GENOVA DIAGNOSTICS
63 Zillicoa Street
Asheville, NC 28801

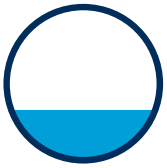
GI effects®

2205 GI Effects™ Microbial Ecology Profile - Stool

Interpretation At-a-Glance

INFECTION

INFLAMMATION



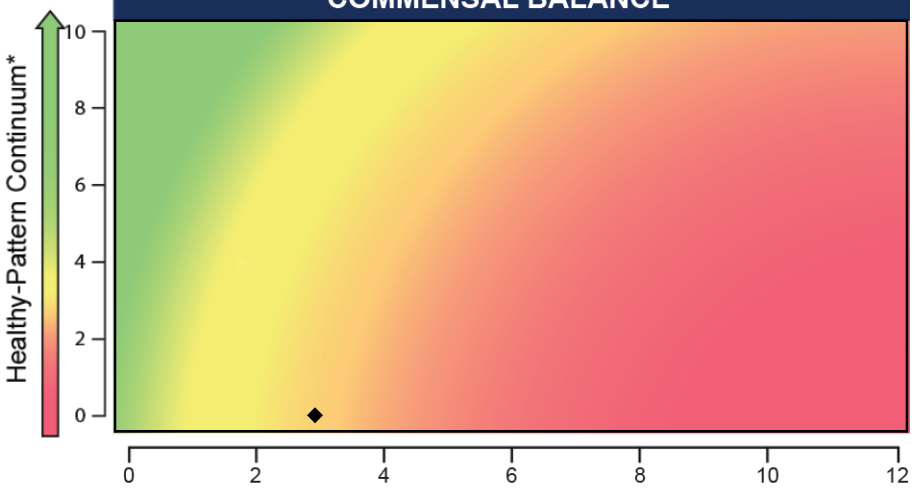
IMBALANCE

PP Bacteria ▲

PP Yeast/Fungi ▲

See individual sections for detailed results

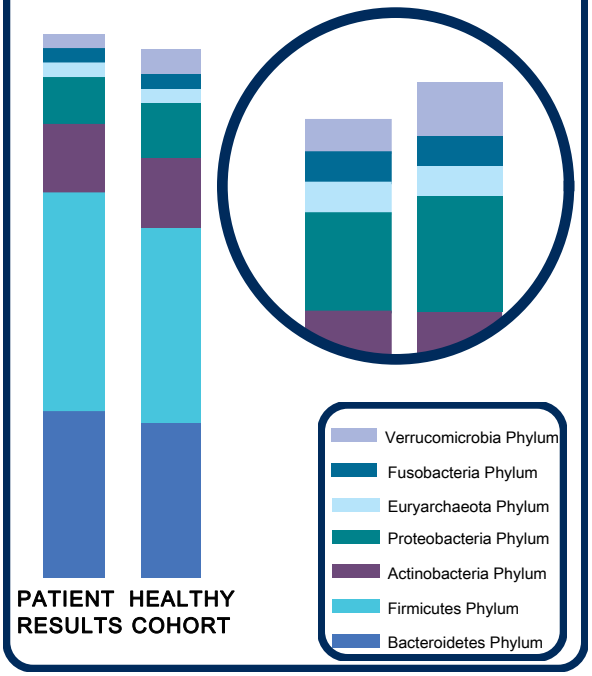
COMMENSAL BALANCE



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 ABUNDANCE



Methodology: DNA by qPCR

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 uniformis	4.7**E8**			<=9.5**E8**
Phocaeicola vulgatus	4.9**E8**			<=8.3**E8**
Barnesiella spp.	1.6**E8**			3.0**E6** -2.9**E8**
Odoribacter spp.	4.0**E7**			<=9.5**E7**
Prevotella spp.	1.3**E9**			6.6**E7** -3.8**E9**
Firmicutes Phylum				
Anaerotruncus colihominis/massiliensis	<DL			<=2.0**E7**
Butyrivibrio crossotus	<DL			<=3.3**E7**
Clostridium spp.	7.0**E5**			<=1.5**E7**
Coprococcus eutactus	<DL			<=1.2**E8**
Faecalibacterium prausnitzii	3.2**E7**			1.1**E6** -1.1**E9**
Lactobacillus spp.	<DL			<=1.6**E6**
Pseudoflavonifractor spp.	3.2**E6**			1.3**E4** -2.9**E7**
Roseburia spp.	4.0**E8**			3.6**E5** -4.6**E8**
Ruminococcus bromii	<DL			<=1.5**E9**
Veillonella spp.	1.9**E7**	H		<=4.1**E6**
Actinobacteria Phylum				
Bifidobacterium spp.	1.7**E9**	H		4.6**E5** -2.6**E8**
Bifidobacterium longum subsp. longum	7.6**E8**	H		<=1.3**E8**
Collinsella aerofaciens	1.7**E8**	H		<=1.3**E8**
Proteobacteria Phylum				
Desulfovibrio piger	<DL			<=5.4**E7**
Escherichia coli	<DL			<=7.5**E6**
Oxalobacter formigenes	<DL			<=1.1**E7**
Euryarchaeota Phylum				
Methanobrevibacter smithii	<DL			<=2.0**E7**
Fusobacteria Phylum				
Fusobacterium spp.	<DL			<=1.8**E5**
Verrucomicrobia Phylum				
Akkermansia muciniphila	<DL	L		>=8.5**E3**

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 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.

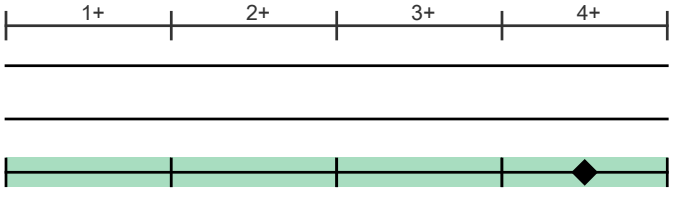
Microbiology Legend

NG	NP	PP	P
No Growth	Non-Pathogen	Potential Pathogen	Pathogen

Additional Bacteria

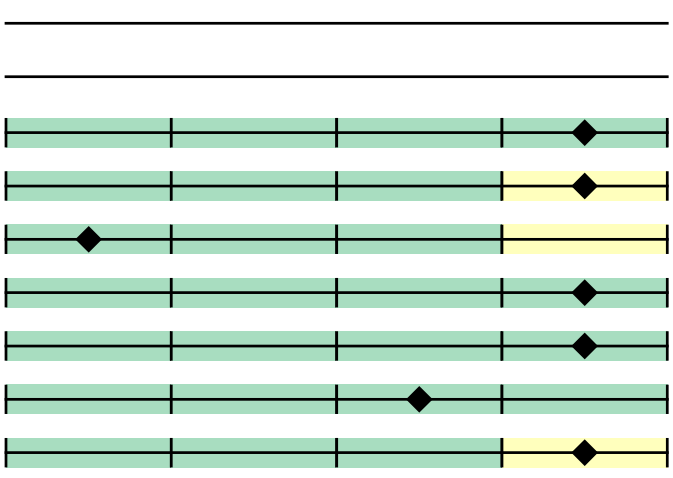
Non-Pathogen: Organisms that fall under this category are those that constitute normal, commensal flora, or have not been recognized as etiological agents of disease.
Potential Pathogen: Organisms that fall under this category are considered potential or opportunistic pathogens when present in heavy 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		NG
Bifidobacterium (Anaerobic Culture)	4+	NP

Additional Bacteria



Salmonella spp.		NG
Shigella spp.		NG
Klebsiella ornithinolytica	4+	NP
Citrobacter species	4+	PP
Staphylococcus aureus	1+	NP
Pantoea species	4+	NP
Enterococcus faecalis	4+	NP
Klebsiella ozaenae	3+	NP
Proteus mirabilis	4+	PP

Mycology (Culture)

Candida albicans/dubliniensis	1+	NP
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.

	Results
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. 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

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.	Not Detected
Chilomastix mesnili	Not Detected
Cryptosporidium spp.	Not Detected
Cyclospora cayetanensis	Not Detected
Dientamoeba fragilis	Not 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.	<2.14e2	femtograms/microliter C&S stool	Not 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	<1.84e2	genome copies/microliter C&S stool	Not 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

Additional Results

	Result
Consistency††	Not Given

††Results provided from patient input

OPTIONAL ADD-ON

Zonulin Family Peptide

Methodology: EIA

	Result	Reference Range
Zonulin Family Peptide, Stool	122.5	22.3-161.1 ng/mL

1

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.

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

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
Clostridium difficile◆	Negative	Negative
Shiga toxin *E. coli*◆	Negative	Negative
Fecal Lactoferrin◆	Negative	Negative

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.

Commentary

Commentary is provided to the practitioner for educational purposes and should not be interpreted as diagnostic or as treatment recommendations. Diagnosis and treatment decisions are the practitioner's responsibility.

For more information regarding GI Effects clinical interpretation, please refer to the GI Effects Support Guide at **www.gdx.net/gieffectsguide.**

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

Bacteria Sensitivity

Prescriptive Agents

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

Natural Agents

Citrobacter species	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

Bacteria Sensitivity

Prescriptive Agents

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

Natural Agents

Proteus mirabilis	LOW INHIBITION	HIGH INHIBITION
Berberine		
Oregano		
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.