

# Gastrointestinal Health



**Breakthrough Assessment of Bacteria, Yeast, Pathogens,  
Parasites and Biochemical Markers**

- GI360™ GI Microbiome Analysis by PCR
- Comprehensive Stool Analysis + Parasitology
- Microbiology Test



**MOSAIC**  
DIAGNOSTICS

# BRIDGING THE GAP BETWEEN RESEARCH AND THE CLINICAL WORLD

Clinical microbiology plays a crucial role in individual and community health. Because most microbes living on or within the body are beneficial, distinguishing those that are disease-producing is a critical function of a clinical microbiology laboratory.

Combining advanced PCR & MALDI-TOF technology with traditional clinical microbiology to provide world-class diagnostic microbiology testing that helps you assess digestive and absorptive functions, detect pathogens or parasites and identify specific bacteria and yeast.

Through the use of advanced assays and technology, test results can help determine what microorganisms are present and which may be causing infection. Our painstaking approach can help you select the most appropriate antimicrobial therapy and the comprehensive nature of our testing represents real value for your patients and practice.

## GI360™ Stool Profiles, multiplex PCR



### Extensive Assessment of the Gastrointestinal Microbiome

- PCR Analysis for the Abundance and Diversity of Key Bacterial Populations of the GI Microbiome
- PCR Detection of Pathogenic Bacteria, Viruses and Parasites
- Comprehensive Parasitology by Microscopy
- MALDI-TOF ID of Cultured Bacteria and Yeast
- Broad Range of Stool Chemistry Markers
- Standardized Susceptibility Testing of Isolated Bacteria and Yeast

Introducing the **GI360™ Profile**: an innovative, comprehensive and clinically-applicable stool profile, utilizing multiplex PCR molecular technology coupled with growth-based culture and ID by MALDI-TOF, sensitive biochemical assays and microscopy to detect and assess the status of pathogens, viruses, parasites and bacteria that may be contributing to acute or chronic gastrointestinal symptoms and disease.

#### **Microbiome Abundance and Diversity**

The GI360™ Profile is a gut microbiota DNA analysis tool that identifies and characterizes the abundance and diversity of

more than 45 targeted analytes that peer-reviewed research has shown to contribute to dysbiosis and other chronic disease states.

The GI360™ can identify the presence of pathogenic viruses, bacteria, and parasites using multiplexed, real-time PCR. Viruses are the primary cause of acute diarrhea, and the least commonly tested. The identification of pathogenic bacteria, viruses and parasites improves treatment strategies and patient outcomes.

# Stool Analysis Profiles and Test Components



**Gut Health  
Detect**

	GI360™	Comprehensive Stool Analysis + Parasitology	Microbiology Test
GI Microbiome Diversity and Abundance; PCR	✓		
Viruses, Pathogens and Parasites; PCR	✓	✓	
Expected/Beneficial Bacteria Culture: Including <i>Bacteroides fragilis</i> , <i>Bifidobacteria</i> , <i>E. coli</i> , <i>Lactobacillus</i> , <i>Enterococcus</i> , <i>Clostridium</i> spp.		✓	✓
Dysbiotic Bacteria Culture and ID: Including <i>Aeromonas</i> , <i>Campylobacter</i> , <i>Plesiomonas</i> , <i>Salmonella</i> , <i>Shigella</i> , <i>Vibrio</i> , <i>Yersinia</i> , <i>Edwardsiella tarda</i>	✓	✓	✓
Commensal/Imbalanced Bacteria Culture and ID	✓	✓	✓
Yeast Culture and ID	✓	✓	✓
Pharmaceutical and Natural Agent Yeast/Bacterial Susceptibilities (performed when indicated)	✓	✓	✓
Parasitology Identification Concentrate and Trichrome Stain	✓	✓	
<i>Giardia lamblia</i>	✓	✓	
<i>Cryptosporidium</i>	✓	✓	
Elastase	✓	✓	
Fat Stain	✓	✓	
Muscle and Vegetable Fibers	✓	✓	
Carbohydrates	✓	✓	
Lysozyme	✓	✓	
Calprotectin	✓	✓	
Lactoferrin	✓	✓	
White Blood Cells (WBC)	✓	✓	
Mucus	✓	✓	
Secretory IgA	✓	✓	
Short Chain Fatty Acids	✓	✓	
Red Blood Cells (RBC)	✓	✓	
pH	✓	✓	
Occult Blood	✓	✓	
Beta-Glucuronidase	✓		

\*Parasitology testing can include one-, two- or three-day collection, based on practitioner preference.



	GI360™	GI360™ ESSENTIALS	GI360™ MICROBIOME
GI Microbiome Diversity and Abundance; PCR	✓	✓	✓
Viruses, Pathogens and Parasites; PCR	✓	✓	
Expanded Parasitology; Microscopy	✓	✓	
Bacterial and Fungal Culturomics w/ Direct Susceptibilities; MALDI-TOF MS	✓	✓	
Stool Chemistries	✓		
Beta-Glucuronidase	✓		

## Consider the GI360™ Profiles for your patients that present with gastrointestinal complaints and chronic systemic conditions:

Gastrointestinal Symptoms  
Autoimmune Disease  
IBD/IBS  
Inflammation

Food Sensitivities  
Nutritional Deficiencies  
Joint Pain  
Chronic or Acute Diarrhea

Bloody Stool  
Mucosal Barrier Dysfunction  
Abdominal Pain  
Fever and Vomiting

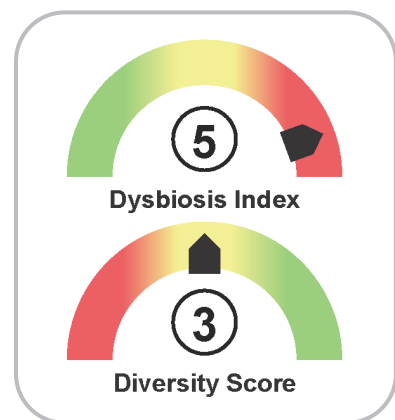
## The Dysbiosis and Diversity Index

These indexes are calculated from the results of the Microbiome Profile, with scores ranging from 1 to 5, and do not include consideration of dysbiotic and pathogenic bacteria, yeast, parasites and viruses that may be reported in subsequent sections of the GI360™ test.

**A dysbiosis score** above 2 indicates dysbiosis; a microbiota profile that differs from the defined normobiotic reference population. The higher the score above 2, the more the sample deviates from the normobiotic profile.

**A diversity score** of 3 indicates an expected amount of diversity, with 4 & 5 indicating an increased distribution of bacteria based on the number of different species and their abundance in the sample, calculated based on Shannon's diversity index. Scores of 1 or 2 indicate less diversity than the defined normobiotic reference population.

This expanded view of clinically significant bacteria offers actionable data to the practitioner, particularly in combination with the complementary methodologies employed in the GI360™ profile.





### Microbiome Bacterial Abundance; Multiplex PCR



Order: 999999-9  
 Client #: 999999  
 Doctor: Sample  
 Doctors Data Inc  
 123 Main St.  
 St. Charles, IL

#### Firmicutes

*Streptococcus salivarius*  
*Streptococcus salivarius*

*Streptococcus* spp.

*Veillonella* spp.

#### Proteobacteria

Proteobacteria

Enterobacteriaceae

*Escherichia* spp.

*Acinetobacter* jun

#### Mycoplasmata

*Metamycoplasma*

#### Verrucomicrobia

*Akkermansia muc*

#### Microbiome

The GI360™ across six reference an individual while the GI360™ the microbiome detailed report

#### Notes:

The gray-shaded area of \*This test was developed Administration (FDA) has means for clinical diagnosis Methodology: Multiplex Page: 4 of 22



### Microbiome Bacterial Abundance; Multiplex PCR



Order: 999999-9  
 Client #: 999999  
 Doctor: Sample  
 Doctors Data Inc  
 123 Main St.  
 St. Charles, IL

#### Firmicutes

*Catenibacterium m*

#### Clostridia Class

*Clostridium methy*

*Clostridium* L2-50

*Coprobacillus* cete

*Dialister inivisus*

*Dialister inivisus* & *micronuiformis*

*Dorea* spp.

*Holdemanelia bifo*

*Anaerobutyricum f*

*Agathobacter recte*

*Eubacterium sirae*

*Faecalibacterium p*

#### Lachnospiraceae

*Ligilactobacillus ru*

*Lactobacillus* famil

*Phascolarctobacte*

*Ruminococcus alb*

*Mediterraneibacte*

*Streptococcus aga*

*rectalis*

#### Firmicutes

Firmicutes

#### Bacilli Class

*Bacillus* spp.

*Bacillus* spp.

*Bacillus* spp.

*Bacillus* spp.

*Bacillus* spp.

*Bacillus* spp.

*Bacillus* spp.

*Bacillus* spp.

*Bacillus* spp.

*Bacillus* spp.

*Bacillus* spp.

*Bacillus* spp.

*Bacillus* spp.

*Bacillus* spp.



### Microbiome Bacterial Abundance; Multiplex PCR



Order: 999999-9  
 Client #: 999999  
 Doctor: Sample  
 Doctors Data Inc  
 123 Main St.  
 St. Charles, IL



#### Actinobacteria

Actinobacteria

Actinomycetales

*Bifidobacterium fa*

#### Bacteroidetes

*Alistipes* spp.

*Alistipes onderdo*

*Bacteroides fragil*

*Bacteroides* spp.

*Bacteroides* spp.

*Bacteroides pectin*

*Bacteroides sterc*

*Bacteroides zoogl*

*Parabacteroides j*

*Parabacteroides s*

#### Firmicutes

Firmicutes

*Bacillus* spp.

*Bacillus* spp.

*Bacillus* spp.

*Bacillus* spp.

*Bacillus* spp.

*Bacillus* spp.

*Bacillus* spp.

*Bacillus* spp.

*Bacillus* spp.

*Bacillus* spp.

*Bacillus* spp.

*Bacillus* spp.

*Bacillus* spp.

*Bacillus* spp.

*Bacillus* spp.

*Bacillus* spp.



### GI360™; stool



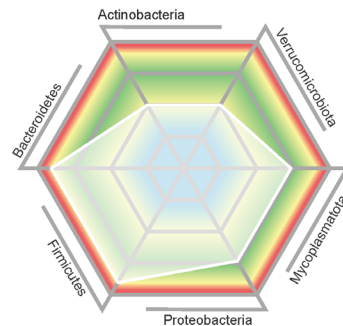
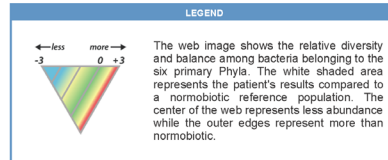
Order: 999999-9999  
 Client #: 999999  
 Doctor: Sample Doctor, MD  
 Doctors Data Inc  
 123 Main St.  
 St. Charles, IL 60174 USA

Patient: Sample Patient  
 Id: 999999  
 Age: 36 DOB: 01/01/1987  
 Sex: Female

Sample Collection Date/Time  
 Date Collected 04/19/2024  
 Date Received 04/20/2024  
 Date Reported 05/01/2024  
 Specimens Collected 3

#### 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.



#### Dysbiosis and Diversity Index

These indexes are calculated from the results of the Microbiome Profile, with scores ranging from 1 to 5, and do not include consideration of dysbiotic and pathogenic bacteria, yeast, parasites and viruses that may be reported in subsequent sections of the GI360™ test.

The Dysbiosis Index (DI) is calculated strictly from the results of the Microbiome Profile, with scores from 1 to 5. A DI score above 2 indicates dysbiosis, a microbiota profile that differs from the defined normobiotic reference population. The higher the DI above 2, the more the sample deviates from the normobiotic profile. The dysbiosis test and DI does not include consideration of dysbiotic and pathogenic bacteria, yeast, parasites and viruses that may be reported in subsequent sections of the GI360™ test.

A diversity score of 3 indicates an expected amount of diversity, with 4 & 5 indicating an increased distribution of bacteria based on the number of different species and their abundance in the sample, calculated based on Shannon's diversity index. Scores of 1 or 2 indicate less diversity than the defined normobiotic reference population.



Dysbiosis Index



Diversity Score

#### GI Health Markers

Butyrate producing bacteria  ●  
 Gut barrier protective bacteria  ●  
 Gut intestinal health marker  ●  
 Pro-inflammatory bacteria  ●  
 Gut barrier protective bacteria vs. opportunistic bacteria  ●

● = Expected ● = Imbalanced

#### Key Findings

*Clostridioides difficile* (Toxin A/B), Detected *Klebsiella pneumoniae/variicola*, Cultured  
 Lysozyme, Very High *Klebsiella oxytoca*, Cultured  
 Secretory IgA, High  
 % Valerate, Very Low  
 pH, Low  
 β-glucuronidase, Low

For more information about this advanced profile, including research publications, a detailed resource guide, abstracts, posters, collection instructions, videos and presentations, visit [mosaicdx.com](http://mosaicdx.com)

# Comprehensive Stool Analysis + Parasitology



Gastrointestinal complaints are among the most common in medical care, with symptoms ranging from diarrhea, constipation, bloating and indigestion to irritable bowel syndrome and malabsorption.

This comprehensive panel is the starting point for pinpointing the causes of gastrointestinal symptoms and chronic conditions, and measures key markers of digestive and absorptive function and inflammation, all to guide targeted treatment selection.

ORDER: 999999-9999  
 PATIENT: Sample Patient  
 ID: 999999  
 SEX: Male  
 AGE: 28  
 DOB: 00/00/1995

CLIENT #: 999999  
 DOCTOR: Sample Doctor, MD  
 Doctors Data Inc  
 123 Main St.  
 St. Charles, IL 60174 USA



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

Nematodes - Roundworms	Result
<i>Ascaris lumbricoides</i>	Not Detected
<i>Capillaria hepatica</i>	Not Detected
<i>Capillaria philippinensis</i>	Not Detected
<i>Enterobius vermicularis</i>	Not Detected
<i>Strongyloides stercoralis</i>	Not Detected
<i>Trichuris trichiura</i>	Not Detected
<i>Hookworm</i>	Not Detected

Cestodes - Tapeworms	Result
<i>Diphyllobothrium latum</i>	Not Detected
<i>Dipylidium caninum</i>	Not Detected
<i>Hymenolepis diminuta</i>	Not Detected
<i>Hymenolepis nana</i>	Not Detected
<i>Taenia</i>	Not Detected

**SPECIMEN DATA**

Comments:  
 Date Collected: 08/25/2023  
 Date Received: 08/28/2023  
 Date Reported: 09/05/2023  
 Methodology: Microscopy

Specimens

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ORDER: 999999-9999  
 PATIENT: Sample Patient  
 ID: 999999  
 SEX: Male  
 AGE: 28  
 DOB: 00/00/1995

CLIENT #: 999999  
 DOCTOR: Sample Doctor, MD  
 Doctors Data Inc  
 123 Main St.  
 St. Charles, IL 60174 USA



BACTERIOLOGY CULTURE		
Expected/Beneficial flora	Commensal (Imbalanced) flora	Dysbiotic flora
4+ <i>Bacteroides</i> family	1+ <i>Klebsiella/Raoultella</i> complex	3+ <i>Enterobacter cloacae</i> complex
4+ <i>Bifidobacterium</i> family	1+ <i>Citrobacter freundii</i> complex	
3+ <i>Escherichia coli</i>		
3+ <i>Lactobacillus</i> family		
3+ <i>Enterococcus</i> family		
3+ <i>Clostridium</i> family		

NG = No Growth

**BACTERIA INFORMATION**

Expected / Beneficial bacteria make up a significant portion of the total microflora in a healthy & balanced GI tract. These beneficial bacteria have many health-protecting effects in the GI tract including manufacturing vitamins, fermenting fibers, digesting proteins and carbohydrates, and propagating anti-tumor and anti-inflammatory factors.

**Clostridia** are prevalent flora in a healthy intestine. *Clostridium* spp. should be considered in the context of balance with other expected/beneficial flora. Absence of clostridia or over abundance relative to other expected/beneficial flora indicates bacterial imbalance. If *C. difficile* associated disease is suspected, review the *Clostridium difficile* toxin A/B results from the GI Pathogens PCR section of this report.

**Commensal (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 known pathogenic bacteria and those that have the potential to cause disease in the GI tract. They can be present due to a number of factors including: consumption of contaminated water or food, 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. *Aeromonas*, *Plesiomonas*, *Salmonella*, *Shigella*, *Vibrio*, *Yersinia*, & *Edwardsiella tarda* have been specifically tested for and found absent unless reported.

YEAST CULTURE	
Normal flora	Dysbiotic flora
1+ <i>Candida parapsilosis</i>	

**YEAST INFORMATION**


Yeast may normally be present in small quantities in the skin, mouth, and GI tract as a component of the resident microbiota. Their presence is generally benign. Recent studies, however, show that high levels of yeast colonization is associated with several inflammatory diseases of the GI tract. Animal models suggest that yeast colonization delays healing of inflammatory lesions and that inflammation promotes colonization. These effects may create a cycle in which low-level inflammation promotes fungal colonization and this colonization promotes further inflammation. Consideration of clinical intervention for yeast should be made in the context of other findings and presentation of symptoms.

**SPECIMEN DATA**

Comments:

Date Collected: 08/25/2023  
 Date Received: 08/28/2023  
 Date Reported: 09/05/2023  
 Methodology: Culture and identification by MALDI-TOF and conventional biochemicals

Specimens Collected: 3



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## Bacteria, Yeast and Parasites

The Comprehensive Stool Analysis + Parasitology utilizes comprehensive bacteriology and yeast cultures to identify the presence of beneficial flora, imbalanced flora including Clostridium species, and dysbiotic flora, as well as the detection of infectious pathogens and parasites by PCR and other gold standard methods. Antimicrobial susceptibility testing to prescriptive and natural agents is also performed for appropriate cultured bacterial and fungal species at no additional charge.

## Digestion and Absorption

For insight into degenerative diseases, compromised immune status or nutritional deficiencies, this comprehensive panel also evaluates the efficiency of digestion and absorption by measuring fecal levels of elastase, an indicator of pancreatic exocrine sufficiency, as well as fat, carbohydrates, and muscle and vegetable fibers.

## Inflammation

Specific inflammatory markers such as calprotectin, lactoferrin, and lysozyme can assist in differentiating between irritable bowel disease (IBD) and irritable bowel syndrome (IBS).

ORDER: 999999-9999  
 PATIENT: Sample Patient  
 ID: 999999  
 SEX: Male  
 AGE: 28  
 DOB: 00/00/1995

- Trematodes - Flukes
- Clonorchis sinensis
- Fasciola hepatica/Fasciolop
- Heterophyes heterophyes
- Paragonimus westermani

### Other Markers

- Yeast
- RBC
- WBC
- Muscle fibers
- Vegetable fibers
- Charcot-Leyden Crystals
- Pollen

### Macroscopic Appearance

Mucus

This test is not designed to detect intestinal parasites are abnormal any parasite within the intestine g host includes parasitic burden, mi a large role in the morbidity of the

There are two main classes of int stage that is the metabolically s environmental conditions outside or parasitic in nature. In their adul In general, acute manifestations o However these symptoms do not parasitic infections can cause dan can also be associated with incre indigestion, skin disorders, joint p In some instances, parasites may cysticercosis. In addition, some la being produced and found in ever

**Red Blood Cells (RBC)** in the ulcerative colitis. Colorectal cance

**White Blood Cells (WBC)** and I bowel diseases such as Crohn's c

**Muscle fibers** in the stool are an muscle fibers.

**Vegetable fibers** in the stool may

### Comments:

**Date Collected:** 08/25/2023  
**Date Received:** 08/28/2023  
**Date Reported:** 09/05/2023  
**Methodology:** Microscopy, Ma

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ORDER: 999999-9999  
 PATIENT: Sample Patient  
 ID: 999999  
 SEX: Male  
 AGE: 28  
 DOB: 00/00/1995

### Digestion / Absorption

- Elastase
- Fat Stain
- Carbohydrates<sup>†</sup>

### Inflammation

- Lactoferrin
- Calprotectin
- Lysozyme\*

### Immunology

- Secretory IgA\*

### Short Chain Fatty Acids

- % Acetate<sup>‡</sup>
- % Propionate<sup>‡</sup>
- % Butyrate<sup>‡</sup>
- % Valerate<sup>‡</sup>
- Butyrate<sup>‡</sup>
- Total SCFA's<sup>‡</sup>

### Intestinal Health Markers

- pH
- Occult Blood

### Macroscopic Appearance

- Color
- Consistency

### Chemistry Information

- Elastase findings can be use
- Fat Stain:** Microscopic dete absorption and to detect stea

### Comments:

**Date Collected:** 08/25/2023  
**Date Received:** 08/28/2023  
**Date Reported:** 09/05/2023  
**Methodology:** Turbidimetric in Macroscopic O

<sup>†</sup>RI= Reference Interval. Toggles: Green = \*This test was developed and its perform Administration (FDA) has not approved o means for clinical diagnosis or patient ma <sup>‡</sup>This test has been modified from the ma requirements. <sup>‡</sup>This test was developed and its perform Administration (FDA) has not approved o

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ORDER: 999999-9999  
 PATIENT: Sample Patient  
 ID: 999999  
 SEX: Male  
 AGE: 28  
 DOB: 00/00/1995

CLIENT #: 999999  
 DOCTOR: Sample Doctor, MD  
 Doctors Data Inc  
 123 Main St.  
 St. Charles, IL 60174 USA



## Enterobacter cloacae complex

	NATURAL ANTIBACTERIALS		
	LOW SENSITIVITY		HIGH SENSITIVITY
Black Walnut*	[Bar chart showing sensitivity levels]		
Caprylic Acid*	[Bar chart showing sensitivity levels]		
Uva Ursi*	[Bar chart showing sensitivity levels]		
Olive Leaf Extract*	[Bar chart showing sensitivity levels]		
Oregano*	[Bar chart showing sensitivity levels]		
Goldenseal*	[Bar chart showing sensitivity levels]		
Ionic Silver*	[Bar chart showing sensitivity levels]		
Colloidal Silver*	[Bar chart showing sensitivity levels]		

	PRESCRIPTIVE AGENTS		
	RESISTANT	INTERMEDIATE	SUSCEPTIBLE
Amoxicillin-Clavulanic Acid	✓		
Ampicillin	✓		
Cefazolin	✓		
Ceftazidime			✓
Ciprofloxacin			✓
Sulfamethoxazole / Trimethoprim			✓

Natural antibacterial agents may be useful for treatment of patients when organisms display in-vitro sensitivity to these agents. The test is performed by using standardized techniques and filter paper disks impregnated with the listed agent. Relative sensitivity 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 sensitivity 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.

### SPECIMEN DATA

### Comments:

**Date Collected:** 08/25/2023  
**Date Received:** 08/28/2023  
**Date Reported:** 09/05/2023  
**Methodology:** Disk Diffusion

Specimens Collected: 3



\*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.

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8400 W 110th Street, Suite 500, Overland Park, KS 66210

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Account Today



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