Metametrix
Clinical Laboratory
3425 Corporate Way
Duluth, GA 30096
770.446.5483 Fax:770.441.2237

Wellcome

Feb 13, 2012
compared with
Sep 22, 2011

2100 Gastrointestinal Function Profile

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

Consistency = Formed/Normal

Percentile Ranking by Quintile

Results CFU/gram | 1st | 2nd | 3rd | 4th | 5th | 95% Reference Range

20% 40% 60% 80%

Predominant Bacteria (E+007)

		2011 9-22	E+007	
Obligate anaerobes				
Bacteroides sp.	8.6	← 2.9	1.6 – 6.7	>= 1.3
Clostridia sp.	1.7	1.7	1.5 – 6.2	>= 1.0
Prevotella sp.	2.0	2.0	1.6 – 6.2	>= 1.1
Fusobacteria sp.	2.0	2.0	1.6 – 7.4	>= 1.1
Streptomyces sp.	1.8	2.0	1.6 – 5.8	>= 1.0
Mycoplasma sp.	1.8	7.7	1.7 – 6.2	>= 1.2
Facultative anaerobes				
Lactobacillus sp.	5.2	5.3	1.8 – 7.8	>= 1.2
Bifidobacter sp.	3.0	2.5	2.3 – 7.6	>= 1.8
Obligate aerobes				
Escherichia coli	1.6	L 2.6	1.7 – 7.7	>= 1.1

Opportunistic Bacteria

No clinically significant amounts.

Key: | = Data point from 9-22-11 stool

Units and Reference Ranges

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 E7 CFU/gram is read as 25 million colony forming units per gram of feces. The cutoff for significance of Opportunistic Bacteria has been set at 1.0E+ 005 (100,000). These are levels above which clinically significant growth may be present. Rather than reporting semi-quantitative +1 to +4 levels, the new methodology provides full quantitative analysis.

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 (sp.) within a genus, so the genera that are reported cover many species.

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.

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Pathogenic Bacteria

		95% Reference Range
Helicobacter pylori	<0.01	<=1.0E+005
E.H.E. coli	<0.01	<=1.0E+005
Clostridium difficile	<0.01	<=1.0E+005
Campylobacter sp.	<0.01	<=1.0E+005

Yeast/Fungi

		Expected Value
Yeast/Fungi; taxonomy unavailable.	**+1 => 100 pg DNA/g specimen**	Neg

2011 Sep22 +2

A taxonomy unavailable finding may indicate ingested mold. The higher the number, the greater the indication for treatment, particularly when accompanied by clinical symptoms.

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.

Parasites

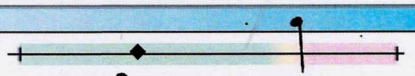
		Expected Value
Parasite present; taxonomy unavailable.	**Positive**	Neg

2011 Sep22 Positive

A taxonomy unavailable finding likely indicates an ingested protozoan and not a human parasite. It does not indicate treatment unless patient symptoms and other inflammatory markers are consistent with parasite infection.

Parasites
Parasite infections are a major cause of non-viral diarrhea. Symptoms may include constipation, gas, bloating, increased allergy response, colitis, nausea and distention.

Adiposity Index

Firmicutes	2011 Sep22 77	50		<= 80
Bacteroidetes	2011 Sep22 23	50		>= 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.

Drug Resistance Genes

aacA, aphD	Neg	gyrB, ParE	Neg
mecA	Neg	PBP1a, 2B	Neg
vanA, B, and C	Neg		

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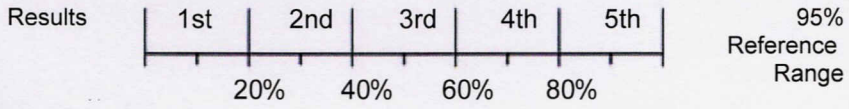
Percentile Ranking by Quintile



Beneficial SCFA

Total SCFA	86	2011 Sep 22: 53	53	>= 35 mM/g
n-Butyrate	20.4	8.3	5.2	>= 3.9 mM/g
Acetate %	63	58	52 – 71	47 - 77 %
Butyrate %	24	16	10 – 25	7 - 30 %
Propionate %	12	23 L	13 – 25	10 - 29 %
Valerate %	0.8	3.2 L	1.0 – 3.6	0.4 - 4.6 %

Inflammation

Lactoferrin	0.7	2.2	3.1	<= 6.3 ug/mL
WBCs	Neg			Neg-Rare
Mucus	Neg			Neg

Immunology

Fecal sIgA	114	167	20 – 144	5 - 161 mg/dl
Anti-gliadin sIgA	2.1	1.1	6.4	<= 21.4 mg/dl

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 epithielial 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

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

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. Anti-gliadin sIgA is a screening marker for gluten sensitivity.

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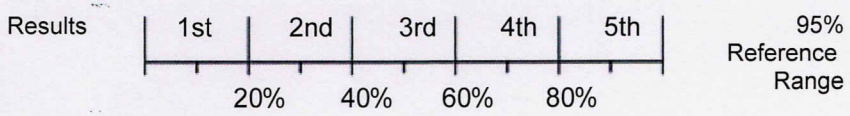

Additional Tests

pH	6.8 (Sep 22, 2011: 6.0)	5.9	6.9	5.7 - 7.1
RBCs	Neg			Neg
Color	Brown			

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

Elastase 1	349 (176)	321		>= 184 ug/g
Triglycerides	<41 (47)		119	<= 181 mg/dL
Putrefactive SCFA	0.5 (3.6)		4.4	<= 7.4 mM/g
Vegetable Fibers	Rare			None-Few

Digestion

Pancreatic elastase 1 levels below the reference limits are strongly correlated with 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

LCFAs	1.5 (3.8)		9.1	<= 15.1 mmol/L
Total Fat	UC*		12.9	<= 18.9 mmol/L
Cholesterol	<56		142	<= 191 mg/dL

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

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

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2155 Sensitivity - Fungi

Methodology: DNA Analysis, ELISA

Unable to determine sensitivity to pharmaceuticals and botanicals due to the lack of growth of fungi in vitro.

2155
Not done for 2011 Sep 22

Fungal growth suppression is measured in a liquid growth medium where bacterial growth is suppressed and specific antifungal agents are introduced before incubation. Growth inhibition is measured after incubation. In contrast to the older isolation and culture techniques, such universal culturing more closely approximates the actions of antifungals in the complex milieu of the colon.

Agents marked as **"Sensitive"** cause effective fungal growth suppression. Those antifungal agent are candidates for suppressing the growth of fungi and yeasts in the patient's colon. The results apply to all organisms reported under **"Yeast/Fungi"**.

Agents indicated as **"Resistant"** have low effectiveness and can increase the risk of inducing drug resistant organisms. If all tested agents are **"Resistant"**, synergistic mixtures of antifungal agents may be effective.

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.

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

Comprehensive Digestive Stool Analysis 2.0

CDSA 2.0

Wellcome
Note: Same stool was sampled for MetaMetrix stool test on Feb 13, 2012.

Feb 13, 2012 compared with Aug 2005

Digestion/Absorption

Analyte	2005 Aug	Result	Reference Range
1. Pancreatic Elastase 1 ◆	same	>500	>= 201 mcg/g
2. Putrefactive SCFAs (Total*)	5.1	0.6	1.3-8.6 micromol/g

*Total values equal the sum of all measurable parts.

Gut Immunology

Analyte	Result	Reference Range
3. Eosinophil Protein X	12.5H (0.9)	<= 7.0 mcg/g
4. Calprotectin ◆	56H (<16)	<=50 mcg/g

Metabolic

Analyte	Result	Reference Range
5. Beneficial SCFAs (Total*)	25.6 (49.4)	>= 13.6 micromol/g
6. n-Butyrate	3.9 (11.6)	>= 2.5 micromol/g
7. pH ◆	7.6 (6.9)	6.1-7.9
8. Beta-glucuronidase	834 (980)	337-4,433 U/g

Secondary Bile Acids

9. Lithocholic acid (LCA)	0.38	(0.51)	0.65-5.21 mg/g
10. Deoxycholic acid (DCA)	0.66	(0.24)	0.67-6.76 mg/g
11. LCA / DCA Ratio	0.58	(2.13)	0.39-2.07

*Total values equal the sum of all measurable parts.

Digestion/Absorption

Digestion encompasses the functional activities of: mastication, gastric acid production, pancreatic activity, bile production and brush border maintenance. Absorption depends on all of the above actions, as well as a healthy gut mucosal barrier.

Gut Immunology

Eosinophil Protein X (EPX) reflects IgE-mediated inflammation and tissue damage and can be elevated in celiac disease, collagenous colitis, helminthic/parasitic infection, and IgE mediated food allergies. Elevated EPX requires further diagnostic testing to determine the cause. Calprotectin is a neutrophilic marker specific for inflammation in the gastrointestinal tract. It is elevated with infection, post-infectious IBS, and NSAID enteropathy. Fecal calprotectin can be used to differentiate IBD vs. IBS, to monitor treatment in IBD, and to determine which patients should be referred for endoscopy and/or colonoscopy. Levels between 50-120 should be repeated at 4-6 weeks and confirmed.

Metabolic

Gut metabolism is representative of the bacterial milieu, primarily through the presence of commensal bacteria. Metabolic activities include: mucous production, vitamin synthesis and absorption, deconjugation of steroid hormones and bile acids, fat regulation, and SCFA metabolism. These metabolic activities require a normal population of commensal bacteria without active bacterial, viral, or parasitic infection.

Genova Diagnostics®
Improving Healthcare for Chronic Disease

63 Zillicoa Street
Asheville, NC 28801

Microbiology

Bacteriology

2005 Aug

12. Beneficial Bacteria

Lactobacillus species	3+	*NG
Escherichia coli	4+	4+
Bifidobacterium	1+	4+

2005 Aug

13. Additional Bacteria

alpha haemolytic Streptococcus	NP	2+	4+
gamma haemolytic Streptococcus	NP	3+	4+
Klebsiella pneumoniae	PP	0	4+

14. Mycology

*NG *NG

2005 Aug

Rhodotorula species NP 1+

Human microflora is influenced by environmental factors and the competitive ecosystem of the organisms in the GI tract. Pathological significance should be based upon clinical symptoms and reproducibility of bacterial recovery.

*NG / *NG	NP	PP	P
No Growth	Non-Pathogen	Potential Pathogen	Pathogen

Lab Comments

All Yeast Sensitivities.

The Markers in this section reflect the bacteriological status of the gut.

Beneficial bacteria Beneficial flora controls potentially pathogenic organisms, influences nutrient production, removes toxins from the gut and stimulates the intestinal immune system (GALT). The composition of the colonic flora is affected by diet, transit time, stool pH, age, microbial interactions, colonic availability of nutrients, bile acids, sulfate and the ability of the microbes to metabolize these substrates. Ideally, levels of Lactobacilli and E. coli should be 2+ or greater. Bifidobacteria being a predominate anaerobe should be recovered at levels of 4+.

Additional bacteria

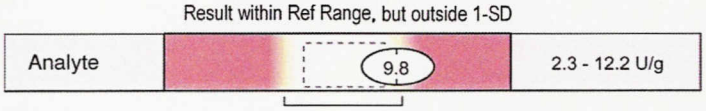
Non-pathogen: Organisms that fall under this category are those that constitute normal, commensal flora, or have not been recognized as etiological agents of disease.

Potential Pathogen: Organisms that fall under this category are considered potential or opportunistic pathogens when present in heavy growth.

Pathogen: The organisms that fall under this category are well-recognized pathogens in clinical literature that have a clearly recognized mechanism of pathogenicity and are considered significant regardless of the quantity that appears in culture.

Mycology: Organisms that fall under this category constitute part of the normal colonic flora when present in small numbers. They may, however, become potential pathogens after disruption of the mucosal lining, which enables fungi to colonize and establish a local infection.

The **Reference Range** is a statistical interval representing 95% or 2 Standard Deviations (2 S.D.) of the reference population. One Standard Deviation (1 S.D.) is a statistical interval representing 68% of the reference population. Values between 1 and 2 S.D. are not necessarily abnormal. Clinical correlation is suggested. (See example below)



Commentary is provided to the practitioner for educational purposes, and should not be interpreted as diagnostic or treatment recommendations. Diagnosis and treatment decisions are the responsibility of the practitioner.

The performance characteristics of all assays have been verified by Genova Diagnostics, Inc. Unless otherwise noted with ◆ as cleared by the U.S. Food and Drug Administration, assays are For Research Use Only.

CDSA 2.0

Wellcome Feb 13, 2012
Note: Same stool was compared with
sampled for MetaMetrix Aug 2005
stool test on Feb 13, 2012.

Parasitology

Microscopic Exam Results:

No Ova or Parasites seen

PARASITOLOGY EIA TESTS:

	In Range	Out of Range
Cryptosporidium	Negative	
Giardia lamblia	Negative	
Entamoeba histolytica/dispar	Negative	

Parasitology

Optimized Parasite Recovery (OPR) is a technique used by Genova Diagnostics Inc. that involves combining multiple stool specimens submitted from the same patient for intestinal parasite examination as compared to individual sample evaluation. Research demonstrates that this method increases parasite recovery.

Data from analysis shows that parasites are detected in 22% of samples submitted to Genova Diagnostics Inc. This implies that a significant portion of the population suffers from infection with parasites, many of whom experience minimal gastrointestinal symptoms.