

# IDENTIFY THE ROOT CAUSE OF GI SYMPTOMS



## CLINICIAN INFORMATION

### COMPREHENSIVE STOOL DIAGNOSTICS

**The GI Effects® Stool Profiles** are advanced stool tests that provide immediate, actionable clinical information for the management of gastrointestinal health. Utilizing cutting-edge technologies and biomarkers, this stool test offers valuable insight into digestive function, gut inflammation, and the gut microbiome. These tests can reveal important information about the root cause of many common gastrointestinal symptoms, such as gas, bloating, indigestion, abdominal pain, diarrhea, and constipation.

These biomarkers are well represented in the literature, and are used to monitor clinical conditions, such as inflammatory bowel disease (calprotectin, EPX), food allergies (EPX), GI infections (slgA), pancreatic insufficiency (pancreatic elastase 1), and malabsorption (fecal fats).

#### Actionable Results

The GI Effects Stool Profile biomarkers provide comprehensive information that can be used to develop interventions. Symptoms often improve as identified functional imbalances and inadequacies become normalized through dietary, lifestyle, nutraceutical and/or pharmaceutical supplementation interventions that may include:

- Antibiotic/antimicrobial therapy
- Anti-inflammatory therapy
- Pancreatic/digestive enzyme therapy
- Prebiotic and probiotic therapy
- Dietary manipulation
- Botanical/natural therapies

#### Why Choose Genova Diagnostics' GI Profiles?

- GI Effects offers a comprehensive GI health assessment *evaluating the root cause of most gut complaints.*
- We use a *combination of qPCR, culture, and microscopic methods* to ensure all relevant organisms are identified.
- We *recover live organisms (yeast and bacteria) for susceptibility testing* and improved treatment options.
- We measure metabolomics to assess the interaction between the microbiome and its host.
- Genova is the *market authority on stool inflammatory markers*, testing calprotectin, EPX and slgA. *Calprotectin was introduced to the USA and gained FDA clearance as a result of Genova's leadership.*
- We have amassed a *database of hundreds of thousands of complete stool profiles.*
- Our data driven and evidence-based analysis ensures the highest standard of analytical validity and clinical utility.

#### The Genova Diagnostics' Difference

With greater than 30 years in laboratory science, Genova's laboratory staff brings extensive experience and expertise. Genova participates in many external proficiency testing programs and is the standard to which other laboratories (Mayo Clinic, Children's Hospital of Philadelphia, Quest, and ARUP) compare samples to ensure reproducibility and accuracy. Genova Diagnostics offers clients access to the Medical Affairs team who provide educational opportunities and patient-specific clinical test interpretation.



DYSBIOSIS



INFLAMMATION



MALDIGESTION



METABOLITE  
IMBALANCE



INFECTION



## GI Effects® Stool Profile Overview

### GI Effects® Comprehensive Profile

This **Comprehensive Profile** is a structured fecal biomarker panel that offers the advantage of assessing multiple functional areas that may be contributing to symptoms. This test offers valuable insight into digestive function, intestinal inflammation, and the intestinal microbiome:

- **Digestion/Absorption**

- **Pancreatic Elastase-1** is a marker of exocrine pancreatic function.
- **Products of Protein Breakdown** are markers of undigested protein reaching the colon.
- **Fecal Fat** is a marker of fat breakdown and absorption.

- **Inflammation/Immunology**

- **Calprotectin** is a marker of neutrophil-driven inflammation. Produced in abundance at sites of inflammation, this biomarker has been proven clinically useful in differentiating between inflammatory bowel disease (IBD) and irritable bowel syndrome (IBS).<sup>1,2</sup>
- **Eosinophil Protein X** is a marker of eosinophil-driven inflammation and allergic response.
- **Fecal Secretory IgA** is a marker of gut secretory immunity and barrier function.

- **Gut Microbiome**

- **Metabolic indicators**, including short-chain fatty acids and beta-glucuronidase, demonstrate specific and vital metabolic functions performed by the microbiota.
- **Commensal Bacteria** demonstrate the composition and relative abundance of gut organisms.
  - More than 95% of commensal gut organisms are anaerobic and are difficult to recover by traditional (aerobic) culture techniques.
  - GI Effects assesses a set of 24 genera/species that map to 7 major phyla via qPCR.
- **Bacterial and mycology cultures** demonstrate the presence of specific beneficial and pathological organisms.
- **Bacteria and mycology sensitivities** are provided for pathogenic or potentially pathogenic organisms that have been cultured. The report includes effective prescriptive and natural agents.
- **Parasitology** includes comprehensive testing for all parasites on every parasitology exam ordered.
  - GI Effects provides **microscopic fecal specimen examination for ova and parasites (O&P)**, the gold standard of diagnosis for many parasites.
  - **6 Polymerase chain reaction (PCR) targets** detect common protozoan parasites including *Blastocystis* spp. *Cryptosporidium parvum/hominis*, *Cyclospora cayentanensis*, *Dientamoeba fragilis*, *Entamoeba histolytica*, and *Giardia*. PCR for pathogenic organisms is emerging as a preferred, highly sensitive method for infectious organism detection.

GI Effects is also available with

### MICROBIOMIX™

**A new way to assess the microbiome**

Microbiomix offers metagenomic shotgun/whole genome sequencing to assess your patient's complete gut microbiome as well as its potential function.

## The Gut Microbiome and Clinical Associations

Genova has amassed a database of hundreds of thousands of complete stool profiles. Ongoing data analysis establishes a firm foundation on which to base clinical decision-making and treatment. Our data driven and evidence-based analysis ensures the highest standard of analytical validity and clinical utility. Continued data analysis allows Genova to tell a complete story regarding each patient's microbiome to uncover subtleties in overall health and wellness.

- Novel Dysbiosis Pattern scores relate to key physiologic disruptions including immunosuppression and inflammation and may change treatment choices.<sup>3</sup>
- The Total and Relative Commensal Abundance, and Commensal Balance graphics demonstrate the degree of dysbiosis compared to a healthy population.

## GI Effects® Microbial Ecology Profile

The **Microbial Ecology Profile** is a subset of the Comprehensive Profile, and provides insight into the diverse gut microbiome. It includes assessment for pathogenic or potentially pathogenic parasites, bacteria, and yeast, as well as providing a valuable assessment of gut microbiota via 24 Commensal Bacteria.

The report features a Relative Abundance graph and Commensal Balance graph to summarize the patient's commensal bacteria patterns.

## GI Effects® Gut Pathogen Profile

The **Gut Pathogen Profile** identifies pathogenic or potentially pathogenic parasites, bacteria, and yeast. Patients with a clinical history suggestive of a gastrointestinal infection can be evaluated with the Gut Pathogen Profile.

Testing is ideal for patients with sudden changes in bowel habits, especially for those who have recently traveled abroad, have been camping, had exposure to untreated water, had close contact with animals, or consumed undercooked meat or seafood. This profile can also be used as a follow-up test to assess organism eradication.

## GI Effects® Fundamentals Profile

The **GI Effects Fundamentals** stool profile offers valuable insight into digestive function, intestinal inflammation, and the intestinal microbiome. Optional add-on tests allow the clinician to choose pertinent markers for each patient, including parasitology and others.

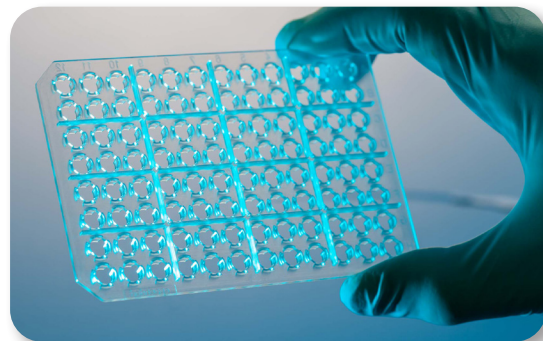
The GI Effects Fundamentals Profile can reveal important information about the root cause of many common gastrointestinal symptoms such as gas, bloating, indigestion, abdominal pain, diarrhea, and constipation.

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## Identifying Clinically-Relevant Organisms

Genova uses a combination of qPCR, culture, and microscopic methods to ensure that any relevant organisms are identified. Utilizing a single technology cannot fully capture the dynamics of the microbiome. The GI Effects Profiles represent the best technical platforms available to assess the gut microbiome, combining:

- 16S rRNA gene polymerase chain reaction (qPCR) amplification technique for anaerobic commensal bacteria
- Matrix Assisted Laser Desorption Ionization Time-of-Flight Mass Spectrometry (MALDI-TOF MS) technology for bacterial and fungal species identification via culture
- Microscopic ova & parasites (O&P) detection
- Real-time PCR for the identification of 6 common parasites



Selection of a one-day or three-day sample collection is based on the clinician's clinical index of suspicion for parasitic infection. If there is no/low suspicion, a one-day sample will likely be adequate. For high suspicion, a three-day sample collection is optimal.

1. Menees SB, et. al. A meta-analysis of the utility of C-reactive protein, erythrocyte sedimentation rate, fecal calprotectin, and fecal lactoferrin to exclude inflammatory bowel disease in adults with IBS. *Am J Gastroenterol*. 2015 Mar;110(3):444-54.

2. Dabritz J, Musci J, Foell D. Diagnostic utility of faecal biomarkers in patients with irritable bowel syndrome. *World J Gastroenterol*. 2014 Jan;20(2):363-375.

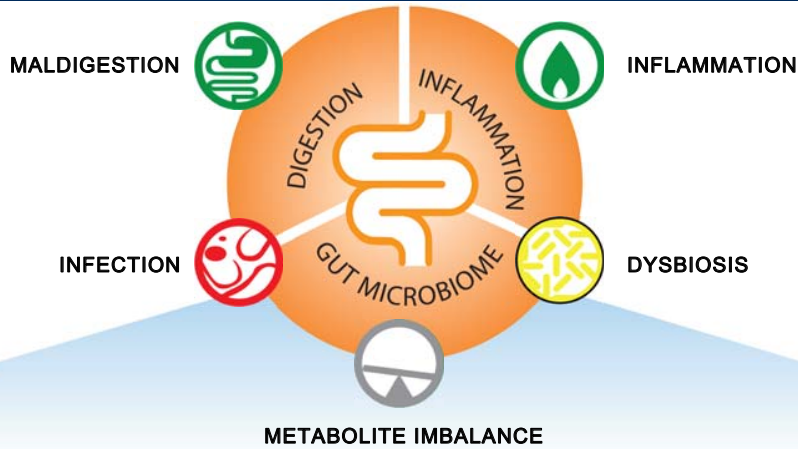
3. Chen L, Reynolds C, David R, Peace Brewer A. Development of an Index Score for Intestinal Inflammation-Associated Dysbiosis Using Real-World Stool Test Results. *Dig Dis Sci*. 2019.

Patient:

2200 GI Effects™ Comprehensive Profile - Stool

Powered by Genova AI

Results Overview



Functional Imbalance Scores

Key < 2 : Low Need for Support    2-3 : Optional Need for Support    4-6 : Moderate Need for Support    7-10 : High Need for Support

	Need for Digestive Support	Need for Inflammation Modulation	Need for Microbiome Support	Need for Prebiotic Support	Need for Antimicrobial Support
	MALDIGESTION	INFLAMMATION	DYSBIOSIS	METABOLITE IMBALANCE	INFECTION
	0	0	4	2	7
<b>Biomarkers</b>	Products of Protein Breakdown ▼ Fecal Fats ▼ Pancreatic Elastase ●	Secretory IgA ▲ Calprotectin ● Eosinophil Protein X ● Occult Blood ●	PP Bacteria/Yeast ▲ IAD/Methane Score ● Reference Variance ● Total Abundance ●	Total SCFA's ▼ n-Butyrate Conc. ▼ SCFA (%) ● Beta-glucuronidase ●	PP Bacteria/Yeast ▲ Parasitic Infection ▲ Pathogenic Bacteria ● Total Abundance ●
<b>Therapeutic Support Options</b>	<ul style="list-style-type: none"> <li>Digestive Enzymes</li> <li>Betaine HCl</li> <li>Bile Salts</li> <li>Apple Cider Vinegar</li> <li>Mindful Eating Habits</li> <li>Digestive Bitters</li> </ul>	<ul style="list-style-type: none"> <li>Elimination Diet/ Food Sensitivity Testing</li> <li>Mucosa Support: Slippery Elm, Althea, Aloe, DGL, etc.</li> <li>Zinc Carnosine</li> <li>L-Glutamine</li> <li>Quercetin</li> <li>Turmeric</li> <li>Omega-3's</li> <li>GI Referral (If Calpro is Elevated)</li> </ul>	<ul style="list-style-type: none"> <li>Pre-/Probiotics</li> <li>Increase Dietary Fiber Intake</li> <li>Consider SIBO Testing</li> <li>Increase Resistant Starches</li> <li>Increase Fermented Foods</li> <li>Meal Timing</li> </ul>	<ul style="list-style-type: none"> <li>Pre-/Probiotics</li> <li>Increase Dietary Fiber Intake</li> <li>Increase Resistant Starches</li> <li>Increase Fermented Foods</li> <li>Calcium D-Glucarate (for high beta-glucuronidase)</li> </ul>	<ul style="list-style-type: none"> <li>Antibiotics (if warranted)</li> <li>Antimicrobial Herbal Therapy</li> <li>Antiparasitic Herbal Therapy (if warranted)</li> <li><i>Saccharomyces boulardii</i></li> </ul>

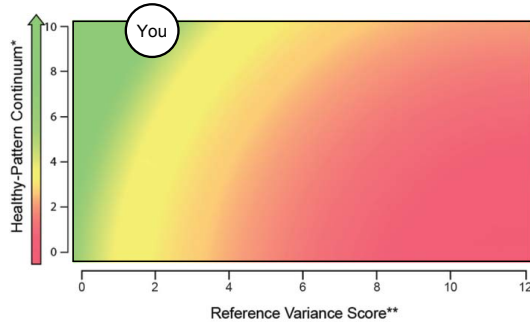
EXPANDED

Commensal Microbiome Analysis

- Commensal Abundance
- Dysbiosis Patterns
- Commensal Balance
- Relative Commensal Abundance

Commensal Microbiome Analysis

Commensal Balance

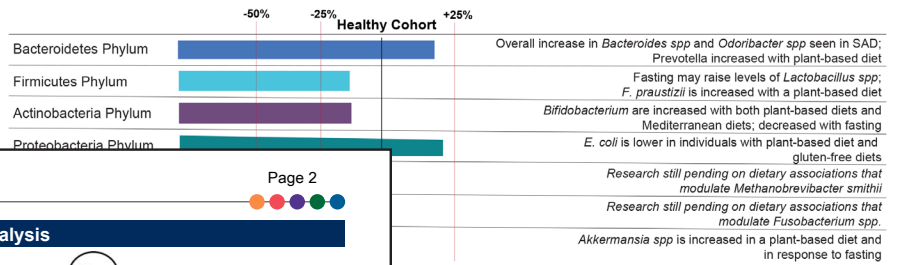


Balanced	Represents 95% of healthy individuals
Borderline	Represents 5% of healthy individuals
Imbalanced	Represents 60% of unhealthy individuals

\*A progressive ranking scale based on a Genova proprietary algorithm that differentiates healthy and unhealthy commensal patterns.

\*\*The total number of commensal bacteria (qPCR) that are out of balance for this individual on a scale of 0 to >12.

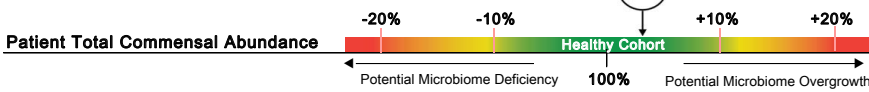
Relative Commensal Abundance



Quantity of bacterial phyla compared to a healthy cohort. This can be used to identify certain interventions that may assist in promoting or limiting individual phyla where

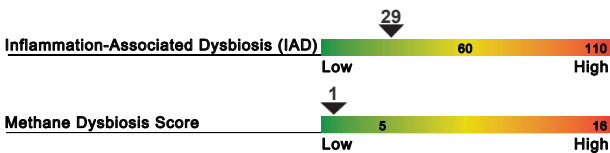
Commensal Microbiome Analysis

Commensal Abundance



**Total Commensal Balance:** The total commensal abundance is a sum-total of the reported commensal bacteria compared to a healthy cohort. Low levels of commensal bacteria are often observed after antimicrobial therapy, or in diets lacking fiber and/or prebiotic-rich foods and may indicate the need for microbiome support. Conversely, higher total commensal abundance may indicate potential bacteria overgrowth or probiotic supplementation.

Dysbiosis Patterns



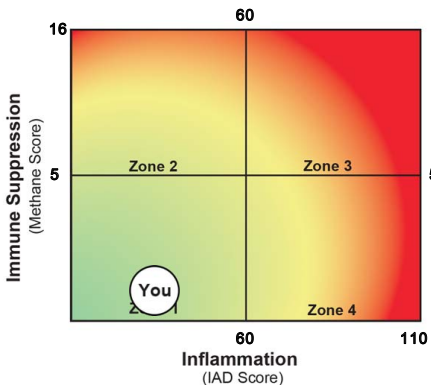
**Dysbiosis Patterns:** Genova's data analysis has led to the development of unique dysbiosis patterns, related to key physiologic disruptions, such as immunosuppression and inflammation. These patterns may represent dysbiotic changes that could pose clinical significance. Please see Genova's published literature for more details: <https://rdcu.be/bRhZv>

**Zone 1:** The commensal profile in this zone does not align with profiles associated with intestinal inflammation or immunosuppression. If inflammatory biomarkers are present, other causes need to be excluded, such as infection, food allergy, or more serious pathology.

**Zone 2:** This pattern of bacteria is associated with impaired intestinal barrier function (low fecal sIgA and EPX). Patients in this zone have higher rates of opportunistic infections (e.g. *Blastocystis* spp. & *Dientamoeba fragilis*) as well as fecal fat malabsorption. Commensal abundance is higher in this group suggesting potential bacterial overgrowth.

**Zone 3:** Patients in this zone may have more inflammation compared to those in zone 4. However, commensal abundance is usually higher making use of antimicrobial therapy relatively safer. Patients in this zone may have higher rates of pathogenic infections.

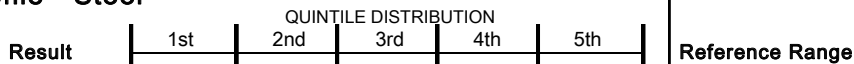
**Zone 4:** This commensal profile is associated with increased intestinal inflammation. IBD patients are more likely to have this pattern of bacteria. Commensal abundance is lower in this zone; therefore, antibiotic use for GI potential pathogens should be used with caution. In addition to standard treatment for intestinal inflammation, modulation of the commensal gut profile is encouraged.





## 2200 GI Effects™ Comprehensive Profile - Stool

Methodology: GC-FID, Automated Chemistry, EIA



### Digestion and Absorption

Parameter	Result	Quintile Distribution	Reference Range
Pancreatic Elastase 1 †	>500	100, 200	>200 mcg/g
Products of Protein Breakdown (Total*) (Valerate, Isobutyrate, Isovalerate)	2.2		1.8-9.9 micromol/g
Fecal Fat (Total*)	6.6		3.2-38.6 mg/g
Triglycerides	0.7		0.3-2.8 mg/g
Long-Chain Fatty Acids	4.6		1.2-29.1 mg/g
Cholesterol	0.8		0.4-4.8 mg/g
Phospholipids	0.5		0.2-6.9 mg/g

### Inflammation and Immunology

Parameter	Result	Quintile Distribution	Reference Range
Calprotectin *†	<16	50, 100	<=50 mcg/g
Eosinophil Protein X (EPX)†	<DL	0.5, 2.7	<=2.7 mcg/g
Fecal secretory IgA	683	680, 2040	<=2,040 mcg/mL

### Gut Microbiome Metabolites

Parameter	Result	Quintile Distribution	Reference Range
<b>Metabolic</b>			
Short-Chain Fatty Acids (SCFA) (Total*) (Acetate, n-Butyrate, Propionate)	29.3		>=23.3 micromol/g
n-Butyrate Concentration	6.7		>=3.6 micromol/g
n-Butyrate %	22.9		11.8-33.3 %
Acetate %	59.2		48.1-69.2 %
Propionate %	18.1		<=29.3 %
Beta-glucuronidase	1,547		368-6,266 U/g

\*Total value is equal to 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.

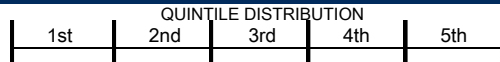
Methodology: DNA by qPCR



**Gastrointestinal Microbiome (PCR)**

**Commensal Bacteria (PCR)**

**Result**  
CFU/g stool



**Reference Range**  
CFU/g stool

**Bacteroidetes Phylum**

<i>Bacteroides uniformis</i>	3.5E8		<=9.5E8
<i>Phocaeicola vulgatus</i>	2.8E8		<=8.3E8
<i>Barnesiella spp.</i>	3.6E7		3.0E6-2.9E8
<i>Odoribacter spp.</i>	<DL		<=9.5E7
<i>Prevotella spp.</i>	1.2E9		6.6E7-3.8E9

**Firmicutes Phylum**

<i>Anaerotruncus colihominis/massiliensis</i>	1.6E7		<=2.0E7
<i>Butyrivibrio crossotus</i>	<DL		<=3.3E7
<i>Clostridium spp.</i>	<DL		<=1.5E7
<i>Coprococcus eutactus</i>	<DL		<=1.2E8
<i>Faecalibacterium prausnitzii</i>	2.4E8		1.1E6-1.1E9
<i>Lactobacillus spp.</i>	5.6E3		<=1.6E6
<i>Pseudoflavonifractor spp.</i>	1.4E6		1.3E4-2.9E7
<i>Roseburia spp.</i>	7.4E7		3.6E5-4.6E8
<i>Ruminococcus bromii</i>	4.6E8		<=1.5E9
<i>Veillonella spp.</i>	4.6E5		<=4.1E6

**Actinobacteria Phylum**

<i>Bifidobacterium spp.</i>	5.0E7		4.6E5-2.6E8
<i>Bifidobacterium longum subsp. longum</i>	<DL		<=1.3E8
<i>Collinsella aerofaciens</i>	<DL		<=1.3E8

**Proteobacteria Phylum**

<i>Desulfovibrio piger</i>	<DL		<=5.4E7
<i>Escherichia coli</i>	2.1E4		<=7.5E6
<i>Oxalobacter formigenes</i>	<DL		<=1.1E7

**Euryarchaeota Phylum**

<i>Methanobrevibacter smithii</i>	<DL		<=2.0E7
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**Fusobacteria Phylum**

<i>Fusobacterium spp.</i>	<DL		<=1.8E5
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**Verrucomicrobia Phylum**

<i>Akkermansia muciniphila</i>	5.9E5		>=8.5E3
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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 methodology for the PCR Commensal Bacteria has been updated to qPCR. The reference ranges have been updated accordingly.

The names of some of the bacteria have been updated as a result of taxonomy changes and method improvements.



Methodology: Culture/MALDI-TOF MS, Automated and Manual Biochemical Methods, Vitek® 2 System Microbial identification and Antibiotic susceptibility

## Gastrointestinal Microbiome (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			
<b>NG</b>  No Growth	<b>NP</b>  Non-Pathogen	<b>PP</b>  Potential Pathogen	<b>P</b>  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.

### Bacteriology (Culture)

*Lactobacillus spp.*

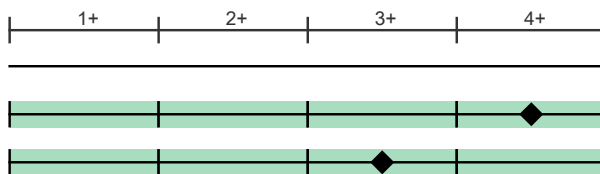
NG

*Escherichia coli*

4+ NP

*Bifidobacterium (Anaerobic Culture)*

3+ NP



### Additional Bacteria

*Salmonella spp.*

NG

*Shigella spp.*

NG

*Klebsiella pneumoniae*

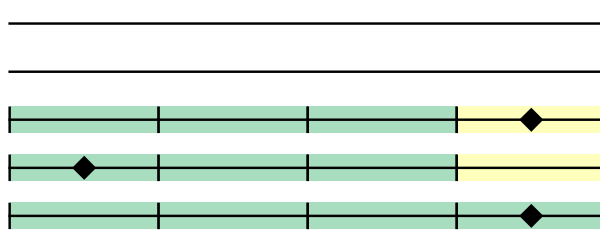
4+ PP

*Bacillus species*

1+ NP

*Enterococcus faecium*

4+ NP



### Mycology (Culture)

*Candida kruseii*

2+ PP

Yeast, not *Candida albicans*

1+ NP



## OPTIONAL ADD-ON

### 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

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





**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. These results were obtained using wet preparation(s) and trichrome stained smear. 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>Many Detected</b>
<i>Chilomastix mesnili</i>	Not Detected
<i>Cryptosporidium</i> spp.	Not Detected
<i>Cyclospora cayetanensis</i>	Not Detected
<i>Dientamoeba fragilis</i>	Not Detected
<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.



**Parasitology**

**PCR Parasitology - Protozoa**

Methodologies: DNA by PCR

Organism	Result	Units		Expected Result
<i>Blastocystis</i> spp.	<2.14e2	femtograms/microliter C&S stool	Detected	Not Detected
<i>Cryptosporidium parvum/hominis</i>	<1.76e2	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>	<1.84e2	genome copies/microliter C&S stool	Not Detected	Not Detected
<i>Entamoeba histolytica</i>	<9.64e1	genome copies/microliter C&S stool	Not Detected	Not Detected
<i>Giardia</i>	<1.36e1	genome copies/microliter C&S stool	Not Detected	Not Detected

**Additional Results**

Methodology: Fecal Immunochemical Testing (FIT)

	Result	Expected Value
Fecal Occult Blood♦	Negative	Negative
Color††	Brown	
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.

**OPTIONAL ADD-ON**

**Zonulin Family Peptide**

Methodology: EIA

	Result	Reference Range	Zonulin Family Peptide
Zonulin Family Peptide, Stool	86.0	22.3-161.1 ng/mL	<p>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.</p> <p>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.</p>

**Reference:**

1. 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.

**OPTIONAL ADD-ON**

**Macroscopic/Direct Exam for Parasites**

Methodology: Macroscopic Evaluation

**Add-on Testing**

Methodology: EIA

	Result	Expected Value
HpSA - <i>H. pylori</i>	Negative	Negative
<i>Campylobacter</i> spp.♦	Negative	Negative

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

**Bacteria Sensitivity**

**Prescriptive Agents**

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

**Natural Agents**

<i>Klebsiella pneumoniae</i>
Berberine
Oregano
Uva-Ursi

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

**Mycology Sensitivity**

**Candida Susceptibility Profile for Azoles\***

Organism	Number of Isolates	% Sensitive	
		Fluconazole	Voriconazole
<i>Candida albicans</i>	25561	99.19%	99.51%
<i>Candida parapsilosis</i>	8777	98.64%	99.33%
<i>Candida kruseii</i>	3420	0.23%	97.79%
<i>Candida tropicalis</i>	1076	93.22%	90.57%
<i>Candida glabrata</i>	2898	27.1%	90.9%

**\*Results of pharmaceutical sensitivities against certain yeast species are based on internal Genova data pertaining to the frequency of susceptibility of the specific yeast to the listed antifungal agent. The pharmaceutical results are not patient-specific. Conversely, the results of inhibition to nystatin and natural agents are patient-specific.**

**Non-absorbed Antifungals**

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

**Natural Agents**

<i>Candida kruseii</i>	LOW INHIBITION	HIGH INHIBITION
Berberine		
Caprylic Acid		
Garlic		
Undecylenic Acid		
Uva-Ursi		

# GI Effects Profiles – Analytes

Base Panel	GIFX COMP 2200	GIFX MIC ECO 2205	GIFX GUT PATH 2207	GIFX FUND 2209
Bacteriology Culture				
Yeast Culture				
Calprotectin				
Eosinophil Protein X (EPX)				
Fecal Fats				
Products of Protein Breakdown				
Pancreatic Elastase				
Short Chain Fatty Acids				
Beta-Glucuronidase				
Occult Blood				
Commensal Bacteria				
Fecal secretory IgA				+
Microscopic O&P Exam				+
ParaPCR				+
<b>Add-Ons</b>				
<i>Campylobacter</i> EIA	+	+	+	+
<i>Clostridium difficile</i> EIA	+	+	+	+
Macroscopic Exam for Worms	+	+	Included	+
Shiga-like Toxin <i>Escherichia coli</i> EIA	+	+	+	+
<i>Helicobacter pylori</i> EIA	+	+	+	+
KOH Preparation for Yeast	+	+	Included	+
Lactoferrin	+	+	+	
Microbiomix™	+			
Zonulin Family Peptide, Stool	+			+

## ● GI Effects Stool Profiles\*

- #2200 GI Effects Comprehensive Profile
- #2205 GI Effects Microbial Ecology Profile
- #2207 GI Effects Gut Pathogen Profile
- #2209 GI Effects Fundamentals Profile
- #2210 GI Effects Comprehensive with Microbiomix

## ● Add-On Tests

- #2202 *Campylobacter*
- #2203 *Clostridium difficile*
- #2204 Shiga toxin *Escherichia coli*
- #2206 Fecal Lactoferrin
- #2208 *Helicobacter pylori*
- #2331 Macro Exam for Worms
- #2336 Zonulin Family Peptide
- #2338 KOH Preparation for Yeast

## ● Specimen Requirements

- Stool; 1-Day or 3-Day Collection

## ● Value-added Services



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