



Order: 999999-9999



Client #: 999999

Doctor: Sample Doctor, MD  
Doctors Data Inc  
123 Main St.  
St. Charles, IL 60174 USA

Patient: Sample Patient

Id: 999999

Age: 41 DOB: 10/13/1977

Sex: Male

Sample Collection

Date/Time

Date Collected

09/22/2019

Date Received

09/26/2019

Date Reported

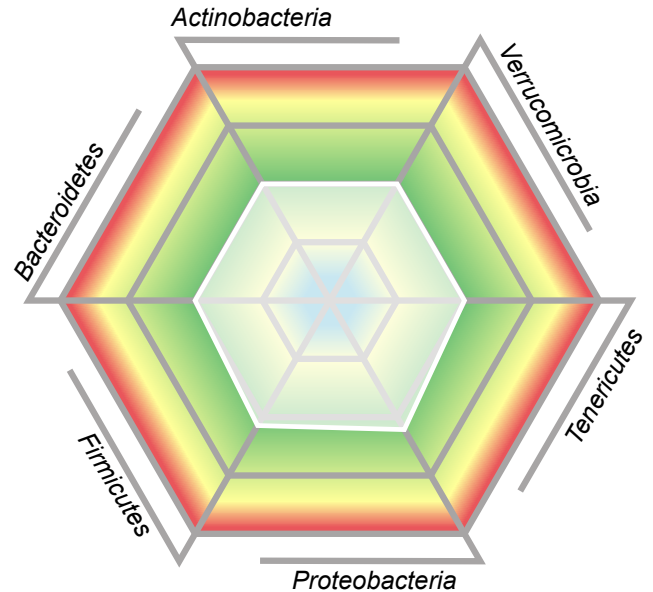
10/09/2019

Specimens Collected

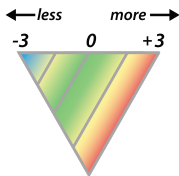
2

### Microbiome Abundance and Diversity Summary

The abundance and diversity of gastrointestinal bacteria provide an indication of gastrointestinal health, and gut microbial imbalances can contribute to dysbiosis and other chronic disease states. The GI360™ Microbiome Profile is a gut microbiota DNA analysis tool that identifies and characterizes more than 45 targeted analytes across six Phyla using PCR and compares the patient results to a characterized normobiotic reference population. The web chart illustrates the degree to which an individual's microbiome profile deviates from normobiosis.



#### LEGEND



The web image shows the relative diversity and balance among bacteria belonging to the six primary Phyla. The white shaded area represents the patient's results compared to a normobiotic reference population. The center of the web represents less abundance while the outer edges represent more than normobiotic.

### Dysbiosis Index

The Dysbiosis Index (DI) is a calculation with scores from 1 to 5 based on the overall bacterial abundance and profile within the patient's sample as compared to a reference population. Values above 2 indicate a microbiota profile that differs from the defined normobiotic reference population (i.e., dysbiosis). The higher the DI above 2, the more the sample is considered to deviate from normobiosis.

DI Score

4



### Expected Flora Summary

Clostridia Class, WRI	◆
<i>Bacteroides fragilis</i> , WRI	◆
<i>Bacteroides</i> spp. & <i>Prevotella</i> spp., WRI	◆
<i>Bifidobacterium</i> spp., WRI	◆
<i>Escherichia</i> spp., WRI	◆
<i>Lactobacillus</i> spp., WRI	◆

### Key Findings

<i>Shigella</i> ( <i>S. boydii</i> , <i>S. sonnei</i> , <i>S. flexneri</i> & <i>S. dysenteriae</i> ), Detected
% Acetate, Very Low
Butyrate, Very High
Possible <i>Shigella</i> group, Detected

Notes:  
WRI = Within Reference Interval



# Microbiome Bacterial Abundance; Multiplex PCR



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## LEGEND



Results are graphed as deviations from a normobiotic population. Normobiosis or a normobiotic state characterizes a composition of the microbiota profile in which microorganisms with potential health benefits predominate in abundance and diversity over potentially harmful ones.

<i>Actinobacteria</i>	Result	-3	-2	-1	0	+1	+2	+3	Reference Interval
<i>Actinobacteria</i>	0				▲				-1 to +1
<i>Actinomycetales</i>	0				▲				0 to +1
<i>Bifidobacterium</i> spp.	0				▲				-1 to +1
<i>Bacteroidetes</i>	Result	-3	-2	-1	0	+1	+2	+3	Reference Interval
<i>Alistipes</i> spp.	0				▲				-1 to +1
<i>Alistipes onderdonkii</i>	0				▲				-1 to +1
<i>Bacteroides fragilis</i>	0				▲				0 to +1
<i>Bacteroides</i> spp. & <i>Prevotella</i> spp.	0				▲				-1 to +1
<i>Bacteroides stercoris</i>	0				▲				0 to +1
<i>Bacteroides zooglyphiformans</i>	0				▲				0 to +1
<i>Parabacteroides johnsonii</i>	0				▲				0 to +1
<i>Parabacteroides</i> spp.	0				▲				-1 to +1
<i>Firmicutes</i>	Result	-3	-2	-1	0	+1	+2	+3	Reference Interval
<i>Firmicutes</i>	0				▲				-1 to +1
Bacilli Class	0				▲				-1 to +1
<i>Catenibacterium mitsuokai</i>	+1					▲			-1 to +1
Clostridia Class	0				▲				-1 to +1
<i>Clostridium</i> L2-50	0				▲				-1 to +1

The gray-shaded area of the bar graph represents reference values outside the reporting limits for this test.

\*This test was developed and its performance characteristics determined by Doctor's Data Laboratories in a manner consistent with CLIA requirements. The U. S. Food and Drug Administration (FDA) has not approved or cleared this test; however, FDA clearance is not currently required for clinical use. The results are not intended to be used as a sole means for clinical diagnosis or patient management decisions.

### Notes:

Methodology: Multiplex PCR



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<i>Firmicutes</i>	Result	-3	-2	-1	0	+1	+2	+3	Reference Interval
<i>Dialister invisus</i>	+1					▲			0 to +1
<i>Dialister invisus</i> & <i>Megasphaera micronuciformis</i>	+1					▲			0 to +1
<i>Dorea</i> spp.	0				▲				0 to +1
<i>Eubacterium bifforme</i>	+1					▲			0 to +1
<i>Eubacterium hallii</i>	0				▲				-1 to +1
<i>Eubacterium rectale</i>	0				▲				0 to +1
<i>Eubacterium siraeum</i>	0				▲				-1 to +1
<i>Faecalibacterium prausnitzii</i>	0				▲				-1 to +1
Lachnospiraceae	0				▲				-1 to +1
<i>Lactobacillus ruminis</i> & <i>Pediococcus acidilactici</i>	0				▲				0 to +1
<i>Lactobacillus</i> spp.	+1					▲			0 to +1
<i>Phascolarctobacterium</i> spp.	0				▲				0 to +1
<i>Ruminococcus albus</i> & <i>R. bromii</i>	+2						▲		0 to +1
<i>Ruminococcus gnavus</i>	0				▲				0 to +1
<i>Streptococcus agalactiae</i> & <i>Eubacterium rectale</i>	0				▲				0 to +1
<i>Streptococcus salivarius</i> ssp. <i>thermophilus</i> & <i>S. sanguinis</i>	0				▲				-1 to +1
<i>Streptococcus salivarius</i> ssp. <i>thermophilus</i>	0				▲				0 to +1
<i>Streptococcus</i> spp.	0				▲				0 to +1
<i>Veillonella</i> spp.	0				▲				-1 to +1

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<b>Proteobacteria</b>	<b>Result</b>	-3	-2	-1	0	+1	+2	+3	<b>Reference Interval</b>
<i>Proteobacteria</i>	0								0 to +1
<i>Escherichia spp.</i>	+1								-1 to +1
<b>Tenericutes</b>	<b>Result</b>	-3	-2	-1	0	+1	+2	+3	<b>Reference Interval</b>
<i>Mycoplasma hominis</i>	0								-1 to +1
<b>Verrucomicrobia</b>	<b>Result</b>	-3	-2	-1	0	+1	+2	+3	<b>Reference Interval</b>
<i>Akkermansia muciniphila</i>	0								0 to +1



## Microbiome Abundance Information:

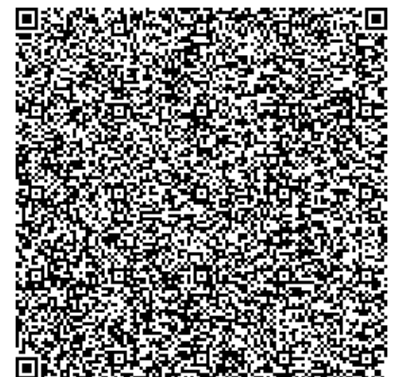
The GI360™ Microbiome Profile is a gut microbiota profiling test that characterizes patient results by determining deviation from a well-defined state of normobiosis using PCR. The profiling approach contrasts to direct diagnosis of a particular disease by detecting one organism. Characteristic sets of bacteria are required in a healthy normobiotic gut, and deviation will represent a potentially dysbiotic state. Measurement of deviation in bacterial microbiota makes it possible to characterize differences in the patient's results based on an established algorithm that defines normobiosis. By combining information from a well-defined set of predetermined PCR probes, this test enables highly reproducible and standardized information to be derived from the complex human microbiota. A summary web graphic chart is provided to represent bacterial abundance and diversity within a stool sample.

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Viruses	Result	
Adenovirus F40/41	Negative	<input checked="" type="checkbox"/>
Norovirus GI/GII	Negative	<input checked="" type="checkbox"/>
Rotavirus A	Negative	<input checked="" type="checkbox"/>

Pathogenic Bacteria	Result	
<i>Campylobacter</i> ( <i>C. jejuni</i> , <i>C. coli</i> and <i>C. lari</i> )	Negative	<input checked="" type="checkbox"/>
<i>Clostridium difficile</i> (Toxin A/B)	Negative	<input checked="" type="checkbox"/>
<i>Escherichia coli</i> O157	Negative	<input checked="" type="checkbox"/>
Enterotoxigenic <i>Escherichia coli</i> (ETEC) It/st	Negative	<input checked="" type="checkbox"/>
<i>Salmonella</i> spp.	Negative	<input checked="" type="checkbox"/>
Shiga-like toxin-producing <i>Escherichia coli</i> (STEC) stx1/stx2	Negative	<input checked="" type="checkbox"/>
<i>Shigella</i> ( <i>S. boydii</i> , <i>S. sonnei</i> , <i>S. flexneri</i> & <i>S. dysenteriae</i> )	Positive	<input type="checkbox"/>
<i>Vibrio cholerae</i>	Negative	<input checked="" type="checkbox"/>

Parasites	Result	
<i>Blastocystis hominis</i> *	Negative	<input checked="" type="checkbox"/>
<i>Blastocystis hominis</i> subtype 1 & 3*	Negative	<input checked="" type="checkbox"/>
<i>Cryptosporidium</i> ( <i>C. parvum</i> and <i>C. hominis</i> )	Negative	<input checked="" type="checkbox"/>
<i>Dientamoeba fragilis</i> *	Negative	<input checked="" type="checkbox"/>
<i>Entamoeba histolytica</i>	Negative	<input checked="" type="checkbox"/>
<i>Giardia duodenalis</i> (AKA <i>intestinalis</i> & <i>lamblia</i> )	Negative	<input checked="" type="checkbox"/>

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Protozoa

Result

<i>Balantidium coli</i>	Not Detected	<input checked="" type="checkbox"/>
<i>Blastocystis spp.</i>	Not Detected	<input checked="" type="checkbox"/>
<i>Chilomastix mesnili</i>	Not Detected	<input checked="" type="checkbox"/>
<i>Dientamoeba fragilis</i>	Not Detected	<input checked="" type="checkbox"/>
<i>Endolimax nana</i>	Not Detected	<input checked="" type="checkbox"/>
<i>Entamoeba coli</i>	Not Detected	<input checked="" type="checkbox"/>
<i>Entamoeba hartmanni</i>	Not Detected	<input checked="" type="checkbox"/>
<i>Entamoeba histolytica/Entamoeba dispar</i>	Not Detected	<input checked="" type="checkbox"/>
<i>Entamoeba polecki</i>	Not Detected	<input checked="" type="checkbox"/>
<i>Enteromonas hominis</i>	Not Detected	<input checked="" type="checkbox"/>
<i>Giardia duodenalis</i>	Not Detected	<input checked="" type="checkbox"/>
<i>Iodamoeba bütschlii</i>	Not Detected	<input checked="" type="checkbox"/>
<i>Isospora belli</i>	Not Detected	<input checked="" type="checkbox"/>
<i>Pentatrichomonas hominis</i>	Not Detected	<input checked="" type="checkbox"/>
<i>Retortamonas intestinalis</i>	Not Detected	<input checked="" type="checkbox"/>

Cestodes - Tapeworms

Result

<i>Diphyllobothrium latum</i>	Not Detected	<input checked="" type="checkbox"/>
<i>Dipylidium caninum</i>	Not Detected	<input checked="" type="checkbox"/>
<i>Hymenolepis diminuta</i>	Not Detected	<input checked="" type="checkbox"/>
<i>Hymenolepis nana</i>	Not Detected	<input checked="" type="checkbox"/>
<i>Taenia</i>	Not Detected	<input checked="" type="checkbox"/>

Trematodes - Flukes

Result

<i>Clonorchis sinensis</i>	Not Detected	<input checked="" type="checkbox"/>
<i>Fasciola hepatica/Fasciolopsis buski</i>	Not Detected	<input checked="" type="checkbox"/>
<i>Heterophyes heterophyes</i>	Not Detected	<input checked="" type="checkbox"/>
<i>Paragonimus westermani</i>	Not Detected	<input checked="" type="checkbox"/>

Nematodes - Round Worms

Result

<i>Ascaris lumbricoides</i>	Not Detected	<input checked="" type="checkbox"/>
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Notes:

Methodology: Microscopy



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Nematodes - Round Worms

Result

Capillaria hepatica	Not Detected	<input checked="" type="checkbox"/>
Capillaria philippinensis	Not Detected	<input checked="" type="checkbox"/>
Enterobius vermicularis	Not Detected	<input checked="" type="checkbox"/>
Hookworm	Not Detected	<input checked="" type="checkbox"/>
Strongyloides stercoralis	Not Detected	<input checked="" type="checkbox"/>
Trichuris trichiura	Not Detected	<input checked="" type="checkbox"/>

Other Markers

Result

Reference Interval

Yeast	Rare	<input checked="" type="checkbox"/>	Not Detected – Rare
RBC	Rare	<input checked="" type="checkbox"/>	Not Detected – Rare
WBC	Not Detected	<input checked="" type="checkbox"/>	Not Detected – Rare
Muscle fibers	Not Detected	<input checked="" type="checkbox"/>	Not Detected – Rare
Vegetable fibers	Rare	<input checked="" type="checkbox"/>	Not Detected – Few
Charcot-Leyden Crystals	Not Detected	<input checked="" type="checkbox"/>	Not Detected
Pollen	Not Detected	<input checked="" type="checkbox"/>	Not Detected

Macroscopic Appearance

Result

Reference Interval

Color	Brown	<input checked="" type="checkbox"/>	Brown
Consistency	Soft	<input checked="" type="checkbox"/>	Soft
Mucus	Negative	<input checked="" type="checkbox"/>	Negative



Parasitology Information:

- One negative parasitology x1 specimen does not rule out the possibility of parasitic disease, parasitology x3 is recommended. This test is not designed to detect *Cyclospora cayatanensis* or *Microsporidia* spp.
- Intestinal parasites are abnormal inhabitants of the gastrointestinal tract that have the potential to cause damage to their host. The presence of any parasite within the intestine generally confirms that the patient has acquired the organism through fecal-oral contamination. Damage to the host includes parasitic burden, migration, blockage and pressure. Immunologic inflammation, hypersensitivity reactions and cytotoxicity also play a large role in the morbidity of these diseases. The infective dose often relates to severity of the disease and repeat encounters can be additive.
- There are two main classes of intestinal parasites, they include protozoa and helminths. The protozoa typically have two stages; the trophozoite stage that is the metabolically active, invasive stage and the cyst stage, which is the vegetative inactive form resistant to unfavorable environmental conditions outside the human host. Helminths are large, multicellular organisms. Like protozoa, helminths can be either free-living or parasitic in nature. In their adult form, helminths cannot multiply in humans.

Notes:

Methodology: Microscopy, Macroscopic Observation



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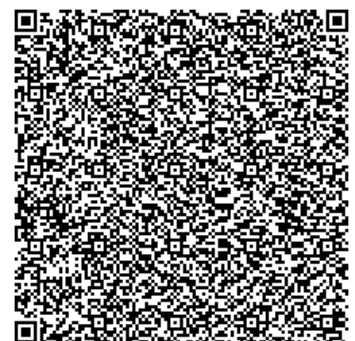
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- In general, acute manifestations of parasitic infection may involve diarrhea with or without mucus and or blood, fever, nausea, or abdominal pain. However these symptoms do not always occur. Consequently, parasitic infections may not be diagnosed or eradicated. If left untreated, chronic parasitic infections can cause damage to the intestinal lining and can be an unsuspected cause of illness and fatigue. Chronic parasitic infections can also be associated with increased intestinal permeability, irritable bowel syndrome, irregular bowel movements, malabsorption, gastritis or indigestion, skin disorders, joint pain, allergic reactions, and decreased immune function.
- In some instances, parasites may enter the circulation and travel to various organs causing severe organ diseases such as liver abscesses and cysticercosis. In addition, some larval migration can cause pneumonia and in rare cases hyper infection syndrome with large numbers of larvae being produced and found in every tissue of the body.
- **Red Blood Cells (RBC)** in the stool may be associated with a parasitic or bacterial infection, or an inflammatory bowel condition such as ulcerative colitis. Colorectal cancer, anal fistulas, and hemorrhoids should also be ruled out.
- **White Blood Cells (WBC)** and **Mucus** in the stool can occur with bacterial and parasitic infections, with mucosal irritation, and inflammatory bowel diseases such as Crohn's disease or ulcerative colitis
- **Muscle fibers** in the stool are an indicator of incomplete digestion. Bloating, flatulence, feelings of "fullness" may be associated with increase in muscle fibers.
- **Vegetable fibers** in the stool may be indicative of inadequate chewing, or eating "on the run".
- **Color:** Stool is normally brown because of pigments formed by bacteria acting on bile introduced into the digestive system from the liver. While certain conditions can cause changes in stool color, many changes are harmless and are caused by pigments in foods or dietary supplements.
- **Consistency:** Stool normally contains about 75% water and ideally should be formed and soft. Stool consistency can vary based upon transit time and water absorption.

**Notes:**

Methodology:







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Pathogenic Bacteria	Result	Result					Reference Interval
		NG	1+	2+	3+	4+	
Aeromonas spp.	NG	▲					No Growth
Edwardsiella tarda	NG	▲					No Growth
Plesiomonas shigelloides	NG	▲					No Growth
Possible Salmonella group	NG	▲					No Growth
Possible Shigella group	4+					▲	No Growth
Possible Vibrio cholerae	NG	▲					No Growth
Vibrio spp	NG	▲					No Growth
Yersinia spp.	NG	▲					No Growth
Imbalance Bacteria	Result	Result					Reference Interval
		NG	1+	2+	3+	4+	
Comamonas kerstersii	1+		▲				No Growth
Klebsiella pneumoniae	2+			▲			No Growth
Lactococcus garvieae	4+					▲	No Growth
Mucoid Escherichia coli	2+			▲			No Growth
Yeast	Result	NG	1+	2+	3+	4+	Reference Interval
No yeast isolated	NG						



Microbiology Information:

- Pathogenic bacteria** consist of known pathogenic bacteria that can cause disease in the GI tract. They are present due to the consumption of contaminated food or water, exposure to animals, fish, or amphibians known to harbor the organism. These organisms can be detected by either Multiplex PCR or microbiology culture.
- Imbalanced bacteria** are usually neither pathogenic nor beneficial to the host GI tract. Imbalances can occur when there are insufficient levels of beneficial bacteria and increased levels of commensal bacteria. Certain commensal bacteria are reported as dysbiotic at higher levels.
- Yeast** may normally be present in small quantities in the skin, mouth, and intestine. When investigating the presence of yeast, disparity may exist between culturing and microscopic examination. Yeast are not uniformly dispersed throughout the stool and this may lead to undetectable or low levels of yeast identified by microscopy, despite culture and identified yeast species. Conversely, microscopic examination may reveal a significant amount of yeast present but no viable yeast cultured. Yeast may not always survive transit through the intestines. Nonviable diet-derived yeast may also be detected microscopically. Consideration of clinical intervention for yeast detected microscopically should be made in the context of other findings and presentation of symptoms.

Notes:

PRELIMINARY REPORT: Shigella sent to state lab for confirmation and serotyping.

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Digestion Absorption	Result	Unit	L	WRI	H	Reference Interval
Elastase	500	µg/mL				> 200
Fat Stain	None					None – Few
Carbohydrates	Negative					Negative
Inflammation	Result	Unit	L	WRI	H	Reference Interval
Lactoferrin	7.9	µg/mL				< 13
Lysozyme*	350	ng/mL				0 – 500
Calprotectin*	118	µg/g				< 50
Immunology	Result	Unit	L	WRI	H	Reference Interval
Secretory IgA*	13.2	mg/dL				30 – 275
Short Chain Fatty Acids	Result	Unit	L	WRI	H	Reference Interval
% Acetate	38.9	%				50 – 72
% Propionate	22.4	%				11 – 25
% Butyrate	35.3	%				11 – 32
% Valerate	3.4	%				0.8 – 5.0
Butyrate	6.3	mg/mL				0.8 – 4.0
Total SCFA's	18	mg/mL				5.0 – 16.0
Intestinal Health Markers	Result	Unit	L	WRI	H	Reference Interval
pH	6.1					5.8 – 7.0
Occult Blood	Negative					Negative



### Chemistry Information:

- Elastase findings** can be used for the diagnosis or the exclusion of exocrine pancreatic insufficiency. Correlations between low levels and chronic pancreatitis and cancer have been reported. **Fat Stain:** Microscopic determination of fecal fat using Sudan IV staining is a qualitative procedure utilized to assess fat absorption and to detect steatorrhea. **Muscle fibers** in the stool are an indicator of incomplete digestion. Bloating, flatulence, feelings of "fullness" may be associated with increase in muscle fibers. **Vegetable fibers** in the stool may be indicative of inadequate chewing, or eating "on the run". **Carbohydrates:** The presence of reducing substances in stool specimens can indicate carbohydrate malabsorption.

#### Notes:

RI= Reference Interval, L (blue)= Low (below RI), WRI (green)= Within RI (optimal), WRI (yellow)= Within RI (not optimal), H (red)= High (above RI)

Methodology: Elisa, Microscopy, Colormetric, Gas Chromatography, pH Electrode



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**Age:** 41 **DOB:** 10/13/1977

**Sex:** Male

**Sample Collection**

**Date/Time**

**Date Collected**

09/22/2019

**Date Received**

09/26/2019

**Date Reported**

10/09/2019

**Specimens Collected**

2

- **Lactoferrin** and **Calprotectin** are reliable markers for differentiating organic inflammation (IBD) from function symptoms (IBS) and for management of IBD. Monitoring levels of fecal lactoferrin and calprotectin can play an essential role in determining the effectiveness of therapy, are good predictors of IBD remission, and can indicate a low risk of relapse. **Lysozyme\*** is an enzyme secreted at the site of inflammation in the GI tract and elevated levels have been identified in IBD patients. **White Blood Cells** (WBC) and **Mucus** in the stool can occur with bacterial and parasitic infections, with mucosal irritation, and inflammatory bowel diseases such as Crohn's disease or ulcerative colitis.
- **Secretory IgA\*** (sIgA) is secreted by mucosal tissue and represents the first line of defense of the GI mucosa and is central to the normal function of the GI tract as an immune barrier. Elevated levels of sIgA have been associated with an upregulated immune response.
- **Short chain fatty acids (SCFAs):** SCFAs are the end product of the bacterial fermentation process of dietary fiber by beneficial flora in the gut and play an important role in the health of the GI as well as protecting against intestinal dysbiosis. Lactobacilli and bifidobacteria produce large amounts of short chain fatty acids, which decrease the pH of the intestines and therefore make the environment unsuitable for pathogens, including bacteria and yeast. Studies have shown that SCFAs have numerous implications in maintaining gut physiology. SCFAs decrease inflammation, stimulate healing, and contribute to normal cell metabolism and differentiation. Levels of **Butyrate** and **Total SCFA** in mg/mL are important for assessing overall SCFA production, and are reflective of beneficial flora levels and/or adequate fiber intake.
- **Red Blood Cells** (RBC) in the stool may be associated with a parasitic or bacterial infection, or an inflammatory bowel condition such as ulcerative colitis. Colorectal cancer, anal fistulas, and hemorrhoids should also be ruled out.
- **pH:** Fecal pH is largely dependent on the fermentation of fiber by the beneficial flora of the gut.
- **Occult blood:** A positive occult blood indicates the presence of free hemoglobin found in the stool, which is released when red blood cells are lysed.

**Notes:**

RI= Reference Interval, L (blue)= Low (below RI), WRI (green)= Within RI (optimal), WRI (yellow)= Within RI (not optimal), H (red)= High (above RI)

Methodology:





**Order:** 999999-9999  
  
**Client #:** 999999  
**Doctor:** Sample Doctor, MD  
 Doctors Data Inc  
 123 Main St.  
 St. Charles, IL 60174 USA

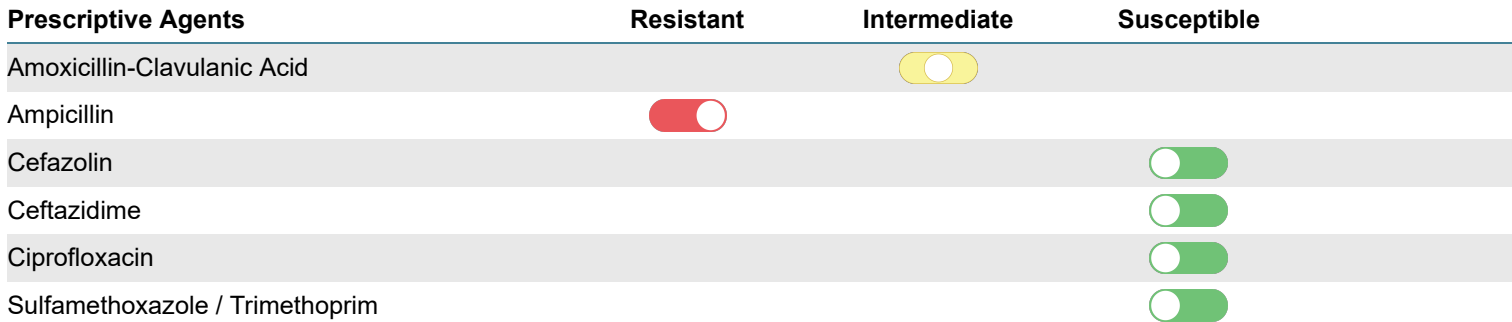
**Patient:** Sample Patient  
**Id:** 999999  
**Age:** 41 **DOB:** 10/13/1977  
**Sex:** Male

**Sample Collection** **Date/Time**  
**Date Collected** 09/22/2019  
**Date Received** 09/26/2019  
**Date Reported** 10/09/2019

### Natural Agents



### Prescriptive Agents



### Susceptibility Information:

- Natural antibacterial** agents may be useful for treatment of patients when organisms display in-vitro susceptibility to these agents. The test is performed by using standardized techniques and filter paper disks impregnated with the listed agent. Relative susceptibility is reported for each natural agent based upon the diameter of the zone of inhibition surrounding the disk. Data based on over 5000 individual observations were used to relate the zone size to the activity level of the agent. A scale of relative susceptibility is defined for the natural agents tested.
- Susceptible** results imply that an infection due to the bacteria may be appropriately treated when the recommended dosage of the tested antimicrobial agent is used. **Intermediate** results imply that response rates may be lower than for susceptible bacteria when the tested antimicrobial agent is used. **Resistant** results imply that the bacteria will not be inhibited by normal dosage levels of the tested antimicrobial agent.

\*Natural antibacterial agent susceptibility testing was developed and its performance characteristics determined by Doctor's Data Laboratories in a manner consistent with CLIA requirements. The U. S. Food and Drug Administration (FDA) has not approve or cleared this test; however, FDA clearance is not currently required for clinical use. The results are not intended to be used as a sole means for clinical diagnosis or patient management decisions.

#### Notes:

