IDENTIFY THE ROOT CAUSE OF GI SYMPTOMS

GI fx GI Effects Stool Profiles℠

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 (sIgA), 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 PCR, 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 sIgA. *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

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

GENOVA DIAGNOSTICS® EUROPE

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:

GI fx GI Effects Comprehensive Profile

- **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).[1,2]
  - **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 PCR.
  - **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. with reflex subtyping 1-9, *Cryptosporidium parvum/hominis, Cyclospora cayetanensis, Dientamoeba fragilis, Entamoeba histolytica, and Giardia*. PCR for pathogenic organisms is emerging as a preferred, highly sensitive method for infectious organism detection.

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.[3]
- 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, Commensal Balance graph, and Commensal Bacteria Clinical Associations chart to summarize the patient's commensal bacteria patterns.

GI fx GI Effects Microbial Ecology Profile

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.

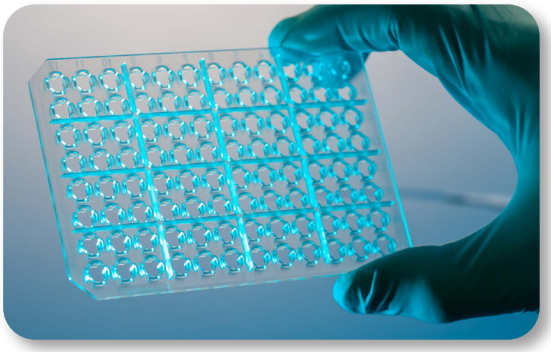
Testing is ideal for patients with sudden changes in bowel habits, especially for those who have recently traveled abroad, have been camping, had exposure to untreated water, had close contact with animals, or consumed undercooked meat or seafood. This profile can also be used as a follow-up test to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

GI fx GI Effects Gut Pathogen Profile

Identifying Clinically-Relevant Organisms

Genova uses a combination of PCR, 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 (PCR) 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
- Next-Generation DNA sequencing for Blastocystis spp. reflex subtyping 1-9



- Enzyme immunoassay (EIA) add-on is available to support the assessment of critical bacterial pathogens (*C. difficile, H. pylori,* Shiga Toxin *E. coli, and Campylobacter* spp.) in targeted patient populations.

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.

GENOVA DIAGNOSTICS
3425 Corporate Way
Duluth, GA 30096

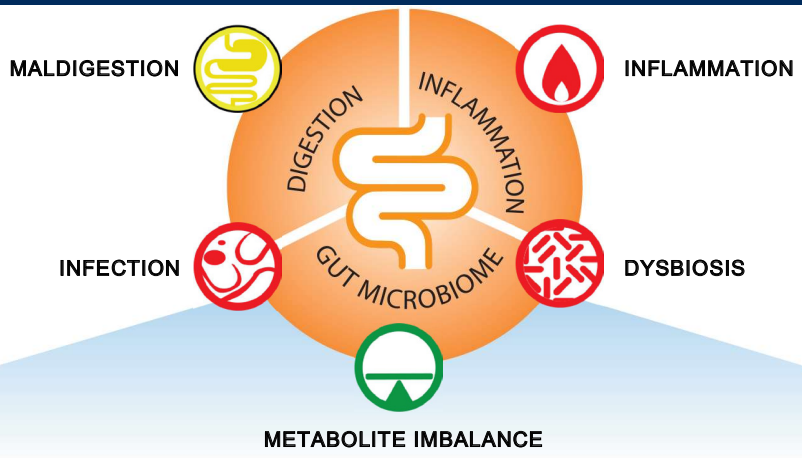
GI fx GI Effects Stool Profiles

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

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	METABOLIC IMBALANCE	INFECTION
	5	10	10	0	10
Biomarkers	Pancreatic Elastase ▽ Products of Protein Breakdown ● Fecal Fats ●	Calprotectin ▲ Eosinophil Protein X ▲ Secretory IgA ● Occult Blood ●	IAD/Methane Score ▲ PP Bacteria/Yeast ▲ Reference Variance ▲ Total Abundance △	Total SCFA's ● n-Butyrate Conc. ● SCFA (%) ● Beta-glucuronidase ●	Parasitic Infection ▲ PP Bacteria/Yeast ▲ Total Abundance △ Pathogenic Bacteria ●
Therapeutic Support Options	• Digestive Enzymes • Betaine HCl • Bile Salts • Apple Cider Vinegar • Mindful Eating Habits • Digestive Bitters	• Elimination Diet/ Food Sensitivity Testing • Mucosa Support: Slippery Elm, Althea, Aloe, DGL, etc. • Zinc Carnosine • L-Glutamine • Quercetin • Turmeric • Omega-3's • GI Referral (If Calpro is Elevated)	• Pre-/Probiotics • Increase Dietary Fiber Intake • Consider SIBO Testing • Increase Resistant Starches • Increase Fermented Foods • Meal Timing	• Pre-/Probiotics • Increased Dietary Fiber Intake • Increase Resistant Starches • increase Fermented Foods • Calcium D-Glucarate (for high beta-glucuronidase)	• Antibiotics (if warranted) • Antimicrobial Herbal Therapy • Antiparasitic Herbal Therapy (if warranted) • *Saccharomyces boulardii*

E X P A N D E D

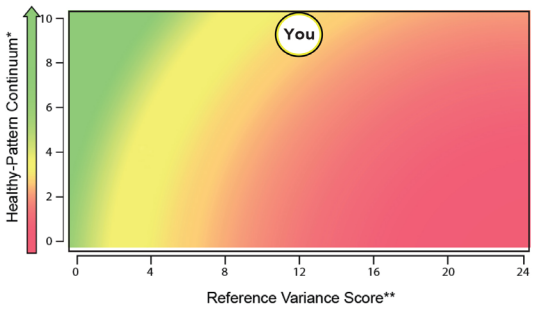
Commensal Microbiome Analysis

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

Patient: SAMPLE PATIENT ID:

Commensal Microbiome Analysis

Commensal Balance

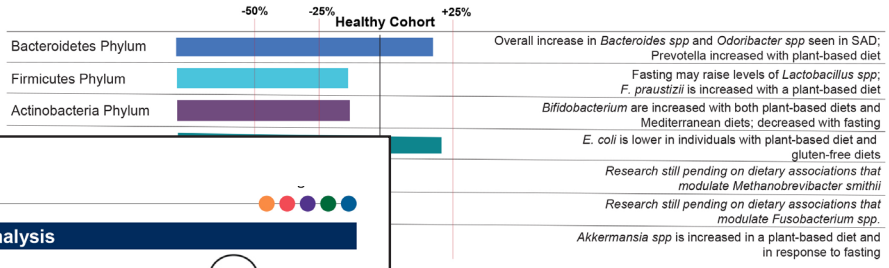


Balanced	Represents 95% of healthy individuals
Borderline	Represents 5% of healthy individuals
Imbalanced	Represents 60% of unhealthy individuals

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

**The total number of Commensal Bacteria (PCR) that are out of reference ranges for this individual.

Relative Commensal Abundance



Overall increase in *Bacteroides spp* and *Odoribacter spp* seen in SAD; Prevotella increased with plant-based diet

Fasting may raise levels of *Lactobacillus spp*; *F. praustizii* is increased with a plant-based diet

Bifidobacterium are increased with both plant-based diets and Mediterranean diets; decreased with fasting

E. coli is lower in individuals with plant-based diet and gluten-free diets

Research still pending on dietary associations that modulate Methanobrevibacter smithii

Research still pending on dietary associations that modulate Fusobacterium spp.

Akkermansia spp is increased in a plant-based diet and in response to fasting

uantity of bacterial phyla compared to a healthy cohort. This can be used to Certain interventions may assist in promoting or limiting individual phyla where

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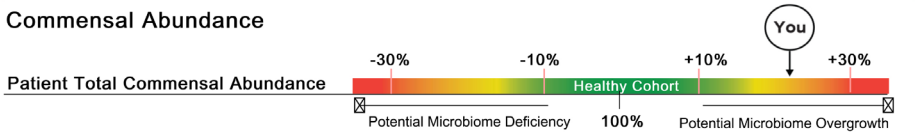
Patient: SAMPLE PATIENT ID:

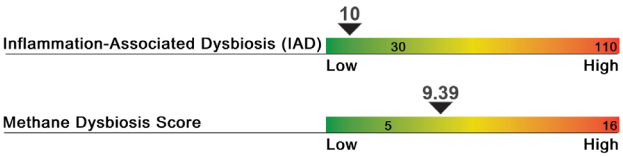
Commensal Microbiome Analysis

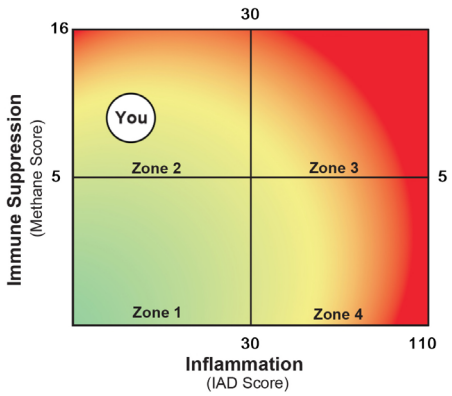
Commensal Abundance



Total Commenal 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 immunosuppresion 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.

Patient: SAMPLE PATENT

2200 GI Effects™ Comprehensive Profile - Stool

Methodology: GC/MS, Automated Chemistry, EIA

	Result	QUINTILE DISTRIBUTION (1st 2nd 3rd 4th 5th)	Reference Range
Digestion and Absorption			
Pancreatic Elastase 1 †	158 L	100 200	>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
Inflammation and Immunology			
Calprotectin †	145 H	50 120	<=50 mcg/g
Eosinophil Protein X (EPX)†	4.9 H	1.1 4.6	<=4.6 mcg/g
Fecal secretory IgA	206		<=885 mcg/g
Gut Microbiome Metabolites			
Metabolic			
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.
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.

Patient: SAMPLE PATENT

Methodology: DNA by PCR

Gastrointestinal Microbiome (PCR)

Commensal Bacteria (PCR)	Result CFU/g stool		QUINTILE DISTRIBUTION 1st 2nd 3rd 4th 5th	Reference Range CFU/g stool
Bacteroidetes Phylum				
Bacteroides-Prevotella group	2.4E8			3.4E6-1.5E9
Bacteroides vulgatus	1.2E9			<=2.2E9
Barnesiella spp.	3.6E7			<=1.6E8
Odoribacter spp.	7.1E7			<=8.0E7
Prevotella spp.	1.4E8	H		1.4E5-1.6E7
Firmicutes Phylum				
Anaerotruncus colihominis	3.4E7	H		<=3.2E7
Butyrivibrio crossotus	5.0E7	H		5.5E3-5.9E5
Clostridium spp.	2.1E8			1.7E8-1.5E10
Coprococcus eutactus	1.0E8			<=1.2E8
Faecalibacterium prausnitzii	7.5E8			5.8E7-4.7E9
Lactobacillus spp.	1.6E8			8.3E6-5.2E9
Pseudoflavonifractor spp.	3.0E8	H		4.2E5-1.3E8
Roseburia spp.	7.6E7	L		1.3E8-1.2E10
Ruminococcus spp.	1.9E9	H		9.5E7-1.6E9
Veillonella spp.	1.5E8	H		1.2E5-5.5E7
Actinobacteria Phylum				
Bifidobacterium spp.	1.5E8			<=6.4E9
Bifidobacterium longum	1.4E8			<=7.2E8
Collinsella aerofaciens	5.1E8			1.4E7-1.9E9
Proteobacteria Phylum				
Desulfovibrio piger	8.7E7	H		<=1.8E7
Escherichia coli	1.3E8	H		9.0E4-4.6E7
Oxalobacter formigenes	5.0E7	H		<=1.5E7
Euryarchaeota Phylum				
Methanobrevibacter smithii	1.4E8	H		<=8.6E7
Fusobacteria Phylum				
Fusobacterium spp.	2.3E7	H		<=2.4E5
Verrucomicrobia Phylum				
Akkermansia muciniphila	3.1E7			>=1.2E6
Firmicutes/Bacteroidetes Ratio				
Firmicutes/Bacteroidetes (F/B Ratio)	11	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.

Patient: SAMPLE PATENT

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.

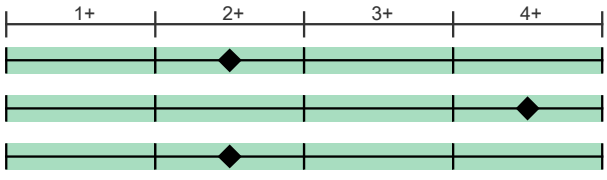
Microbiology Legend

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.

Bacteriology (Culture)



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

Additional Bacteria

alpha haemolytic Streptococcus	4+	NP
Klebsiella pneumoniae	4+	PP

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 Zillicoa St., Asheville, NC 28801-0174*
A. L. Peace-Brewer, PhD, D(ABMLI), Lab Director - CLIA Lic. #34D0655571 - Medicare Lic. #34-8475

Patient: SAMPLE PATENT

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

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

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

Patient: SAMPLE PATENT

Parasitology

PCR Parasitology - Protozoa**

Methodologies: DNA by PCR, Next Generation Sequencing

Organism	Result	Units		Expected Result
Blastocystis spp.	6.00e2	femtograms/microliter C&S stool	Detected	Not Detected
Cryptosporidium parvum/hominis	<1.76e2	genome copies/microliter C&S stool	Not Detected	Not Detected
Cyclospora cayetanensis	<2.65e2	genome copies/microliter C&S stool	Not Detected	Not Detected
Dientamoeba fragilis	6.40e2	genome copies/microliter C&S stool	Detected	Not Detected
Entamoeba histolytica	<9.64e1	genome copies/microliter C&S stool	Not Detected	Not Detected
Giardia	<1.36e1	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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A. L. Peace-Brewer, PhD, D(ABMLI), Lab Director - CLIA Lic. #34D0655571 - Medicare Lic. #34-8475

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, Stool	100.0	22.3-161.1 ng/mL

Zonulin Family Peptide

This test is for research use only. Genova will not provide support on interpreting the test results. This test does not detect zonulin.[1] 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:

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.

Patient: SAMPLE PATENT

Macroscopic/Direct Exam for Parasites **

Methodology: Macroscopic Evaluation

No human parasite detected in sample.

Add-on Testing

Methodology: EIA

	Result	Expected Value
HpSA - *H. pylori*	Negative	Negative
Campylobacter spp.◆**	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.

Patient: SAMPLE PATENT

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

Bacteria Sensitivity

Prescriptive Agents

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

Natural Agents

Klebsiella pneumoniae	
Berberine	
Oregano	
Plant Tannins	
Uva-Ursi	

Clostridium difficile

Patient: SAMPLE PATENT

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

Mycology Sensitivity

Azole Antifungals

Candida species	R	I	S-DD	S	NI
Fluconazole				0.5	
Voriconazole				<=0.008	
Nystatin	=50				

Natural Agents

Candida species	LOW INHIBITION	HIGH INHIBITION
Berberine		
Caprylic Acid		

Patient: SAMPLE PATENT ID:

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	H								
Clostridium spp.									
Coprococcus eutactus		↑			↑	↑		↑	↑
Faecalibacterium prausnitzii		↑				↑			↑
Lactobacillus spp.									
Pseudoflavonifractor spp.	H	↑	↑	↑	↑	↑	↑	↑	↑
Roseburia spp.	L		↓						
Ruminococcus spp.	H	↑↑	↓	↓	↓	↑↑	↑↑	↑↑	↑↑
Veillonella spp.	H	↑	↑	↑	↑	↑	↑		↑
Actinobacteria Phylum									
Bifidobacterium spp.									
Bifidobacterium longum									
Collinsella aerofaciens		↑↑	↑↑	↓	↑↑	↑↑	↑↑	↑↑	↑↑
Proteobacteria Phylum									
Desulfovibrio piger	H								↑
Escherichia coli	H	↑	↑	↑	↑	↑	↑	↑	↑
Oxalobacter formigenes	H	↑		↑	↑				↑
Euryarchaeota Phylum									
Methanobrevibacter smithii	H	↑				↑			↑
Fusobacteria Phylum									
Fusobacterium spp.	H	↑	↑	↑	↑	↑	↑	↑	↑
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.

GIECA

Patient: SAMPLE PATENT ID:

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	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						↑↓			↑↓

*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.

GIECA.2

GI Effects Profiles – Analytes

Gastrointestinal Profiles Biomarkers Comparison Table			
BIOMARKERS REPORTED	**2200***	**2205***	**2207***
*Not Available in New York			
Digestion and Absorption			
Pancreatic Elastase 1	•		
Products of Protein Breakdown (Total) (Valerate+Isobutyrate+ Isovalerate)	•		
Fecal Fat (Total)	•		
Triglycerides	•		
Long Chain Fatty Acids	•		
Cholesterol	•		
Phospholipids	•		
Inflammation and Immunology			
Calprotectin	•		
Eosinophil Protein X (EPX)	•		
Fecal sIgA	•		
Metabolic			
SCFA (Total) (Acetate, n-Butyrate, Propionate)	•		
n-Butyrate Concentration	•		
n-Butyrate %	•		
Acetate %	•		
Propionate %	•		
Beta- glucuronidase	•		
Gastrointestinal Microbiome			
Commensal Bacteria (PCR)			
***Bacteroides-Prevotella* group**	•	•	
Bacteroides vulgatus	•	•	
Barnesiella spp.	•	•	
Odoribacter spp.	•	•	
Prevotella spp.	•	•	
Firmicutes Phylum	•	•	
Anaerotruncus colihominis	•	•	
Butyrivibrio crossotus	•	•	
Clostridium spp.	•	•	
Coprococcus eutactus	•	•	
Faecalibacterium prausnitzii	•	•	
Lactobacillus spp.	•	•	
Pseudoflavonifractor spp.	•	•	
Roseburia spp.	•	•	
Ruminococcus spp.	•	•	
Veillonella spp.	•	•	

BIOMARKERS REPORTED	**2200***	**2205***	**2207***
Gastrointestinal Microbiome continued			
Commensal Bacteria (PCR)			
***Actinobacteria* Phylum**	•	•	
Bifidobacterium spp.	•	•	
Bifidobacterium longum	•	•	
Collinsella aerofaciens	•	•	
***Proteobacteria* Phylum**	•	•	
Desulfovibrio piger	•	•	
Escherichia coli	•	•	
Oxalobacter formigenes	•	•	
***Euryarchaeota* Phylum**	•	•	
Methanobrevibacter smithii	•	•	
***Fusobacteria* Phylum**	•	•	
Fusobacterium spp.	•	•	
***Verrucomicrobia* Phylum**	•	•	
Akkermansia muciniphila	•	•	
Firmicutes/Bacteroidetes (F/B Ratio)	•	•	
Bacteriology	•	•	•
Mycology (Yeast/Fungi)	•	•	•
Parasitology			
Microscopic Exam Results	•	•	•
Parasitology PCR Tests	•	•	•
Other Biomarkers			
Fecal Occult Blood	•	•	
Color	•	•	
Consistency	•	•	
Mic Sensitivities, Yeast or Bacteria	•	•	•
+ Add-ons			
2203 *Clostridium difficile* EIA	+	+	+
2204 Shiga toxin *E. coli* EIA	+	+	+
2202 *Campylobacter* spp. EIA	+	+	+
2206 Fecal Lactoferrin	+	+	
2208 *Helicobacter pylori* EIA	+	+	+
2331 Macro Exam for Worms	+	+	•
2336 Zonulin Family Peptide	+	+	
2338 KOH Preparation for Yeast	+	+	•

GI Effects Stool Profiles*

- #2200 GI Effects Comprehensive Profile
- #2205 GI Effects Microbial Ecology Profile
- #2207 GI Effects Gut Pathogen Profile

Add-On Tests (for 2200 and 2205):

- #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

*** Also available as an add-on for the 2207**

Specimen Requirements:

- Stool; 1-Day or 3-Day Collection

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