulin Family. *Front Endocrinol.* 2018;9:22.



## Macroscopic Exam for Worms \*\*

Methodology: Macroscopic Evaluation

No larvae seen macroscopically.

## Add-on Testing

Methodology: EIA

	Result	Expected Value	
HpSA - <i>H. pylori</i>	Negative	Negative	<p><b>HpSA (<i>Helicobacter pylori</i> stool antigen)</b></p> <p><i>Helicobacter pylori</i> 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.</p>
<i>Campylobacter</i> spp. ♦**	Negative	Negative	<p><b><i>Campylobacter</i> spp.</b></p> <p><i>Campylobacter jejuni</i> 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.</p> <p><b><i>Clostridium difficile</i></b></p> <p><i>Clostridium difficile</i> is an anaerobic, spore-forming gram-positive bacterium. After a disturbance of the gut flora (usually with antibiotics), colonization with <i>Clostridium difficile</i> can take place. <i>Clostridium difficile</i> infection is much more common than once thought.</p> <p><b>Shiga toxin <i>E. coli</i></b></p> <p>Shiga toxin-producing <i>Escherichia coli</i> (STEC) is a group of bacterial strains that have been identified as worldwide causes of serious human gastrointestinal disease. The subgroup enterohemorrhagic <i>E. coli</i> 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.</p>
<i>Clostridium difficile</i> ♦**	Negative	Negative	
Shiga toxin <i>E. coli</i> ♦**	Negative	Negative	
Fecal Lactoferrin ♦**	Negative	Negative	

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## Mycology Sensitivity

### Azole Antifungals

<i>Candida species</i>	R	I	S-DD	S	NI
Fluconazole				0.5	
Voriconazole				<=0.008	

### 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.





## 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
<b>Bacteroidetes Phylum</b>									
<i>Bacteroides-Prevotella</i> group		↑	↑	↑	↑	↑	↑	↑	↑
<i>Bacteroides vulgatus</i>		↑			↑	↑		↑	↑
<i>Barnesiella</i> spp.									
<i>Odoribacter</i> spp.									
<i>Prevotella</i> spp.	H	↑		↑	↑	↑		↑	↑
<b>Firmicutes Phylum</b>									
<i>Anaerotruncus colihominis</i>	H	↑	↑	↑	↑	↑	↑	↑	↑
<i>Butyrivibrio crossotus</i>	H								
<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.	L		↓						
<i>Ruminococcus</i> spp.	H	↕	↓	↓	↓	↕	↕	↕	↕
<i>Veillonella</i> spp.	H	↑	↑	↑	↑	↑	↑		↑
<b>Actinobacteria Phylum</b>									
<i>Bifidobacterium</i> spp.									
<i>Bifidobacterium longum</i>									
<i>Collinsella aerofaciens</i>		↕	↕	↓	↕	↕	↕	↕	↕
<b>Proteobacteria Phylum</b>									
<i>Desulfovibrio piger</i>	H								↑
<i>Escherichia coli</i>	H	↑	↑	↑	↑	↑	↑	↑	↑
<i>Oxalobacter formigenes</i>	H	↑		↑	↑				↑
<b>Euryarchaeota Phylum</b>									
<i>Methanobrevibacter smithii</i>	H	↑				↑			↑
<b>Fusobacteria Phylum</b>									
<i>Fusobacterium</i> spp.	H	↑	↑	↑	↑	↑	↑	↑	↑
<b>Verrucomicrobia Phylum</b>									
<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.



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### 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	H		↑					↑	
Eosinophil Protein X (EPX)	H		↑						
Fecal secretory IgA		↑	↑	↑	↑	↑	↑	↑	↑
Short-Chain Fatty Acids (SCFA) (Total)					↓	↓			
n-Butyrate Concentration				↓					
n-Butyrate %									
Acetate %					↕		↕		
Propionate %				↑			↑	↑	
Beta-glucuronidase						↕			↕

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