GENOVA DIAGNOSTICS
3425 Corporate Way • Duluth GA 30096

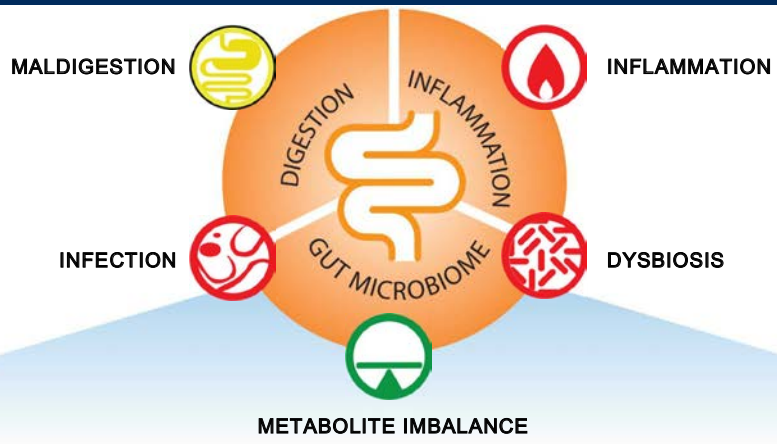
THE WELLNESS WAY
Do Health Differently.

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

2200 GI Effects™ Comprehensive Profile - Stool

Powered by ***Genova AI***

Results Overview



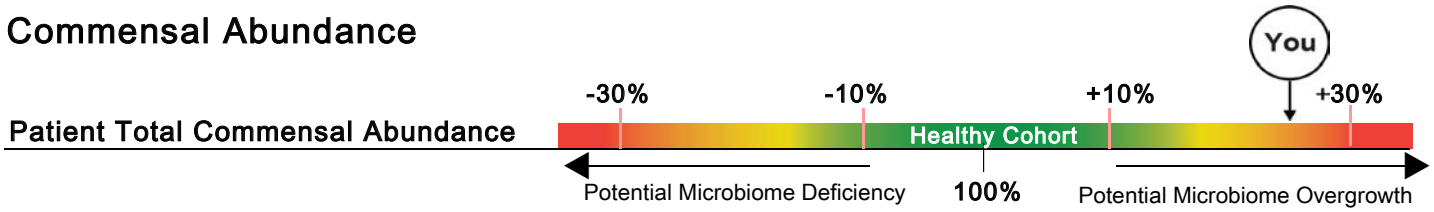
Functional Imbalance Scores

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					

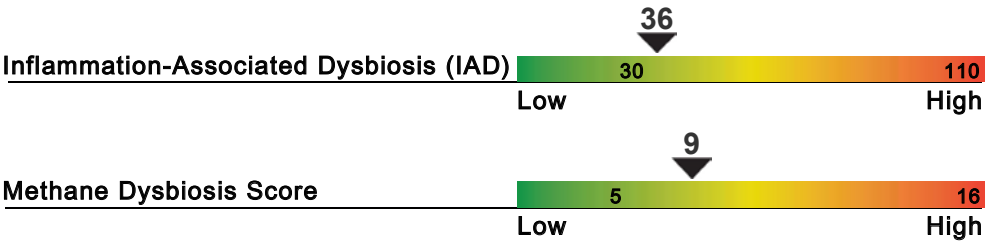
Commensal Microbiome Analysis

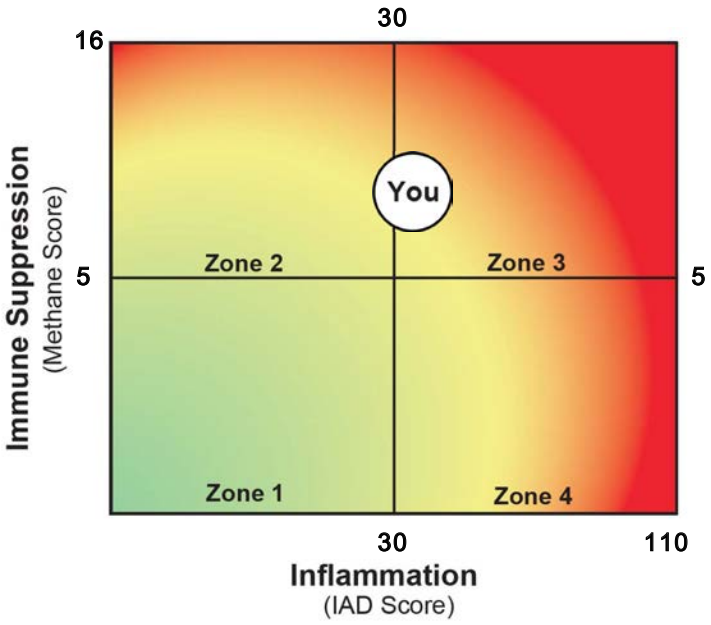
Commensal Abundance



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.

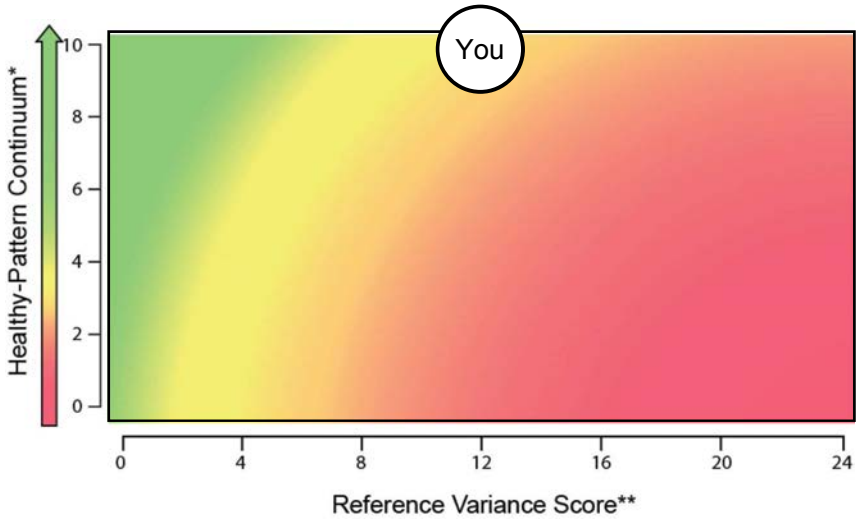
Zone 2: This pattern of bacteria is associated with impaired intestinal barrier function (low fecal sIgA and EPX). Patients in this zone have higher rates of opportunistic infections (e.g. *Blastocystis spp.* & *Dientamoeba fragilis*) as well as fecal fat malabsorption. Commensal abundance is higher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

Commensal Microbiome Analysis

Commensal Balance

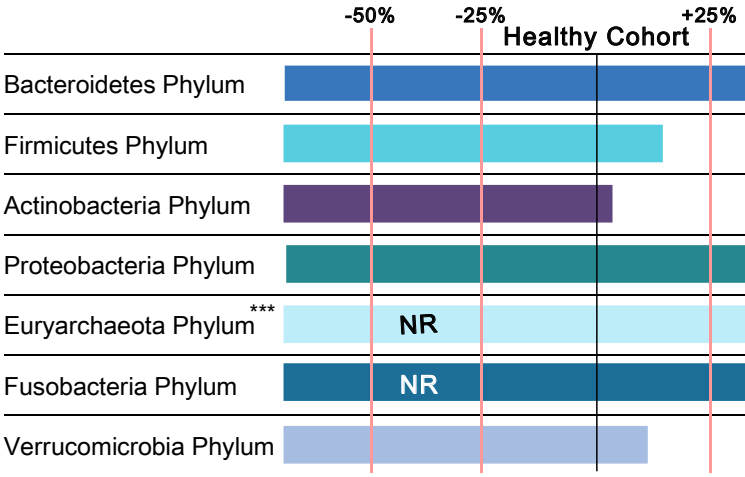


Balanced	Represents 95% of healthy individuals
Borderline	Represents 5% of healthy individuals
Imbalanced	Represents 60% of unhealthy individuals

*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



Bacteroidetes Phylum	Increase in *Bacteroides spp.* and *Odoribacter spp.* seen in animal-based diets; *Prevotella* increased with plant-based diet
Firmicutes Phylum	Contains many butyrate-producers; most species responsive to plant-based diets; *Faecalibacterium spp.* is anti-inflammatory
Actinobacteria Phylum	*Bifidobacterium* is increased with plant-based diets; *Collinsella* may be proinflammatory, and is elevated with a Western-diet
Proteobacteria Phylum	Some species may be proinflammatory; *E. coli* consumes simple sugars and is lower in individuals on plant-based diets
Euryarchaeota Phylum***	*Methanobrevibacter smithii* is associated with methane production and with diets high in carbohydrates
Fusobacteria Phylum	Certain *Fusobacterium spp.* may be proinflammatory and increased on low fiber, high fat diets
Verrucomicrobia Phylum	*Akkermansia spp.* is involved in gut membrane integrity and may be increased with polyphenols and prebiotics

Relative Abundance: The relative abundance compares the quantity of each of 7 major bacterial phyla to a healthy cohort. This can indicate broader variances in the patient's gut microbiome profile. Certain interventions may promote or limit individual phyla when clinically appropriate. Please refer to Genova's Stool Testing Support Guide for more information on modulation of commensal bacteria through diet & nutrient interventions. ***Roughly 75% of the healthy cohort had below detectable levels of *Methanobrevibacter smithii.*

Physician Notes/Recommendations

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
Gastrointestinal Microbiome			
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.

Methodology: DNA by PCR

Gastrointestinal Microbiome

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

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

Gastrointestinal Microbiome**

Human microflora is influenced by environmental factors and the competitive ecosystem of the organisms in the GI tract. Pathogenic significance should be based upon clinical symptoms.

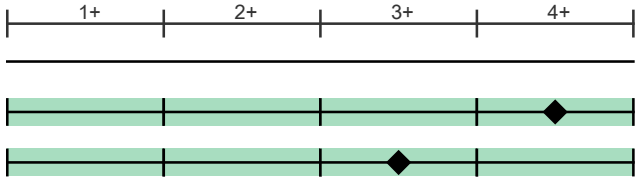
Microbiology Legend

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
Klebsiella pneumoniae	4+	PP
Bacillus species	1+	NP
Enterococcus faecium	4+	NP

Mycology (Culture)

Candida kruseii	2+	PP
Yeast, not Candida albicans	1+	NP

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

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

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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.

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 Exam for Worms **

Methodology: Macroscopic Evaluation

No larvae seen macroscopically.

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

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.

***Campylobacter* spp.**
Campylobacter jejuni is the most frequent cause of bacterial-induced diarrhea. While transmission can occur via the fecal-oral route, infection is primarily associated with the ingestion of contaminated and poorly cooked foods of animal origin, notably, red meat and milk.

Clostridium difficile
Clostridium difficile is an anaerobic, spore-forming gram-positive bacterium. After a disturbance of the gut flora (usually with antibiotics), colonization with *Clostridium difficile* can take place. *Clostridium difficile* infection is much more common than once thought.

Shiga toxin *E. coli*
Shiga toxin-producing *Escherichia coli* (STEC) is a group of bacterial strains that have been identified as worldwide causes of serious human gastrointestinal disease. The subgroup enterohemorrhagic *E. coli* includes over 100 different serotypes, with 0157:H7 being the most significant, as it occurs in over 80% of all cases. Contaminated food continues to be the principal vehicle for transmission; foods associated with outbreaks include alfalfa sprouts, fresh produce, beef, and unpasteurized juices.

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

Mycology Sensitivity

Natural Agents

Candida albicans/dubliniensis	LOW INHIBITION	HIGH INHIBITION
Berberine		
Caprylic Acid		
Garlic		
Undecylenic Acid		
Plant tannins		
Uva-Ursi		

Prescriptive Agents:
The R (Resistant) category implies isolate is not inhibited by obtainable levels of pharmaceutical agent.
The I (Intermediate) category includes isolates for which the minimum inhibition concentration (MIC) values usually approach obtainable pharmaceutical agent levels and for which response rates may be lower than for susceptible isolates.
The S-DD (Susceptible-Dose Dependent) category implies clinical efficacy when higher than normal dosage of a drug can be used and maximal concentration achieved.
The S (Susceptible) column implies that isolates are inhibited by the usually achievable concentrations of the pharmaceutical agent.
NI (No Interpretive guidelines established) category is used for organisms that currently do not have established guidelines for MIC interpretation.
Refer to published pharmaceutical guidelines for appropriate dosage therapy.

Nystatin and Natural Agents:
Results for Nystatin are being reported with natural antifungals in this category in accordance with laboratory guidelines for reporting sensitivities. In this assay, inhibition is defined as the reduction level on organism growth as a direct result of inhibition by a natural substance. The level of inhibition is an indicator of how effective the substance was at limiting the growth of an organism in an in vitro environment. High inhibition indicates a greater ability by the substance to limit growth, while Low Inhibition a lesser ability to limit growth. The designated natural products should be considered investigational in nature and not be viewed as standard clinical treatment substances.