



Patient: Jane Doe

Order Number:

DOB: September 16, 1960

Completed: October 05, 2017

Sex: F

Received: September 21, 2017

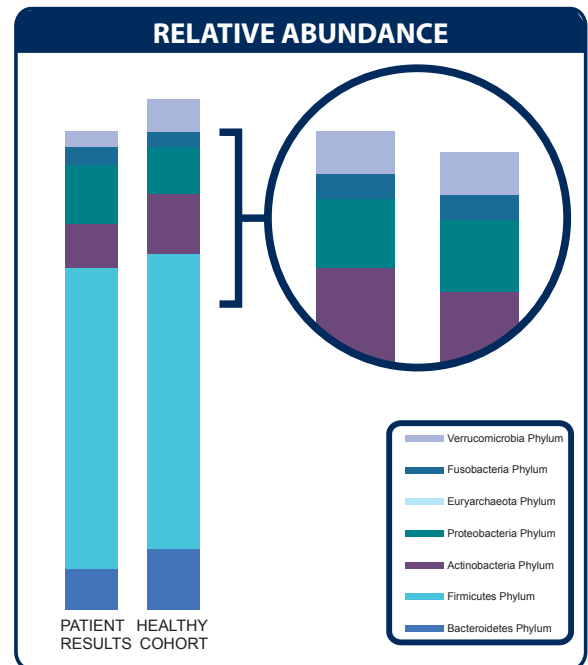
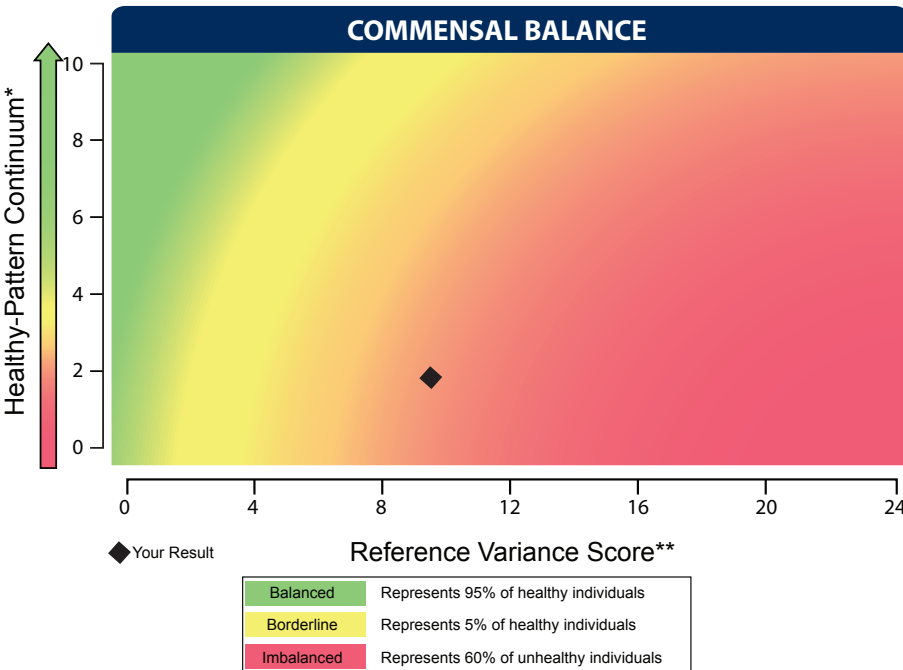
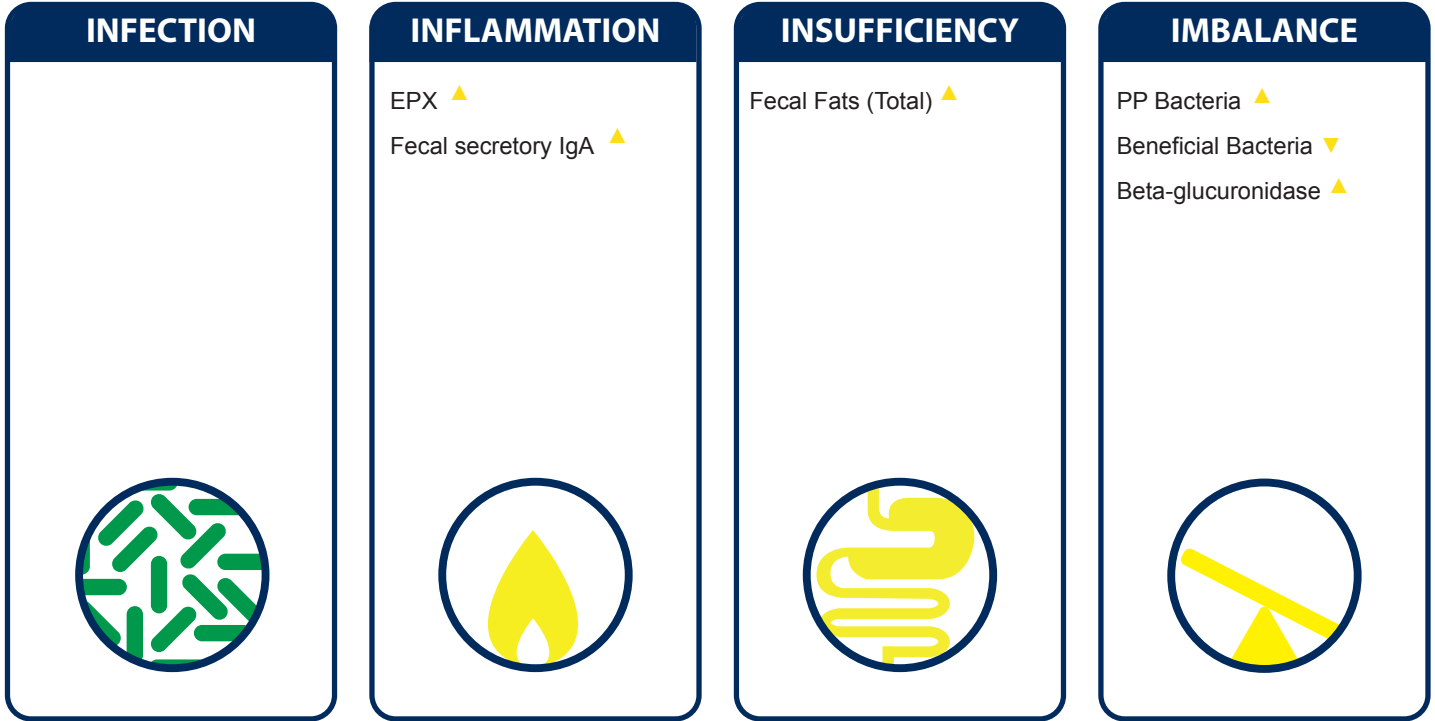
MRN:

Collected: September 20, 2017

SAMPLE REPORT

2200 GI Effects™ Comprehensive Profile – Stool

Interpretation At-a-Glance



* 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 range for this individual



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									
<i>Bacteroides-Prevotella</i> group		↑	↑	↑	↑	↑	↑	↑	↑
<i>Bacteroides vulgatus</i>		↑			↑	↑		↑	↑
<i>Barnesiella</i> spp.									
<i>Odoribacter</i> spp.									
<i>Prevotella</i> spp.	H	↑		↑	↑	↑		↑	↑
Firmicutes Phylum									
<i>Anaerotruncus colihominis</i>	H	↑	↑	↑	↑	↑	↑	↑	↑
<i>Butyrivibrio crossotus</i>									
<i>Clostridium</i> spp.									
<i>Coprococcus eutactus</i>		↑			↑	↑		↑	↑
<i>Faecalibacterium prausnitzii</i>	H	↑				↑			↑
<i>Lactobacillus</i> spp.									
<i>Pseudoflavonifractor</i> spp.	H	↑	↑	↑	↑	↑	↑	↑	↑
<i>Roseburia</i> spp.			↓						
<i>Ruminococcus</i> spp.	L	↓↑	↓	↓	↓	↓↑	↓↑	↓↑	↓↑
<i>Veillonella</i> spp.		↑	↑	↑	↑	↑	↑		↑
Actinobacteria Phylum									
<i>Bifidobacterium</i> spp.	H								
<i>Bifidobacterium longum</i>									
<i>Collinsella aerofaciens</i>	L	↓↑	↓↑	↓	↓↑	↓↑	↓↑	↓↑	↓↑
Proteobacteria Phylum									
<i>Desulfovibrio piger</i>									↑
<i>Escherichia coli</i>	H	↑	↑	↑	↑	↑	↑	↑	↑
<i>Oxalobacter formigenes</i>	H	↑		↑	↑				↑
Euryarchaeota Phylum									
<i>Methanobrevibacter smithii</i>		↑				↑			↑
Fusobacteria Phylum									
<i>Fusobacterium</i> spp.		↑	↑	↑	↑	↑	↑	↑	↑
Verrucomicrobia Phylum									
<i>Akkermansia muciniphila</i>		↓	↓	↓	↓	↓	↓	↓	↓

*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.



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		↓	↓	↓	↓	↓	↓	↓	↓
Products of Protein Breakdown (Total)							↓↑		
Fecal Fat (Total)		↑		↑	↑	↑	↓↑	↑	↑
Triglycerides	H	↑			↑	↑	↑	↑	↑
Long Chain Fatty Acids		↑			↑	↑	↓↑	↑	↑
Cholesterol							↓↑	↑	
Phospholipids		↑	↑	↑	↑	↑	↑	↑	↑
Calprotectin			↑					↑	
Eosinophil Protein X (EPX)			↑						
Fecal sIgA	H	↑	↑	↑	↑	↑	↑	↑	↑
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.

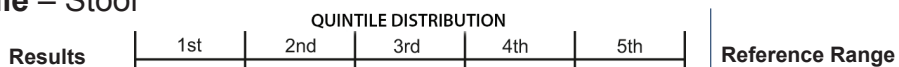
↓↑ Indicates Genova's clinical condition cohort test results falling below and above the reference range that are greater than that of Genova's healthy cohort.

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.



2200 GI Effects™ Comprehensive Profile – Stool

Methodology: GC/MS, Automated Chemistry, EIA



Digestion and Absorption

Parameter	Results	Quintile Distribution	Reference Range
Pancreatic Elastase 1†	>500	100 200	>200 mcg/g
Products of Protein Breakdown (Total) (Valerate+Isobutyrate+Isovalerate)	5.7		1.8 - 9.9 micromol/g
Fecal Fat (Total*)	34.0		3.2 - 38.6 mg/g
Triglycerides	3.2 H		0.3 - 2.8 mg/g
Long Chain Fatty Acids	23.3		1.2 - 29.1 mg/g
Cholesterol	1.2		0.4 - 4.8 mg/g
Phospholipids	6.3		0.2 - 6.9 mg/g

Inflammation and Immunology

Parameter	Results	Quintile Distribution	Reference Range
Calprotectin†	<16	50 120	<= 50 mcg/g
Eosinophil Protein X (EPX)†	1.7	2 7	<=4.6 mcg/g
Fecal sIgA	2,033 H		<=885 mcg/g

Gastrointestinal Microbiome

Metabolic

Parameter	Results	Quintile Distribution	Reference Range
SCFA (Total*) (Acetate, n-Butyrate, Propionate)	52.3		> = 23.3 micromol/g
n-Butyrate Concentration	9.1		> = 3.6 micromol/g
n-Butyrate %	17.4		11.8 - 33.3 %
Acetate%	59.7		48.1 - 69.2 %
Propionate%	22.8		<=29.3 %
Beta-Glucuronidase	4,592		368 - 6266 U/g

*Total Value equals 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

	Result CFU/g stool	QUINTILE DISTRIBUTION					Reference Range CFU/g stool
		1st	2nd	3rd	4th	5th	
Commensal Bacteria (PCR)							
Bacteroidetes Phylum							
<i>Bacteroides-Prevotella</i> group	1.1E9						3.4E6 - 1.5E9
<i>Bacteroides vulgatus</i>	2.2E9						<=2.2E9
<i>Barnesiella</i> spp.	<DL						<=1.6E8
<i>Odoribacter</i> spp.	<DL						<=8.0E7
<i>Prevotella</i> spp.	1.7E7 H						1.4E5 - 1.6E7
Firmicutes Phylum							
<i>Anaerotruncus colihominis</i>	7.0E7 H						<=3.2E7
<i>Butyrivibrio crossotus</i>	5.9E4						5.5E3 - 5.9E5
<i>Clostridium</i> spp.	5.5E9						1.7E8 - 1.5E10
<i>Coprococcus eutactus</i>	1.2E7						<=1.2E8
<i>Faecalibacterium prausnitzii</i>	1.2E10 H						5.8E7 - 4.7E9
<i>Lactobacillus</i> spp.	1.0E8						8.3E6 - 5.2E9
<i>Pseudoflavonifractor</i> spp.	2.7E8 H						4.2E5 - 1.3E8
<i>Roseburia</i> spp.	3.3E9						1.3E8 - 1.2E10
<i>Ruminococcus</i> spp.	7.1E7 L						9.5E7 - 1.6E9
<i>Veillonella</i> spp.	9.1E6						1.2E5 - 5.5E7
Actinobacteria Phylum							
<i>Bifidobacterium</i> spp.	6.7E9 H						<=6.4E9
<i>Bifidobacterium longum</i>	2.0E8						<=7.2E8
<i>Collinsella aerofaciens</i>	<DL L						1.4E7 - 1.9E9
Proteobacteria Phylum							
<i>Desulfovibrio piger</i>	<DL						<=1.8E7
<i>Escherichia coli</i>	7.4E7 H						9.0E4 - 4.6E7
<i>Oxalobacter formigenes</i>	1.6E7 H						<=1.5E7
Euryarchaeota Phylum							
<i>Methanobrevibacter smithii</i>	<DL						<=8.6E7
Fusobacteria Phylum							
<i>Fusobacterium</i> spp.	6.0E4						<=2.4E5
Verrucomicrobia Phylum							
<i>Akkermansia muciniphila</i>	3.6E6						>=1.2E6
Firmicutes/Bacteroidetes Ratio							
<i>Firmicutes/Bacteroidetes</i> (F/B Ratio)	19						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 10⁶ 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

Bacteriology (Culture)

Lactobacillus spp.

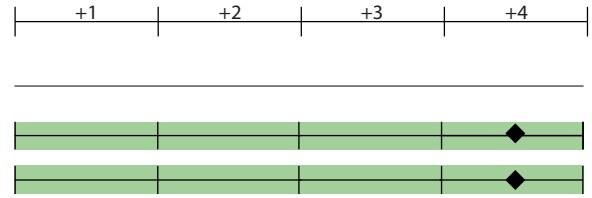
NG

Escherichia coli

4+ NP

Bifidobacterium

4+ NP



Additional Bacteria

Citrobacter braakii

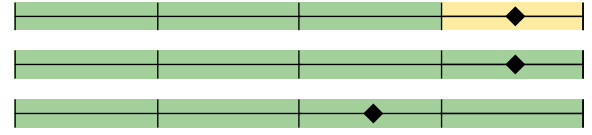
4+ PP

alpha haemolytic Streptococcus

4+ NP

gamma haemolytic Streptococcus

3+ NP



Mycology (Culture)

NG



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 are well-recognized pathogens in clinical literature that have a clearly recognized mechanism of pathogenicity and are considered significant regardless of the quantity that appears in culture.



Methodology: Direct Microscopic Examination, EIA

Parasitology

Microscopic Exam Results:

No Ova or Parasites seen

Parasitology

Parasite Recovery: Literature suggests that >90% of enteric parasitic infections may be detected in a sample from a single stool collection. Increased sensitivity results from the collection of additional specimens on separate days.

Parasitology EIA Tests:

	In Range	Out of Range
<i>Cryptosporidium</i> ◆	Negative	
<i>Giardia lamblia</i> ◆	Negative	
<i>Entamoeba histolytica</i> ◆	Negative	



Methodology: EIA, Fecal Immunochemical Testing (FIT)

Additional Results

	Result	Expected Value	
Fecal Occult Blood [◆]	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.
Color ^{††}	Brown		
Consistency ^{††}	Formed/Normal		
HpSA - <i>H.pylori</i>	Negative	Negative	Campylobacter 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.
<i>Campylobacter</i> spp [◆]	Negative	Negative	
<i>Clostridium difficile</i> ^{◆**}	Negative	Negative	
Shiga toxin <i>E. coli</i> ^{◆**}	Negative	Negative	Clostridium difficile is an anaerobic, spore-forming gram-positive bacterium. After a disturbance of the gut flora (usually with antibiotics), colonization with <i>Clostridium difficile</i> can take place. <i>Clostridium difficile</i> infection is much more common than once thought.
Fecal Lactoferrin ^{◆**}	Negative	Negative	
			Shiga toxin E. coli Shiga toxin-producing <i>Escherichia coli</i> (STEC) is a group of bacterial strains that have been identified as worldwide causes of serious human gastrointestinal disease. The subgroup enterohemorrhagic <i>E. coli</i> 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.

†† Results provided from patient input.

** 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

Tests were developed and their performance characteristics determined by Genova Diagnostics. Unless otherwise noted with [◆], the assays have not been cleared or approved by the U.S. Food and Drug Administration.



Bacteria Sensitivity

Prescriptive Agents	R	I	S-DD	S	NI
<i>Citrobacter braakii</i>	R				
Ampicillin	R				
Amox./Clavulanic Acid	R				
Cephalothin					
Ciprofloxacin				S	
Tetracycline				S	
Trimethoprim/Sulfa				S	

Natural Agents

<i>Citrobacter braakii</i>	LOW INHIBITION	HIGH INHIBITION
Berberine		
Oregano		
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.

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.



Mycology Sensitivity

Azole Antifungals

	S	I	R
Candida albicans/dubliniensis	S		R
Fluconazole	=0.25		
Caspofungin		=0.25	
Voriconazole	=0.25		

Prescriptive Agents:

Microbial testing has been performed in vitro to determine antibiotic sensitivity and resistance at standard dosages. Prudent use of antimicrobials requires knowledge of appropriate blood or tissue levels of those agents. Antibiotics that appear in the "S" (susceptible) column are more effective at inhibiting the growth of this organism. Antibiotics that appear in the "I" (intermediate) column are partially effective at inhibiting the growth of this organism. Antibiotics that appear in the "R" (resistant) column allow continued growth of the organism in vitro and are usually less effective clinically. Inappropriate use of antibacterials often results in the emergence of resistance.

Non-absorbed Antifungals

	LOW INHIBITION	HIGH INHIBITION
Candida albicans/dubliniensis		
Nystatin		

Natural Agents

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

Natural Agents:

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 natural substance was at limiting the growth of an organism in an in vitro environment. High Inhibition indicates a greater ability by the natural substance to limit growth, while Low Inhibition a lesser ability to limit growth. In accordance with laboratory guidelines for reporting sensitivities, results for Nystatin are now being reported with natural antifungals in this category.



Methodology: EIA

Zonulin Family Peptide

	Result		Reference Range
Zonulin Family Peptide, Stool	200.0	H	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.

References

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 Front Endocrinol. Family. 2018;9:22.

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.

*Methodology: Microscopy*

Potassium Hydroxide (KOH) Preparation for Yeast

Result

KOH Preparation, stool

Rare Yeast Present

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.

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