



GENOVA
DIAGNOSTICS
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The DNA probe results for the organisms reported in the Opportunistic Bacteria section are identified at the genus level and have not been confirmed by traditional microbial culturing.

GI **GI Effects**
fx Stool Profiles
U.S. patent pending 2008

2200 GI Effects Comprehensive Profile

Methodology: DNA Analysis, GC/MS, Microscopic, Colorimetric, Automated Chemistry, EIA



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The DNA probe results for the organisms reported in the Opportunistic Bacteria section are identified at the genus level and have not been confirmed by traditional microbial culturing.



2200 GI Effects Comprehensive Profile

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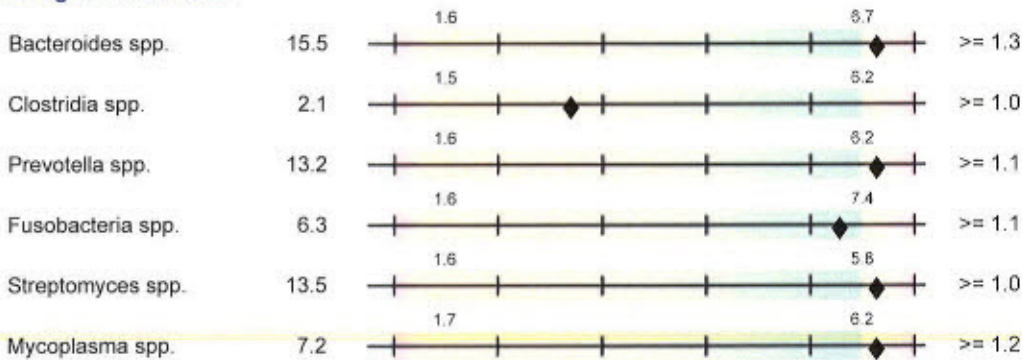
Results | Quintile Ranking | 95% Reference Range | Consistency = Loose

| Results | 1st | 2nd | 3rd | 4th | 5th | 95% Reference Range | Consistency = Loose |
|---------|-----|-----|-----|-----|-----|---------------------|---------------------|
|---------|-----|-----|-----|-----|-----|---------------------|---------------------|

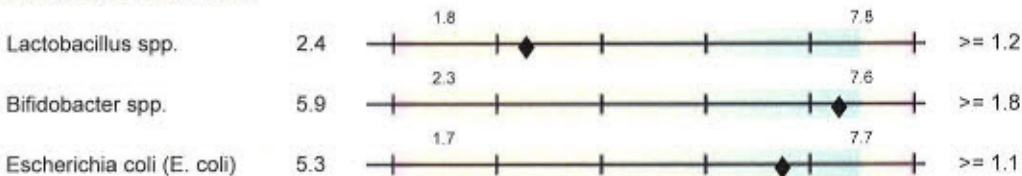
Predominant Bacteria

E+007

Obligate Anaerobes



Facultative Anaerobes



Predominant Bacteria play major roles in health. They provide colonization resistance against potentially pathogenic organisms, aid in digestion and absorption, produce vitamins and SCFA's, and stimulate the GI immune system. DNA probes allow detection of multiple species (spp.) within a genus, so the genera that are reported cover many species.

Organisms are detected by DNA analysis. One colony forming unit (CFU) is equivalent to one bacterium. Each genome detected represents one cell, or one CFU. Results are expressed in scientific notation, so an organism reported as 2.5 E+007 CFU/gram is read as 25 million colony forming units per gram of feces.

Opportunistic Bacteria

Expected Value

Salmonella spp. Positive Negative

Opportunistic Bacteria may cause symptoms and be associated with disease. They can affect digestion and absorption, nutrient production, pH and immune state. Antibiotic sensitivity tests will be performed on all opportunistic bacteria found, although clinical history is usually considered to determine treatment since the organisms are not generally considered to be pathogens.

Gastrointestinal Effects Interpretation

Interpretive Guides are downloadable at: www.gdx.net/tests/interpretive-guides

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Yeast/Fungi

No clinically significant amounts.

Expected Value

Yeast/Fungi

Yeast overgrowth has been linked to many chronic conditions, in part because of antigenic responses in some patients to even low rates of yeast growth. Potential symptoms include diarrhea, headache, bloating, atopic dermatitis and fatigue. Positives are reported as +1, +2, +3 or +4 indicating >100, >1000, >10000 or >100000 pg DNA/g.

Parasitology

Microscopic Exam Results:*

No ova or parasites seen

Parasitology

Parasite Recovery: Literature suggests that >90% of enteric parasitic infections are detected in a sample from a single stool collection. Increased sensitivity results from the collection of additional specimens on separate days. Parasites have been detected in 20-24% of U.S. patients with mild to moderate GI symptoms.

Parasitology EIA Tests:

| | In Range | Out of Range |
|-----------------------|----------|--------------|
| Cryptosporidium | Negative | |
| Giardia lamblia | Negative | |
| E. histolytica/dispar | Negative | |

*Indicates testing performed by Genova, Inc. 63 Zillicoa St., Asheville, NC 28801-1074
A. L. Peace-Brewer, PhD, D(ABMLI), Lab Director · CLIA Lic. #34D0655571 · Medicare Lic. #34-8475

Adiposity Index

Expected Value

| | | | |
|-----------------|----|---|---------|
| Firmicutes % | 29 |  | <= 80 % |
| Bacteroidetes % | 71 |  | >= 20 % |

The **Adiposity Index** is derived by using DNA probes that detect multiple genera of the phyla Firmicutes and Bacteroidetes. Abnormalities of these phyla may be associated with increased caloric extraction from food.

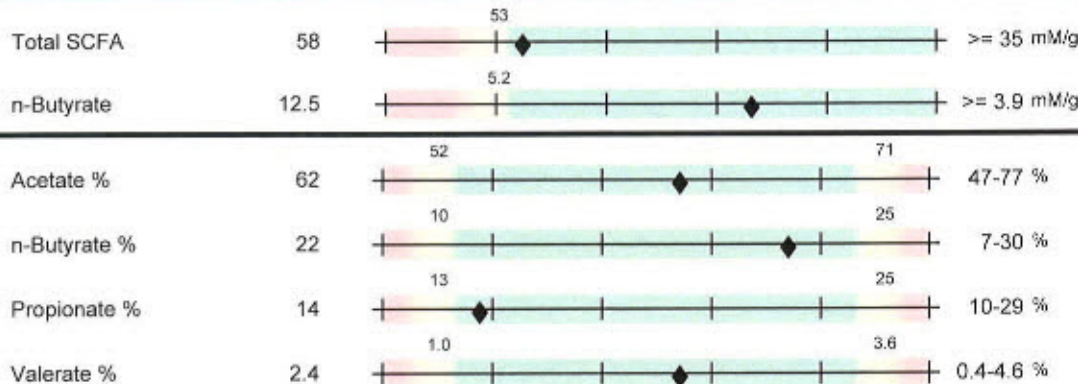


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Beneficial SCFA



Beneficial SCFA

Short chain fatty acids (SCFA) are produced by bacterial fermentation of dietary polysaccharides and fiber. The product, N-butyrate, is taken up and used to sustain the normal activity of colonic epithelial cells. Butyrate has been shown to lower the risk of colitis and colorectal cancer. A healthy balance of GI microbes depends on production of SCFA by one specie to allow the normal growth of another one in a complex cross-feeding network.

Inflammation



Inflammation

Lactoferrin, an iron-binding glycoprotein, is released in IBD but not in non-inflammatory IBS. High levels are found in Crohn's, UC or infection. WBC's are elevated in general inflammation/infection. Mucus is often visualized in acute GI inflammation.

Immunology



Immunology

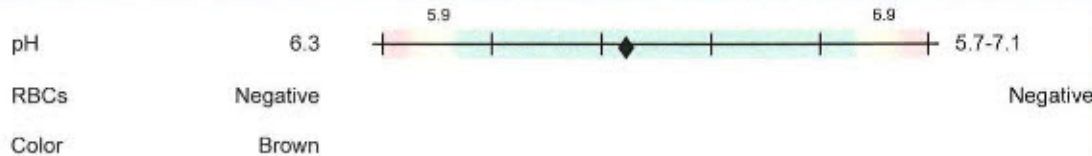
High fecal sIgA indicates immune system reactions to the presence of antigens from bacteria, yeast or other microbes. Low sIgA can result from stress or malnutrition.

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Methodology: DNA Analysis, GC/MS, Microscopic, Colorimetric, Automated Chemistry, EIA



Additional Tests



Additional Tests

pH is influenced by numerous factors, but it is strongly related to the bacterial release of pH-lowering organic acids and pH-raising ammonia. Positive RBCs can signify GI tract bleeding. Color (other than brown) abnormalities can be due to upper GI bleeding, or bile duct blockage, steatorrhea or antibiotic use.

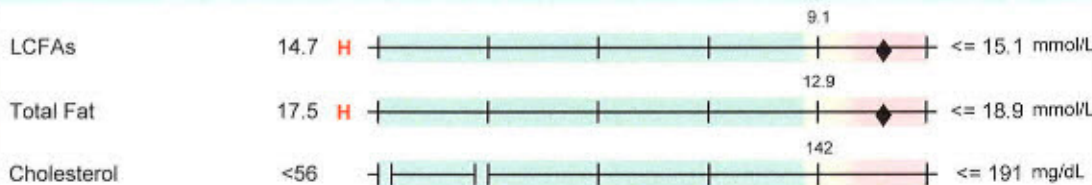
Digestion



Digestion

Pancreatic elastase 1 levels below 100 are strongly correlated with severe pancreatic insufficiency; levels of 100-200 identify moderate pancreatic insufficiency. High triglycerides signify fat maldigestion. Putrefactive SCFA are a result of bacterial fermentation of undigested protein. High numbers of vegetable fibers indicate maldigestion.

Absorption



Absorption

High LCFA indicates fat malabsorption due to pancreatic or biliary insufficiency, or acute bacterial infection that produces intestinal cell destruction. High total fat usually signals malabsorption, as does elevated fecal cholesterol.

*UC = Unable to Calculate

REJ* = *Unable to perform; sample was rejected.

Decisions involving diagnosis and treatment are the responsibility of the clinician.



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2133 Helicobacter pylori Stool Antigen EIA (HpSA)

Methodology: EIA

| | Results | Expected Value |
|---------------------|-----------------|----------------|
| 1. HpSA - H. pylori | Positive | Negative |

HpSA (Helicobacter pylori stool antigen)

Helicobacter pylori is a bacterium which causes peptic ulcer disease and plays a role in the development of gastric cancer. Direct stool testing of the antigen (HpSA) is highly accurate and is appropriate for diagnosis and follow-up of infection.

Decisions involving diagnosis and treatment are the responsibility of the clinician.

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2150 GI Effects® Sensitivity Bacteria Profile - Stool

Methodology: DNA Analysis, ELISA

Pharmaceuticals

| | Sensitive | Resistant |
|------------------------|-----------|-----------|
| 1. Amoxicillin | S | |
| 2. Ampicillin | S | |
| 3. Cefuroxime | S | |
| 4. Ciprofloxacin | S | |
| 5. Clindamycin | S | |
| 6. Erythromycin | S | |
| 7. Levofloxacin | S | |
| 8. Potassium Clavula | | R |
| 9. Rifaximin | S | |
| 10. Sulfamethoxazole | S | |
| 11. Tetracyclin | S | |
| 12. Trimethoprim-Sulfa | S | |

Bacterial growth suppression is measured in a liquid growth medium where fungal growth is suppressed and specific antibacterial agents are introduced before incubation. In contrast to the older isolation and culture techniques, such universal culturing more closely approximates the actions of antibacterials in the complex milieu of the colon.

Agents marked as "Sensitive" cause effective bacterial growth suppression. Those antibacterial agents are candidates for suppressing the growth of bacteria in the patient's colon. The results apply to all organisms reported under "Opportunistic".

Agents indicated as "Resistant" have low effectiveness. If all tested agents are resistant, synergistic mixtures of antibacterial agents may be effective.

Botanicals

| | Sensitive | Resistant |
|--|-----------|-----------|
| 13. 5-Hydroxy-1,4-naphthoquinone Black Walnut | S | |
| 14. Alliin Garlic | S | |
| 15. Arbutin Uva Ursi | S | |
| 16. Artemisinin Wormwood | S | |
| 17. Berberine Goldenseal | S | |
| 18. Caprylic acid Octanoic acid | S | |
| 19. Carvacrol Oregano | S | |
| 20. Oleuropein Olive Leaf | S | |
| 21. Quinic Acid Cats Claw | S | |
| 22. Thymol Oil of Thyme | S | |
| 23. Undecylenic acid Undecylenic acid | S | |

For Botanical sensitivity testing the active ingredients are tested and an example of the available source is shown.

Sensitivities are not performed on "Pathogens" or "Parasites" because they do not grow in culture under normal laboratory conditions. Standard protocols are generally used for treatment of pathogens and parasites.