GENOVA DIAGNOSTICS
63 Zillicoa Street
Asheville, NC 28801

GI effects

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

2209 GI Effects™ Fundamentals - Stool

Methodologies: GC/MS, Automated Chemistry, EIA, Immunoturbidimetric

	Result	QUINTILE DISTRIBUTION (1st 2nd 3rd 4th 5th)	Reference Range
Digestion and Absorption			
Pancreatic Elastase 1 †	250	100 200	>200 mcg/g
Products of Protein Breakdown (Total*) (Valerate, Isobutyrate, Isovalerate)	3.9		1.8-9.9 micromol/g
Fecal Fat (Total*)	8.4		3.2-38.6 mg/g
Triglycerides	1.1		0.3-2.8 mg/g
Long-Chain Fatty Acids	2.8		1.2-29.1 mg/g
Cholesterol	2.8		0.4-4.8 mg/g
Phospholipids	1.7		0.2-6.9 mg/g
Inflammation and Immunology			
Calprotectin † ◆	33	50 100	<50 mcg/g
Eosinophil Protein X (EPX) †	1.2	0.5 2.7	<=2.7 mcg/g
Gut Microbiome Metabolites			
Metabolic			
Short-Chain Fatty Acids (SCFA) (Total*) (Acetate, n-Butyrate, Propionate)	153.5		>=23.3 micromol/g
n-Butyrate Concentration	38.5		>=3.6 micromol/g
n-Butyrate %	25.1		11.8-33.3 %
Acetate %	66.9		48.1-69.2 %
Propionate %	7.9		<=29.3 %
Beta-glucuronidase	466		368-6,266 U/g

**Total value is equal to the sum of all measurable parts.*
†These results are not represented by quintile values.

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.

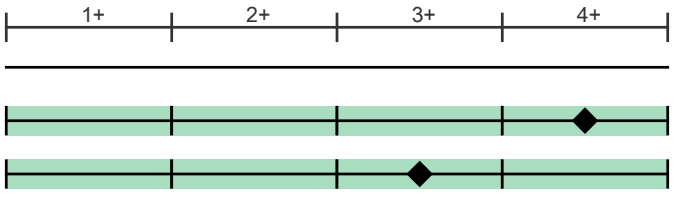
Microbiology Legend

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.		NG
Escherichia coli	4+	NP
Bifidobacterium (Anaerobic Culture)	3+	NP

Additional Bacteria

Salmonella spp.		NG
Shigella spp.		NG
alpha haemolytic Streptococcus	1+	NP
Klebsiella pneumoniae	4+	PP
gamma haemolytic Streptococcus	2+	NP

Mycology (Culture)

Candida albicans	3+	PP
Rhodotorula species	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	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

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	

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 spp.	<4.87e2	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	<1.14e3	genome copies/microliter C&S stool	Not Detected	Not Detected
Giardia	<1.57e2	genome copies/microliter C&S stool	Not Detected	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.

OPTIONAL ADD-ON

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.

Macroscopic/Direct Exam for Parasites

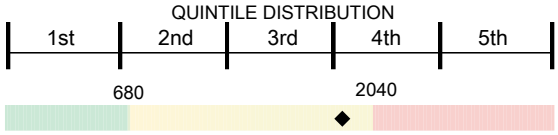
Methodology: Macroscopic Evaluation

No human parasite detected in sample.

OPTIONAL ADD-ON

Add-on Testing

Methodology: EIA



	Result	Reference Range
Fecal secretory IgA	1,875	<=2,040 mcg/mL

	Result	Expected Value
HpSA - *H. pylori*	Negative	Negative
Campylobacter spp.◆	Negative	Negative
Clostridium difficile◆	Negative	Negative
Shiga toxin *E. coli*◆	Negative	Negative

HpSA (*Helicobacter pylori* stool antigen)
Helicobacter pylori is a bacterium that 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* spp.**
Campylobacter is a foodborne pathogen and cause of gastroenteritis. Infection occurs after consumption of contaminated food, particularly poultry, unpasteurized milk, and water. Patients may experience acute watery or bloody diarrhea, weight loss, and abdominal cramping. C. jejuni can also lead to autoimmune conditions like Guillain-Barre' syndrome.

Clostridium difficile
Clostridium difficile is an anaerobic, spore-forming gram-positive bacterium that can be part of the normal intestinal flora. After a disturbance of the gut flora (usually with antibiotics), colonization with toxin producing *Clostridium difficile* can take place. Not all colonized patients develop symptoms. When present, symptoms include bloody and non-bloody diarrhea, fever, abdominal pain and vomiting.

Shiga toxin *E. coli*
A positive result on the STEC EIA assay confirms the presence of Shiga-toxin 1 (STX-1) and/or Shiga-toxin 2 (STX-2). Shiga-toxin producing strains of E. coli have been demonstrated as important etiological agents of diarrhea and sporadic cases of hemorrhagic colitis and Hemolytic Uremic Syndrome. They are transmitted via fecal-oral route. They are also transmitted by personal contact with an infected person or consumption of contaminated food or water.

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

Bacteria Sensitivity

Prescriptive Agents

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

Natural Agents

Klebsiella pneumoniae	LOW INHIBITION	HIGH INHIBITION
Berberine		
Oregano		
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.
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 products should be considered investigational in nature and not be viewed as standard clinical treatment substances.

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
Candida albicans	25561	99.19%	99.51%
Candida parapsilosis	8777	98.64%	99.33%
Candida kruseii	3420	0.23%	97.79%
Candida tropicalis	1076	93.22%	90.57%
Candida glabrata	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

Candida albicans	LOW INHIBITION	HIGH INHIBITION
Nystatin		

Natural Agents

Candida albicans	LOW INHIBITION	HIGH INHIBITION
Berberine		
Caprylic Acid		
Garlic		
Undecylenic Acid		
Uva-Ursi		

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.