Gastrointestinal Health

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

- GI360™ GI Microbiome Analysis by PCR
- Comprehensive Stool Analysis + Parasitology
- Comprehensive Vaginosis Profile
- GI Pathogen Profile, PCR
- Celiac and Gluten Sensitivity Profile

DOCTOR'S DATA INC.

SCIENCE + INSIGHT

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.

Doctor's Data combines 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 specimens collected from a variety of body sites and the use of advanced assays and technology, Doctor's Data determines 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

	GI 360	CSA+P Comprehensive Stool Analysis + Parasitology	CSA Comprehensive Stool Analysis	CP+P Culture, PCR + Parasites	GI Pathogen Profile
GI Microbiome Diversity and Abundance; PCR	✔				
Viruses, Pathogens and Parasites; PCR	✔	✔	✔	✔	✔
Expected/Beneficial Bacteria Culture: Including *Bacteroides fragilis, Bifidobacteria, E. coli, Lactobacillus, Enterococcus, Clostridium* spp.		✔	✔	✔	
Dysbiotic Bacteria Culture and ID: Including *Aeromonas, Campylobacter, Plesiomonas, Salmonella, Shigella, Vibrio, Yersinia, Edwardsiella tarda*	✔	✔	✔	✔	
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	✔	✔		✔	
Giardia lamblia	✔	✔		✔	
Cryptosporidium	✔	✔		✔	
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.**

Individual Or Add-On Tests

- *H. Pylori* Stool Antigen
- Macroscopic Worm Identification
- Zonulin Family Protein

Smaller profiles and single-analyte tests are also available. Call Doctor's Data for assistance in selecting the tests that will maximize value for your patients.

GI360™ Stool Profiles

	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

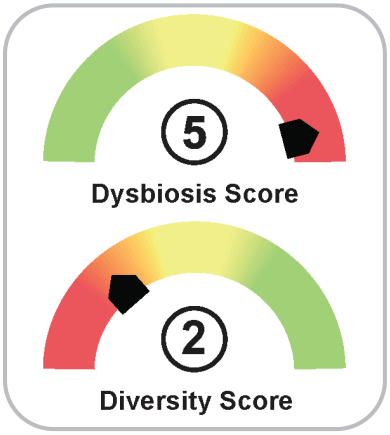
The Dysbiosis and Diversity Index

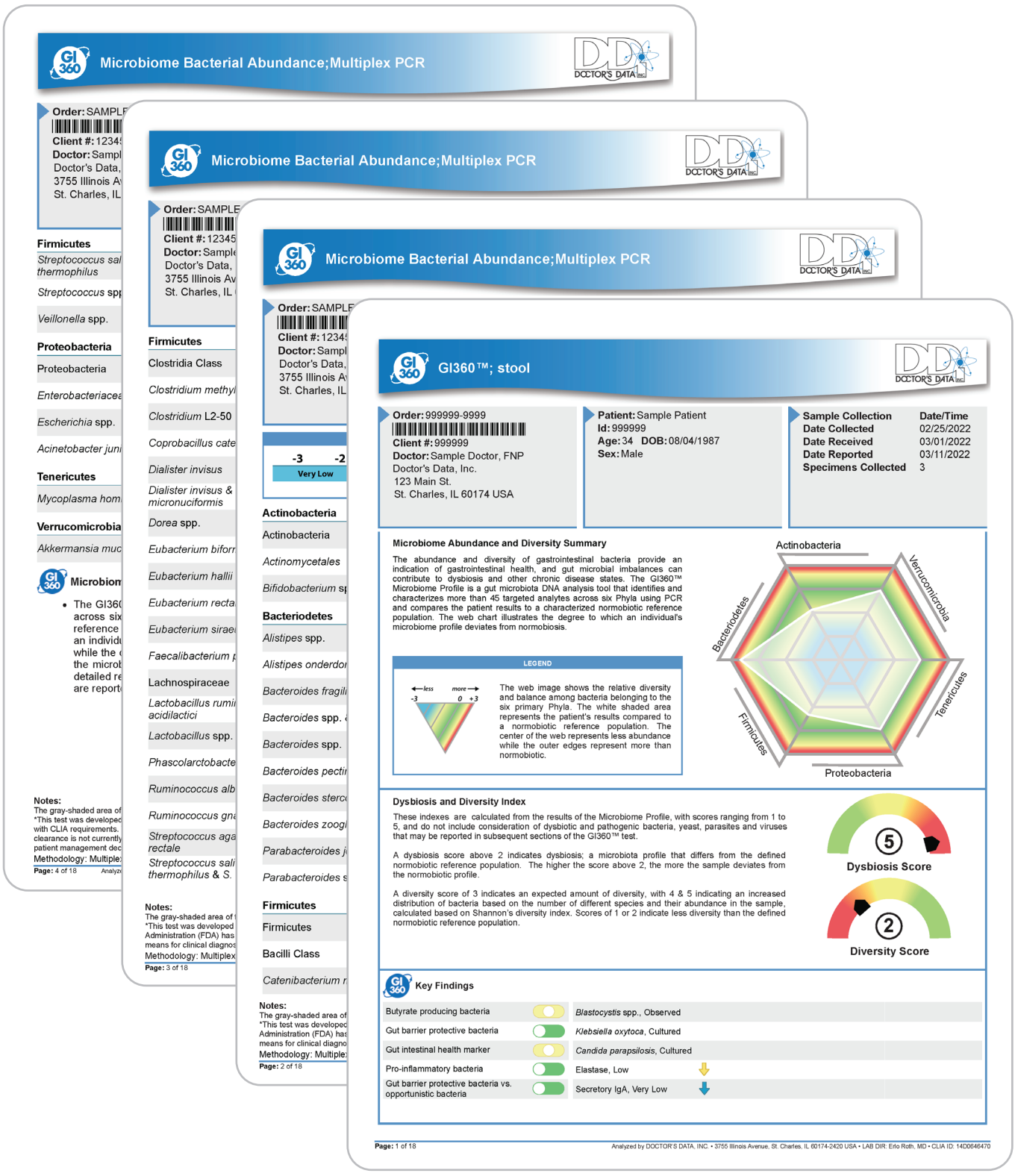
These indexes are calculated from the results of the Microbiome Profile, with scores ranging from 1 to 5, and do not include consideration of dysbiotic and pathogenic bacteria, yeast, parasites and viruses that may be reported in subsequent sections of the GI360™ test.

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 by Doctor's Data in the GI360™ profile.





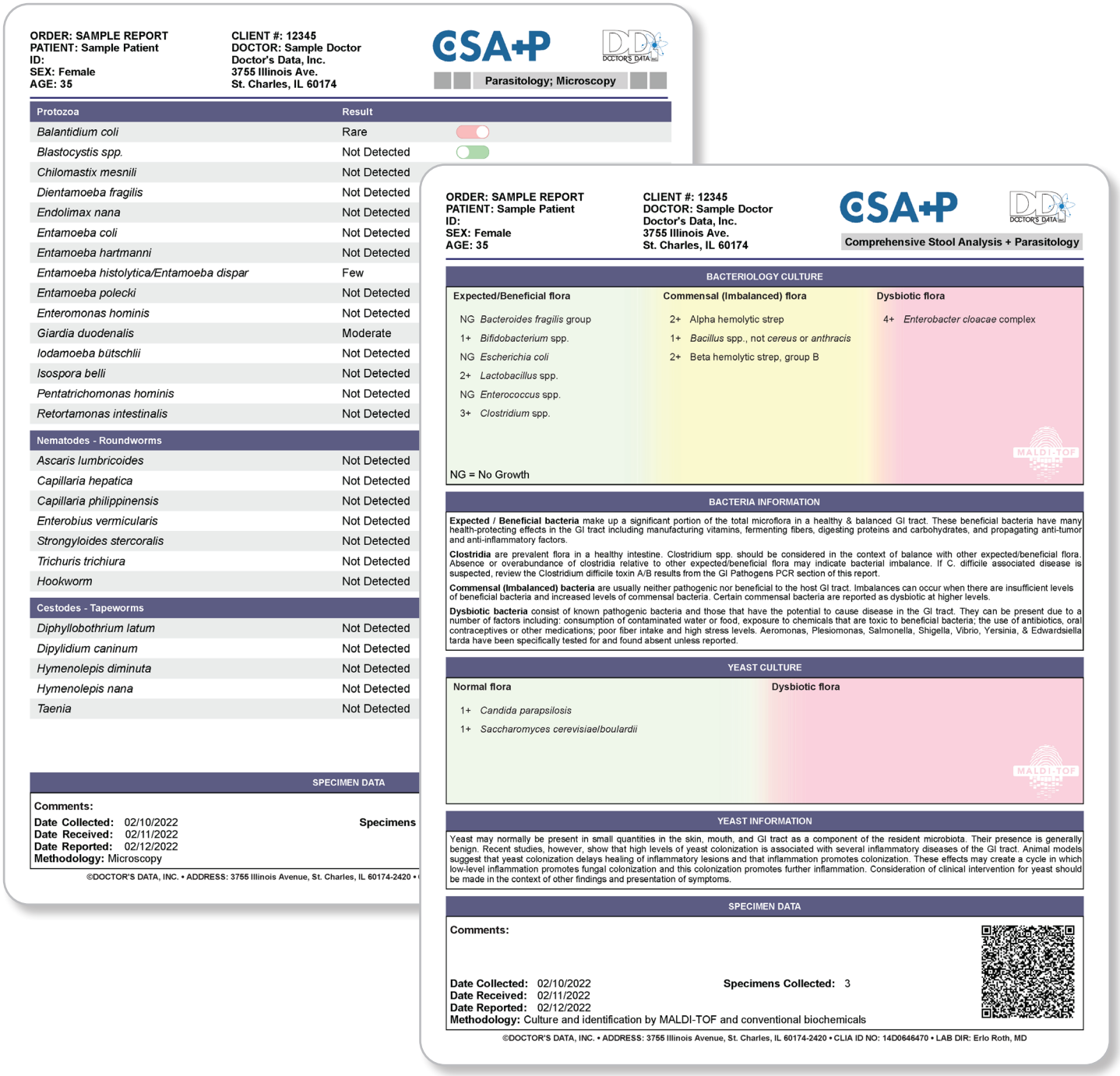
For more information about this advanced profile, including research publications, a detailed resource guide, abstracts, posters, collection instructions, videos and presentations,

visit GI360.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: SAMPLE REPORT
PATIENT: Sample Patient
ID:
SEX: Female
AGE: 35

CLIENT #: 12345
DOCTOR: Sample Doctor
Doctor's Data, Inc.
3755 Illinois Ave.
St. Charles, IL 60174

CSA+P — Parasitology; Microscopy

Protozoa	Result
Balantidium coli	Rare
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	Few
Entamoeba polecki	Not Detected
Enteromonas hominis	Not Detected
Giardia duodenalis	Moderate
Iodamoeba bütschlii	Not Detected
Isospora belli	Not Detected
Pentatrichomonas hominis	Not Detected
Retortamonas intestinalis	Not Detected
Nematodes - Roundworms	
Ascaris lumbricoides	Not Detected
Capillaria hepatica	Not Detected
Capillaria philippinensis	Not Detected
Enterobius vermicularis	Not Detected
Strongyloides stercoralis	Not Detected
Trichuris trichiura	Not Detected
Hookworm	Not Detected
Cestodes - Tapeworms	
Diphyllobothrium latum	Not Detected
Dipylidium caninum	Not Detected
Hymenolepis diminuta	Not Detected
Hymenolepis nana	Not Detected
Taenia	Not Detected

SPECIMEN DATA

Comments:

Date Collected: 02/10/2022
Date Received: 02/11/2022
Date Reported: 02/12/2022
Methodology: Microscopy

Specimens

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CSA+P — Comprehensive Stool Analysis + Parasitology

BACTERIOLOGY CULTURE

Expected/Beneficial flora	Commensal (Imbalanced) flora	Dysbiotic flora
NG *Bacteroides fragilis* group	2+ Alpha hemolytic strep	4+ *Enterobacter cloacae* complex
1+ *Bifidobacterium* spp.	1+ *Bacillus* spp., not *cereus* or *anthracis*	
NG *Escherichia coli*	2+ Beta hemolytic strep, group B	
2+ *Lactobacillus* spp.		
NG *Enterococcus* spp.		
3+ *Clostridium* spp.		

MALDI-TOF

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 or overabundance of clostridia relative to other expected/beneficial flora may indicate 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+ *Candida parapsilosis*	
1+ *Saccharomyces cerevisiae/boulardii*	

MALDI-TOF

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: 02/10/2022
Date Received: 02/11/2022
Date Reported: 02/12/2022
Methodology: Culture and identification by MALDI-TOF and conventional biochemicals

Specimens Collected: 3

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Bacteria, Yeast and Parasites

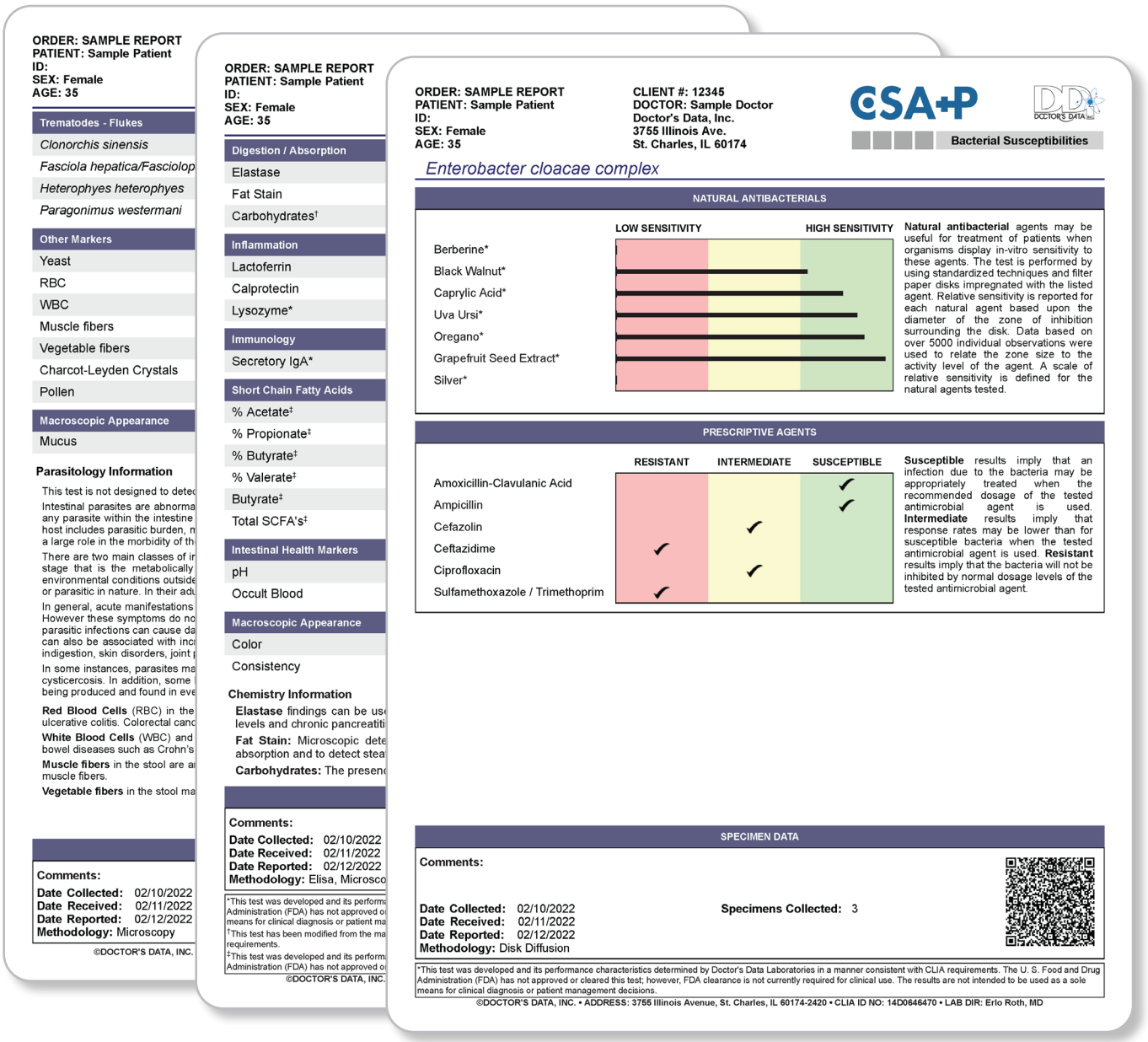
The Comprehensive Stool Analysis + Parasitology utilizes comprehensive bacteriology and yeast cultures to identify the presence of beneficial flora, imbalanced flora including Clostridium species, and dysbiotic flora, as well as the detection of infectious pathogens and parasites by PCR and other gold 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).



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SEX: Female
AGE: 35

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

Parasitology Information

This test is not designed to detec
Intestinal parasites are abnorma
any parasite within the intestine
host includes parasitic burden, n
a large role in the morbidity of th
There are two main classes of ir
stage that is the metabolically
environmental conditions outside
or parasitic in nature. In their adu
In general, acute manifestations
However these symptoms do no
parasitic infections can cause da
can also be associated with incr
indigestion, skin disorders, joint p
In some instances, parasites ma
cysticercosis. In addition, some
being produced and found in eve

Red Blood Cells (RBC) in the
ulcerative colitis. Colorectal canc
White Blood Cells (WBC) and
bowel diseases such as Crohn's
Muscle fibers in the stool are a
muscle fibers.
Vegetable fibers in the stool ma

Comments:
Date Collected: 02/10/2022
Date Received: 02/11/2022
Date Reported: 02/12/2022
Methodology: Microscopy

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ORDER: SAMPLE REPORT
PATIENT: Sample Patient
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SEX: Female
AGE: 35

Digestion / Absorption
Elastase
Fat Stain
Carbohydrates†
Inflammation
Lactoferrin
Calprotectin
Lysozyme*
Immunology
Secretory IgA*
Short Chain Fatty Acids
% Acetate‡
% Propionate‡
% Butyrate‡
% Valerate‡
Butyrate‡
Total SCFA's‡
Intestinal Health Markers
pH
Occult Blood
Macroscopic Appearance
Color
Consistency

Chemistry Information

Elastase findings can be us
levels and chronic pancreatiti
Fat Stain: Microscopic dete
absorption and to detect stea
Carbohydrates: The presen

Comments:
Date Collected: 02/10/2022
Date Received: 02/11/2022
Date Reported: 02/12/2022
Methodology: Elisa, Microsco

*This test was developed and its performa
Administration (FDA) has not approved o
means for clinical diagnosis or patient ma
†This test has been modified from the ma
requirements.
‡This test was developed and its perform
Administration (FDA) has not approved o
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ORDER: SAMPLE REPORT
PATIENT: Sample Patient
ID:
SEX: Female
AGE: 35

CLIENT #: 12345
DOCTOR: Sample Doctor
Doctor's Data, Inc.
3755 Illinois Ave.
St. Charles, IL 60174

CSA-P

Bacterial Susceptibilities

Enterobacter cloacae complex

NATURAL ANTIBACTERIALS

	LOW SENSITIVITY	HIGH SENSITIVITY
Berberine*		
Black Walnut*		
Caprylic Acid*		
Uva Ursi*		
Oregano*		
Grapefruit Seed Extract*		
Silver*		

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.

PRESCRIPTIVE AGENTS

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

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: 02/10/2022
Date Received: 02/11/2022
Date Reported: 02/12/2022
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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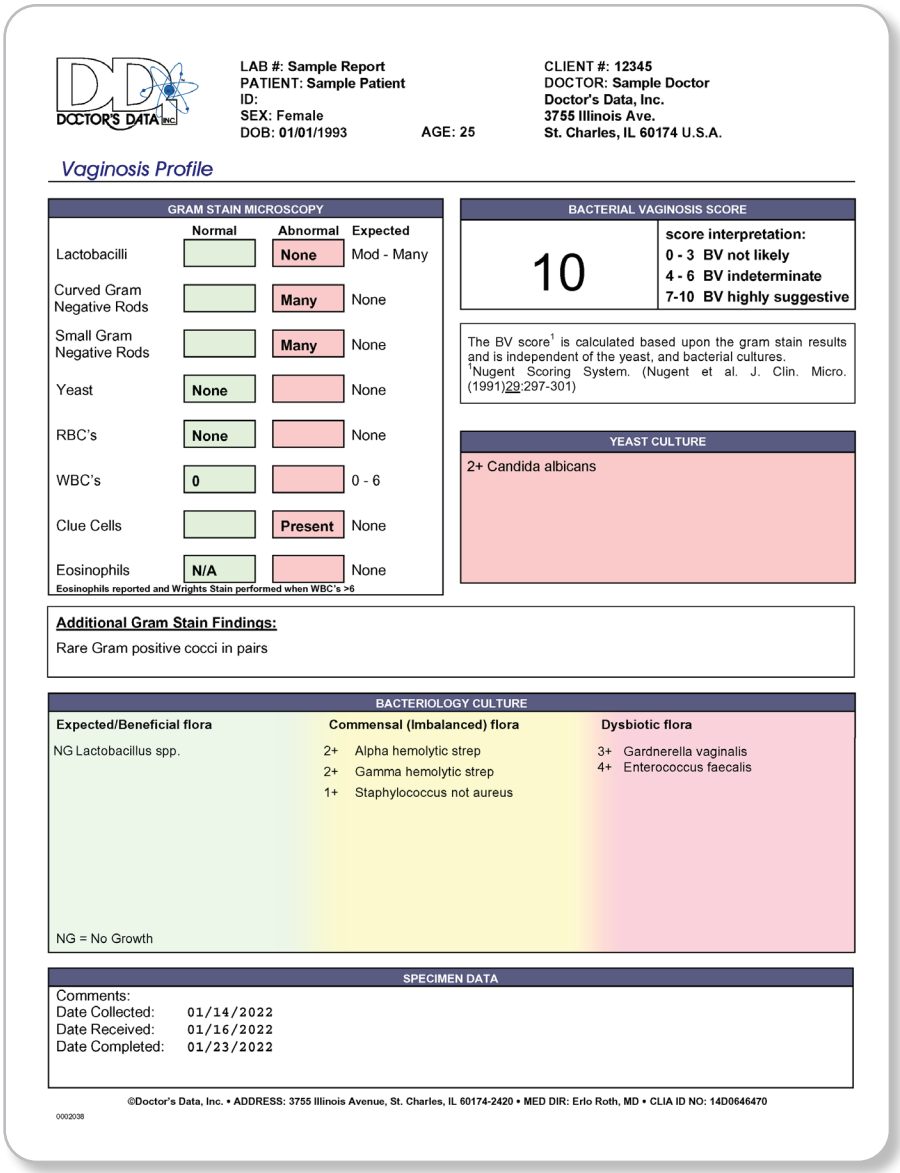
Vaginosis Profile

SWAB

While common, diagnosis of vaginal infections by symptoms alone is not reliable. Properly identifying the cause, as well as factors which might upset the balance of microflora, are critical to successfully treating the infection.

Based on a self-collected sample, the Vaginosis Profile differentiates between bacterial vaginosis and vulvovaginal candidiasis to guide effective treatment. A bacterial vaginosis score based upon the Nugent Scoring System is provided. Antimicrobial susceptibility testing is also performed for appropriate bacterial and fungal species at no additional charge.



DOCTOR'S DATA INC

LAB #: Sample Report
PATIENT: Sample Patient
ID:
SEX: Female
DOB: 01/01/1993
AGE: 25

CLIENT #: 12345
DOCTOR: Sample Doctor
Doctor's Data, Inc.
3755 Illinois Ave.
St. Charles, IL 60174 U.S.A.

Vaginosis Profile

GRAM STAIN MICROSCOPY

	Normal	Abnormal	Expected
Lactobacilli		None	Mod - Many
Curved Gram Negative Rods		Many	None
Small Gram Negative Rods		Many	None
Yeast	None		None
RBC's	None		None
WBC's	0		0 - 6
Clue Cells		Present	None
Eosinophils	N/A		None

Eosinophils reported and Wrights Stain performed when WBC's >6

BACTERIAL VAGINOSIS SCORE

10

score interpretation:
0 - 3 BV not likely
4 - 6 BV indeterminate
7-10 BV highly suggestive

The BV score[1] is calculated based upon the gram stain results and is independent of the yeast, and bacterial cultures.
[1]Nugent Scoring System. (Nugent et al. J. Clin. Micro. (1991)29:297-301)

YEAST CULTURE

2+ Candida albicans

Additional Gram Stain Findings:

Rare Gram positive cocci in pairs

BACTERIOLOGY CULTURE

Expected/Beneficial flora	Commensal (Imbalanced) flora	Dysbiotic flora
NG Lactobacillus spp.	2+ Alpha hemolytic strep 2+ Gamma hemolytic strep 1+ Staphylococcus not aureus	3+ Gardnerella vaginalis 4+ Enterococcus faecalis

NG = No Growth

SPECIMEN DATA

Comments:
Date Collected: 01/14/2022
Date Received: 01/16/2022
Date Completed: 01/23/2022

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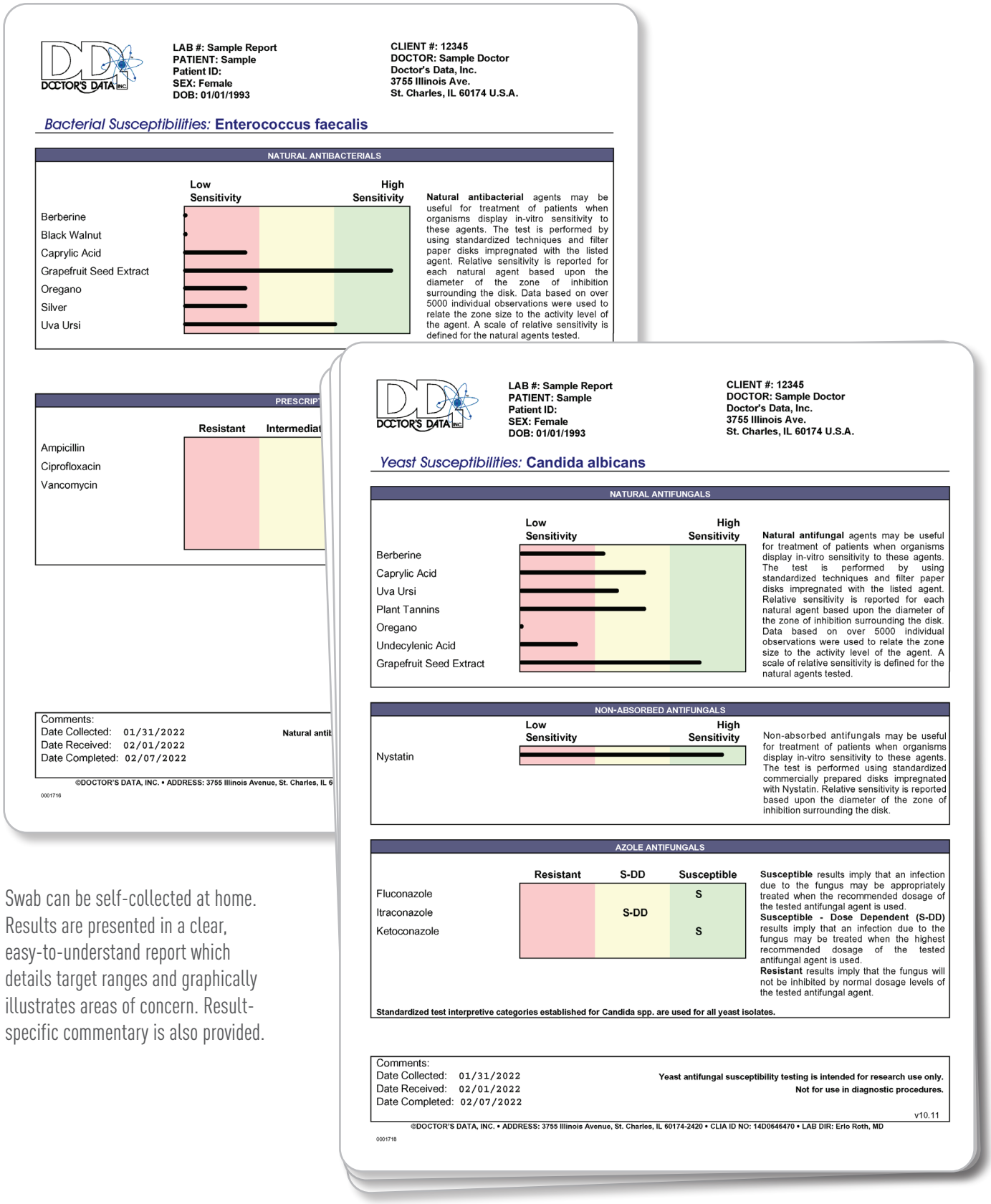
0002038



LAB #: Sample Report
PATIENT: Sample
Patient ID:
SEX: Female
DOB: 01/01/1993

CLIENT #: 12345
DOCTOR: Sample Doctor
Doctor's Data, Inc.
3755 Illinois Ave.
St. Charles, IL 60174 U.S.A.

Bacterial Susceptibilities: **Enterococcus faecalis**

NATURAL ANTIBACTERIALS

Low Sensitivity — High Sensitivity

Berberine
Black Walnut
Caprylic Acid
Grapefruit Seed Extract
Oregano
Silver
Uva Ursi

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.

PRESCRIPT

Resistant — Intermediat

Ampicillin
Ciprofloxacin
Vancomycin

Comments:
Date Collected: 01/31/2022
Date Received: 02/01/2022
Date Completed: 02/07/2022

Natural antit

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0001716

LAB #: Sample Report
PATIENT: Sample
Patient ID:
SEX: Female
DOB: 01/01/1993

CLIENT #: 12345
DOCTOR: Sample Doctor
Doctor's Data, Inc.
3755 Illinois Ave.
St. Charles, IL 60174 U.S.A.

Yeast Susceptibilities: **Candida albicans**

NATURAL ANTIFUNGALS

Low Sensitivity — High Sensitivity

Berberine
Caprylic Acid
Uva Ursi
Plant Tannins
Oregano
Undecylenic Acid
Grapefruit Seed Extract

Natural antifungal 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.

NON-ABSORBED ANTIFUNGALS

Low Sensitivity — High Sensitivity

Nystatin

Non-absorbed antifungals may be useful for treatment of patients when organisms display in-vitro sensitivity to these agents. The test is performed using standardized commercially prepared disks impregnated with Nystatin. Relative sensitivity is reported based upon the diameter of the zone of inhibition surrounding the disk.

AZOLE ANTIFUNGALS

Resistant — S-DD — Susceptible

Fluconazole — S
Itraconazole — S-DD
Ketoconazole — S

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.

Standardized test interpretive categories established for Candida spp. are used for all yeast isolates.

Comments:
Date Collected: 01/31/2022
Date Received: 02/01/2022
Date Completed: 02/07/2022

Yeast antifungal susceptibility testing is intended for research use only.
Not for use in diagnostic procedures.

v10.11

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0001718

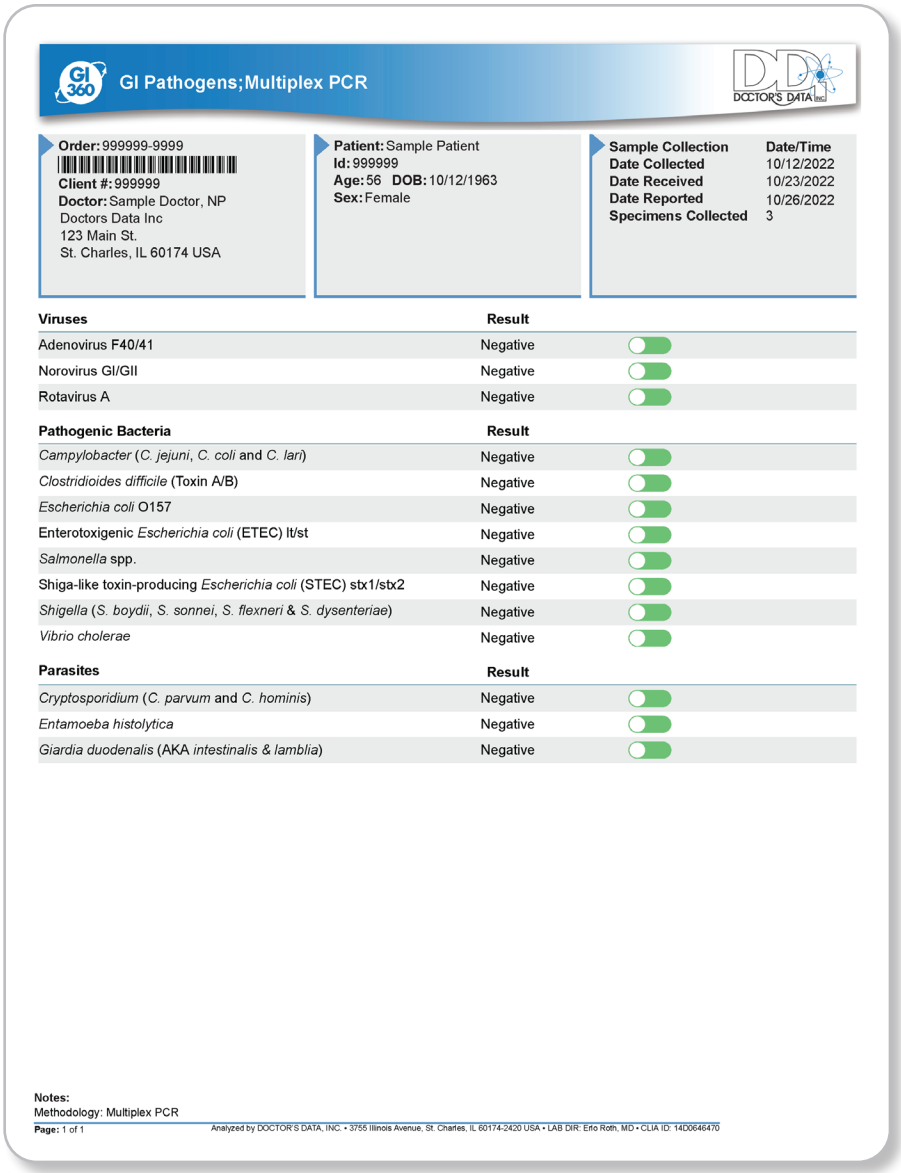
Swab can be self-collected at home. Results are presented in a clear, easy-to-understand report which details target ranges and graphically illustrates areas of concern. Result-specific commentary is also provided.

GI Pathogen Profile, multiplex PCR

Overlapping symptoms—compounded by the lack of testing methods that could identify a full range of viruses, parasites, and bacteria—have historically made GI infections difficult to diagnose. The GI Pathogen Profile, an FDA-cleared molecular test, uses a multiplex PCR system to identify 14 viruses, parasites, and bacteria with the test's 99.9% overall negative predictive value.

The GI Pathogen Profile provides results to target treatment for greater therapeutic efficacy and reduced risk of complications and side effects associated with incorrect treatment or unwarranted antimicrobial administration.

Use the GI Pathogen Profile as a standalone test, or explore other larger profiles where these markers are included (GI360™, Comprehensive Stool Analysis profiles, or Culture, PCR + Parasitology).



GI Pathogens;Multiplex PCR

DOCTOR'S DATA Inc

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

Patient: Sample Patient
Id: 999999
Age: 56 **DOB:** 10/12/1963
Sex: Female

Sample Collection	Date/Time
Date Collected	10/12/2022
Date Received	10/23/2022
Date Reported	10/26/2022
Specimens Collected	3

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
Clostridioides difficile (Toxin A/B)	Negative
Escherichia coli O157	Negative
Enterotoxigenic *Escherichia coli* (ETEC) lt/st	Negative
Salmonella spp.	Negative
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

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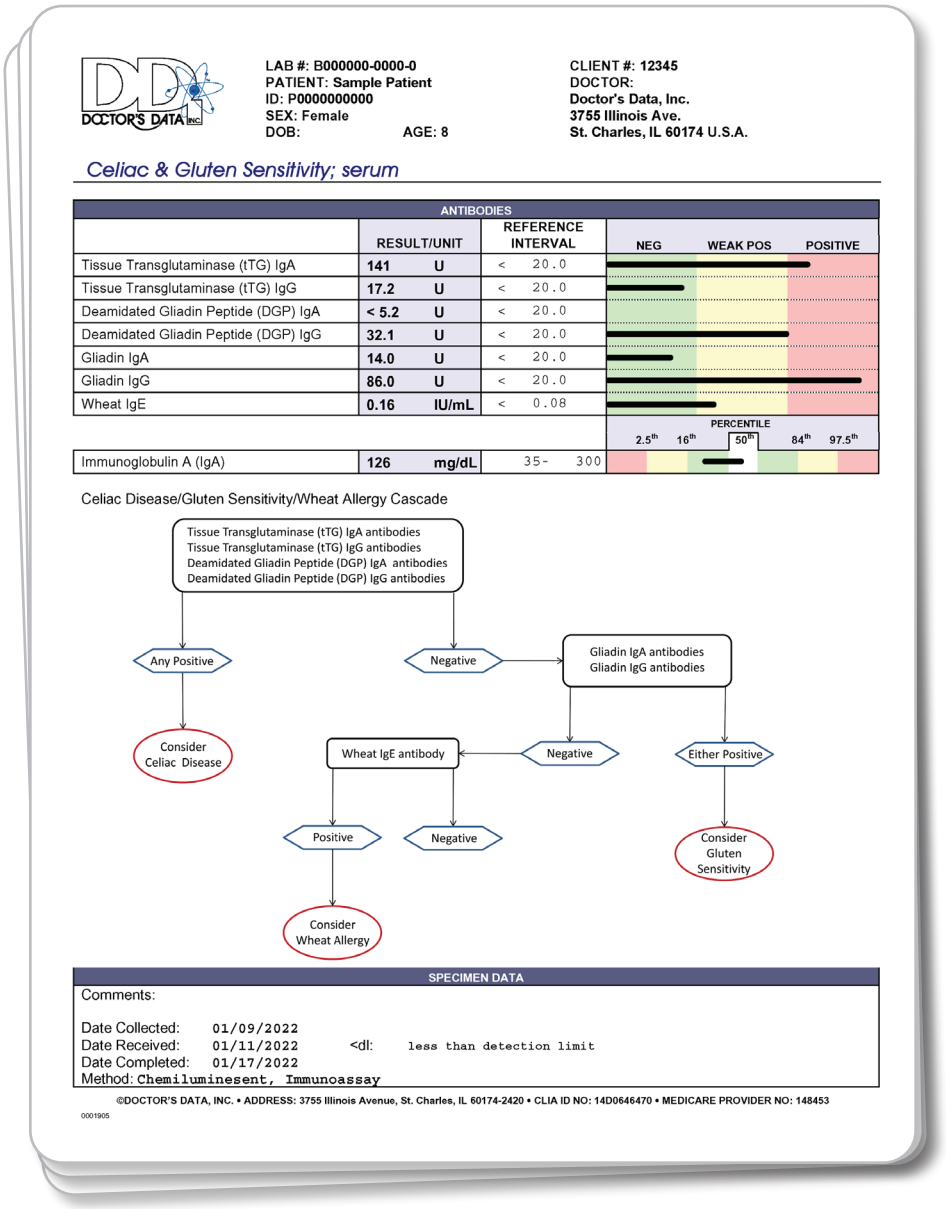
Celiac and Gluten Sensitivity Profile

Celiac disease (CD) is often undiagnosed. It is caused, in genetically predisposed individuals, by abnormal intestinal permeability and abnormal immune response to gluten, a protein complex found in wheat, barley, spelt and rye. The inflammatory autoimmune response damages the lining of the small bowel and is associated with diarrhea, bloating, fatigue, nutritional deficiencies and systemic autoimmune conditions. Gluten sensitivity can cause similar symptoms, but without the same level of tissue damage. The Celiac and Gluten Sensitivity Profile from Doctor's Data helps differentiate between CD, non-celiac gluten sensitivity (NCGS) and wheat allergy by evaluating the serum titers of IgA and IgG for tissue transglutaminase, deamidated gliadin peptide and gliadin. Wheat allergy is assessed by titers of IgE for wheat. Indications of possible CD and NCGS will only be accurate if the patient is on a gluten-inclusive diet. The test is also useful for monitoring adherence to a gluten-free diet.



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LAB #: B000000-0000-0
PATIENT: Sample Patient
ID: P0000000000
SEX: Female
DOB: AGE: 8

CLIENT #: 12345
DOCTOR:
Doctor's Data, Inc.
3755 Illinois Ave.
St. Charles, IL 60174 U.S.A.

Celiac & Gluten Sensitivity; serum

ANTIBODIES

	RESULT/UNIT	REFERENCE INTERVAL	NEG / WEAK POS / POSITIVE
Tissue Transglutaminase (tTG) IgA	141 U	< 20.0	
Tissue Transglutaminase (tTG) IgG	17.2 U	< 20.0	
Deamidated Gliadin Peptide (DGP) IgA	< 5.2 U	< 20.0	
Deamidated Gliadin Peptide (DGP) IgG	32.1 U	< 20.0	
Gliadin IgA	14.0 U	< 20.0	
Gliadin IgG	86.0 U	< 20.0	
Wheat IgE	0.16 IU/mL	< 0.08	
			PERCENTILE 2.5th 16th 50th 84th 97.5th
Immunoglobulin A (IgA)	126 mg/dL	35- 300	

Celiac Disease/Gluten Sensitivity/Wheat Allergy Cascade

SPECIMEN DATA

Comments:

Date Collected: 01/09/2022
Date Received: 01/11/2022 <dl: less than detection limit
Date Completed: 01/17/2022
Method: Chemiluminesent, Immunoassay

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This test is useful for

- Patients who have rash or other persistent skin conditions, ataxia, idiopathic neurological conditions, autoimmune arthritis or thyroiditis, unexplained weight loss, or persistent gastrointestinal symptoms that are not associated with enteropathogens
- Symptomatic individuals that have tested positive for the HLA DQ2/DQ8 genotypes
- Patients with symptoms or symptom exacerbation with dietary gluten or re-introduction of gluten after a trial elimination of gluten
- Individuals that have a first-degree relative with a diagnosis of CD
- Any child with a history of three or more antibiotic-treated cases of gastroenteritis while less than six months of age
- Patients on a gluten-inclusive diet who have type I diabetes, multiple sclerosis or schizophrenia
- Individuals on a gluten-inclusive diet who have other laboratory evidence that may be associated with CD:
  - Elevated liver function tests
  - Bone demineralization
  - Evidence of impaired absorption of fat-soluble vitamins, iron, B12 or folic acid

OUR MISSION:

To research, develop and offer innovative specialty tests that help doctors identify health risks and improve outcomes for patients with chronic conditions.

To educate and support healthcare professionals.

To improve lives through science.

DOCTOR'S DATA INC.

SCIENCE + INSIGHT

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About Doctor's Data

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As a pioneer in the laboratory testing industry, Doctor's Data provides a wide array of testing solutions to aid in decision making and better patient outcomes. Choose Doctor's Data to help you assess and treat heavy metal burden, nutritional deficiencies, gastrointestinal function, hormone status, cardiovascular risk, liver and metabolic abnormalities, and more.