GI360™; stool

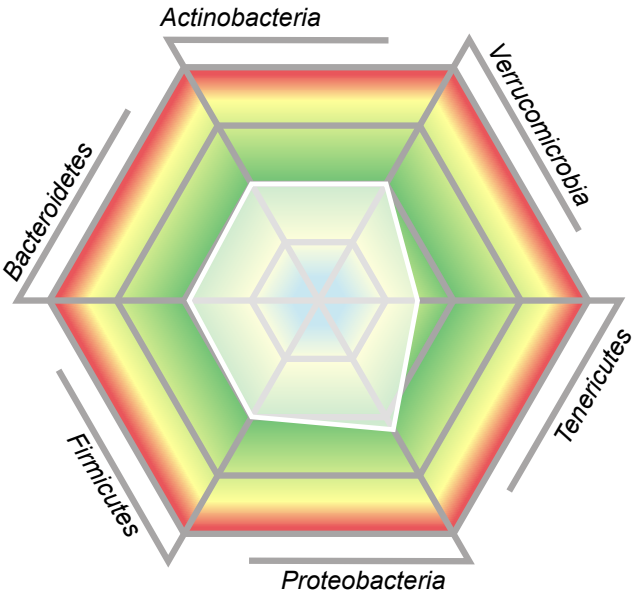
Order:999999-9999
Client #:99999
Doctor: Sample Doctor
Sample Clinic
1234 Main St
Saint Charles, IL 60174 U.S.A.

Patient:SAMPLE PATIENT
Id:99999999
Age:62 **DOB:**01/12/1957
Sex: Male

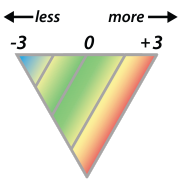
Sample Collection	Date/Time
Date Collected	09/23/2019
Date Received	09/26/2019
Date Reported	10/10/2019
Specimens Collected	2

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

5

Expected Flora Summary

Clostridia Class, WRI	◆
Bacteroides fragilis, WRI	◆
Bacteroides spp. & *Prevotella* spp., WRI	◆
Bifidobacterium spp., WRI	◆
Escherichia spp., WRI	◆
Lactobacillus spp., WRI	◆

Key Findings

Salmonella spp., Detected
Lactoferrin, Very High
Calprotectin, Very High
Morganella morganii, Detected
Salmonella group, Detected
Yeast, Detected
Candida albicans, Detected

Notes:
WRI = Within Reference Interval

Microbiome Bacterial Abundance;Multiplex PCR

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LEGEND

-3	-2	-1	0	+1	+2	+3
Very Low	Low	Within Reference Interval			High	Very High

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.

Actinobacteria	**Result**	**Reference Interval**
Actinobacteria	0	-1 to +1
Actinomycetales	0	0 to +1
Bifidobacterium spp.	0	-1 to +1

Bacteroidetes	**Result**	**Reference Interval**
Alistipes spp.	-1	-1 to +1
Alistipes onderdonkii	-1	-1 to +1
Bacteroides fragilis	+1	0 to +1
Bacteroides spp. & *Prevotella* spp.	0	-1 to +1
Bacteroides stercoris	0	0 to +1
Bacteroides zoogleoformans	0	0 to +1
Parabacteroides johnsonii	0	0 to +1
Parabacteroides spp.	0	-1 to +1

Firmicutes	**Result**	**Reference Interval**
Firmicutes	0	-1 to +1
Bacilli Class	-1	-1 to +1
Catenibacterium mitsuokai	0	-1 to +1
Clostridia Class	+1	-1 to +1
Clostridium 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

Microbiome Bacterial Abundance;Multiplex PCR

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

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Notes:

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Microbiome Bacterial Abundance;Multiplex PCR

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Proteobacteria	Result	-3 -2 -1 0 +1 +2 +3	Reference Interval
Proteobacteria	0		0 to +1
Escherichia spp.	+1		-1 to +1

Tenericutes	Result	-3 -2 -1 0 +1 +2 +3	Reference Interval
Mycoplasma hominis	-1		-1 to +1

Verrucomicrobia	Result	-3 -2 -1 0 +1 +2 +3	Reference Interval
Akkermansia muciniphila	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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Notes:

Methodology: Multiplex PCR

GI Pathogens;Multiplex PCR

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Viruses	Result
Adenovirus F40/41	Negative
Norovirus GI/GII	Negative
Rotavirus A	Negative

Pathogenic Bacteria	Result
Campylobacter (*C. jejuni*, *C. coli* and *C. lari*)	Negative
Clostridium difficile (Toxin A/B)	Negative
Escherichia coli O157	Negative
Enterotoxigenic *Escherichia coli* (ETEC) lt/st	Negative
Salmonella spp.	Positive
Shiga-like toxin-producing *Escherichia coli* (STEC) stx1/stx2	Negative
Shigella (*S. boydii*, *S. sonnei*, *S. flexneri* & *S. dysenteriae*)	Negative
Vibrio cholerae	Negative

Parasites	Result
Cryptosporidium (*C. parvum* and *C. hominis*)	Negative
Entamoeba histolytica	Negative
Giardia duodenalis (AKA *intestinalis & lamblia*)	Negative

Notes:
Methodology: Multiplex PCR

Parasitology; Microscopy

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Protozoa	Result
Balantidium coli	Not Detected
Blastocystis spp.	Not Detected
Chilomastix mesnili	Not Detected
Dientamoeba fragilis	Not Detected
Endolimax nana	Not Detected
Entamoeba coli	Not Detected
Entamoeba hartmanni	Not Detected
Entamoeba histolytica/Entamoeba dispar	Not Detected
Entamoeba polecki	Not Detected
Enteromonas hominis	Not Detected
Giardia duodenalis	Not Detected
Iodamoeba bütschlii	Not Detected
Isospora belli	Not Detected
Pentatrichomonas hominis	Not Detected
Retortamonas intestinalis	Not Detected

Cestodes - Tapeworms	Result
Diphyllobothrium latum	Not Detected
Dipylidium caninum	Not Detected
Hymenolepis diminuta	Not Detected
Hymenolepis nana	Not Detected
Taenia	Not Detected

Trematodes - Flukes	Result
Clonorchis sinensis	Not Detected
Fasciola hepatica/Fasciolopsis buski	Not Detected
Heterophyes heterophyes	Not Detected
Paragonimus westermani	Not Detected

Nematodes - Round Worms	Result
Ascaris lumbricoides	Not Detected

Notes:
Methodology: Microscopy

Parasitology; Microscopy

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Nematodes - Round Worms	Result
Capillaria hepatica	Not Detected
Capillaria philippinensis	Not Detected
Enterobius vermicularis	Not Detected
Hookworm	Not Detected
Strongyloides stercoralis	Not Detected
Trichuris trichiura	Not Detected

Other Markers	Result	Reference Interval
Yeast	Many	Not Detected – Rare
RBC	Not Detected	Not Detected – Rare
WBC	Not Detected	Not Detected – Rare
Muscle fibers	Not Detected	Not Detected – Rare
Vegetable fibers	Rare	Not Detected – Few
Charcot-Leyden Crystals	Not Detected	Not Detected
Pollen	Not Detected	Not Detected

Macroscopic Appearance	Result	Reference Interval
Color	Brown	Brown
Consistency	Soft	Soft
Mucus	Negative	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 cayetanensis* or *Microsproridia* 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

Parasitology; Microscopy

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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.

Microbiology

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Pathogenic Bacteria	Result	NG 1+ 2+ 3+ 4+	Reference Interval
Aeromonas spp.	NG		No Growth
Edwardsiella tarda	NG		No Growth
Plesiomonas shigelloides	NG		No Growth
Salmonella group	2+		No Growth
Shigella spp.	NG		No Growth
Vibrio cholerae	NG		No Growth
Vibrio spp	NG		No Growth
Yersinia spp.	NG		No Growth

Imbalance Bacteria	Result	NG 1+ 2+ 3+ 4+	Reference Interval
Alpha *hemolytic strep*	4+		No Growth
Gamma *hemolytic strep*	3+		No Growth
Staphylococcus aureus	2+		No Growth

Dysbiotic Bacteria	Result	NG 1+ 2+ 3+ 4+	Reference Interval
Morganella morganii	4+		No Growth

Yeast	Result	NG 1+ 2+ 3+ 4+	Reference Interval
Candida albicans	2+		0+ – 1+

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.
- **Dysbiotic bacteria** consist of those bacteria that have the potential to cause disease in the GI tract. They can be present due to a number of factors including: exposure to chemicals that are toxic to beneficial bacteria; the use of antibiotics, oral contraceptives or other medications; poor fiber intake and high stress levels.

Notes:
Methodology: Culture and identification by MALDI-TOF and conventional biochemicals

MALDI-TOF

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- **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.

MALDI-TOF

Stool Chemistries

Order:999999-9999
Client #:99999
Doctor: Sample Doctor
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1234 Main St
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Digestion Absorption	Result	Unit	L WRI H	Reference Interval
Elastase	270	µg/mL		> 200
Fat Stain	None			None – Few
Carbohydrates	Negative			Negative

Inflammation	Result	Unit	L WRI H	Reference Interval
Lactoferrin	219	µg/mL		< 13
Lysozyme*	538	ng/mL		0 – 500
Calprotectin*	930	µg/g		< 50

Immunology	Result	Unit	L WRI H	Reference Interval
Secretory IgA*	163	mg/dL		30 – 275

Short Chain Fatty Acids	Result	Unit	L WRI H	Reference Interval
% Acetate	66.9	%		50 – 72
% Propionate	17.6	%		11 – 25
% Butyrate	13.1	%		11 – 32
% Valerate	2.4	%		0.8 – 5.0
Butyrate	2.1	mg/mL		0.8 – 4.0
Total SCFA's	16	mg/mL		5.0 – 16.0

Intestinal Health Markers	Result	Unit	L WRI H	Reference Interval
pH	5.9			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 Chromotography,ph Electrode

Stool Chemistries

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- **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:

Bacterial Susceptibilities; Salmonella group

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Natural Agents	Low Susceptibility	High Susceptibility
Berberine		
Black Walnut		
Caprylic Acid		
Grapefruit Seed Extract		
Oregano		
Silver		
Uva Ursi		

Prescriptive Agents	Resistant	Intermediate	Susceptible
Ampicillin			
Ciprofloxacin			
Sulfamethoxazole / Trimethoprim			

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:

Bacterial Susceptibilities; Morganella morganii

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Natural Agents	Low Susceptibility	High Susceptibility
Berberine		
Black Walnut		
Caprylic Acid		
Grapefruit Seed Extract		
Oregano		
Silver		
Uva Ursi		

Prescriptive Agents	Resistant	Intermediate	Susceptible
Amoxicillin-Clavulanic Acid	●		
Ampicillin	●		
Cefazolin	●		
Ceftazidime			●
Ciprofloxacin			●
Sulfamethoxazole / Trimethoprim			●

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:

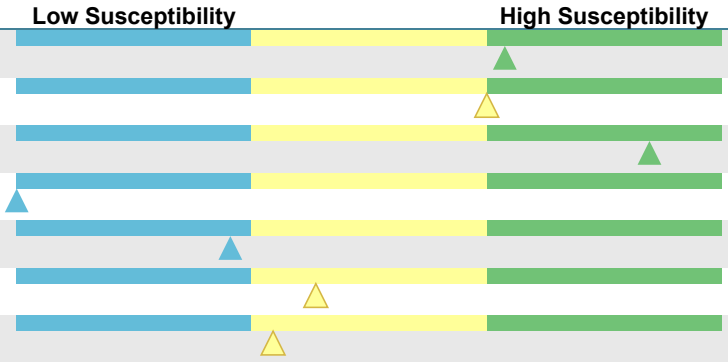
Yeast Susceptibilities; Candida albicans

Order: 999999-9999
Client #: 99999
Doctor: Sample Doctor
Sample Clinic
1234 Main St
Saint Charles, IL 60174 U.S.A.

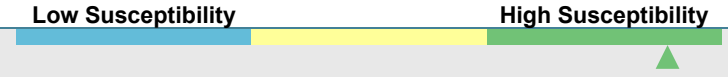
Patient: SAMPLE PATIENT
Id: 99999999
Age: 62 **DOB:** 01/12/1957
Sex: Male

Sample Collection	Date/Time
Date Collected	09/23/2019
Date Received	09/26/2019
Date Reported	10/10/2019
Specimens Collected	2

Natural Agents



Non-Absorbed Antifungals



Azole Antifungals	Resistant	S-DD	Susceptible
Fluconazole			●
Ketoconazole			●

Susceptibility Information:

- **Natural antifungal** 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 activity is reported for each natural agent based upon the diameter of the zone of inhibition or no growth zone 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 activity is defined for the natural agents tested.
- **Non-absorbed antifungals** may be useful for treatment of patients when organisms display in-vitro susceptibility to these agents. The test is performed using standardized commercially prepared disks impregnated with Nystatin. Relative activity is reported based upon the diameter of the zone of inhibition or no growth zone surrounding the disk.
- **Susceptible** results imply that an infection due to the fungus may be appropriately treated when the recommended dosage of the tested antifungal agent is used. **Susceptible - Dose Dependent (S-DD)** results imply that an infection due to the fungus may be treated when the highest recommended dosage of the tested antifungal agent is used. **Resistant** results imply that the fungus will not be inhibited by normal dosage levels of the tested antifungal 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: