GENOVA DIAGNOSTICS
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Ordering Physician:
The Natural Medicine Clinic
Thomas Rofrano, DC

2401 PGA Blvd
Ste 132
Palm Beach Gardens, FL 33410

Accession #:	**A1312310035**	Date Collected:	12/30/2013
Order #:	**G8310455**	Date Received:	12/31/2013
Reference #:		Date of Report:	01/17/2014
Patient:	**Jeffrey Epstein**		
Date of Birth:	01/20/1953	Telephone:	5616275816
Age:	60	Fax:	5616275895
Sex:	Male		
Reprinted:			
Comment:			

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

2200 GI Effects Comprehensive Profile

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

The GI Effects Gastrointestinal Function Profile (2100) and the GI Effects Microbial Ecology Profile (2105) have been replaced by GI Effects Comprehensive Profile (2200) and a new version of the Microbial Ecology Profile (2205), respectively. Updates on the new GI Effects Comprehensive Profile (2200) and Microbial Ecology Profile (2205) include:

- **The 2200 and 2205 will include [redacted] for parasitology, replacing PCR.** To enhance clinical utility for our clients, Genova Diagnostics will now offer gold standard [redacted] technology on its GI Effects Profiles. When multiple stool samples are provided, Genova utilizes a pooled [redacted] process known as Optimized Parasitology Recovery (OPR).
- In order to optimize clinical utility, **pathogens (C. difficile, H. pylori, Shiga Toxin E. coli, and Campylobacter spp.) will now only be offered as EIA add ons.** Clinical utility is best achieved by applying diagnostic assessment for these pathogens within an appropriate clinical differential.
- **Drug Resistant Genes will be discontinued from reported profiles.** Measurement of drug resistant genes indicates presence of DNA for the gene in stool, but does not provide evidence of gene expression. Therefore, no specific treatment indications can be inferred.
- **PCR will continue to be utilized for assessment of gut microbiota,** including predominant and opportunistic bacteria, and yeast/fungi.

If you have any questions regarding these important changes, please feel free to contact Client Services at 800-522-4762, or contact us online at *www.gdx.net*.

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Results | Quintile Ranking: 1st | 2nd | 3rd | 4th | 5th | 95% Reference Range | ***Consistency = Hard/Constipated***

Predominant Bacteria — E+007

Obligate Anaerobes

	Results	Quintile Ranking (1st | 2nd | 3rd | 4th | 5th)	95% Reference Range
Bacteroides spp.	6.2	1.6 … 6.7	>= 1.3
Clostridia spp.	5.3	1.5 … 6.2	>= 1.0
Prevotella spp.	4.6	1.6 … 6.2	>= 1.1
Fusobacteria spp.	5.1	1.6 … 7.4	>= 1.1
Streptomyces spp.	4.7	1.6 … 5.8	>= 1.0
Mycoplasma spp.	3.7	1.7 … 6.2	>= 1.2

Facultative Anaerobes

	Results	Quintile Ranking (1st | 2nd | 3rd | 4th | 5th)	95% Reference Range
Lactobacillus spp.	3.8	1.8 … 7.8	>= 1.2
Bifidobacter spp.	7.1	2.3 … 7.6	>= 1.8
Escherichia coli (E. coli)	5.4	1.7 … 7.7	>= 1.1

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

No clinically significant amounts.

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.

Gastronintesinal Effects Interpretation
Interpretive Guides are downloadable at: *www.gdx.net/tests/interpretive-guides*

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Yeast/Fungi

Expected Value

No clinically significant amounts.

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:*

Dientamoeba fragilis: Few Trophozoites

Parasitology EIA Tests:

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

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.

*Indicates testing performed by Genova, Inc. 63 Zillicoa St., Asheville, NC 28801-1074
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Adiposity Index

Expected Value

Firmicutes %	54		<= 80 %
Bacteroidetes %	46		>= 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

	Results		Quintile Ranking (1st / 2nd / 3rd / 4th / 5th)	95% Reference Range
Total SCFA	34	L	53	>= 35 mM/g
n-Butyrate	3.4	L	5.2	>= 3.9 mM/g
Acetate %	67		52 – 71	47-77 %
n-Butyrate %	10		10 – 25	7-30 %
Propionate %	21		13 – 25	10-29 %
Valerate %	3.2		1.0 – 3.6	0.4-4.6 %

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

	Results		Quintile Ranking	95% Reference Range
Lactoferrin	0.5		3.1	<= 6.3 ug/mL
WBCs	Negative			Negative-Rare
Mucus	Negative			Negative

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

	Results		Quintile Ranking	95% Reference Range
Fecal sIgA	32		20 – 144	5-161 mg/dl

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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Additional Tests

	Results	Quintile Ranking (1st 2nd 3rd 4th 5th)	95% Reference Range
pH	6.6	5.9 – 6.9	5.7-7.1
RBCs	Negative		Negative
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

	Results		95% Reference Range
Elastase 1	236	200	> 100 ug/g
Triglycerides	74	119	<= 181 mg/dL
Putrefactive SCFA	1.1	4.4	<= 7.4 mM/g
Vegetable Fibers	Rare		None-Few

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

	Results		95% Reference Range
LCFAs	6.8	9.1	<= 15.1 mmol/L
Total Fat	9.1	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

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

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

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2130 Campylobacter EIA

Methodology: EIA

	Results	Expected Value
1. Campylobacter spp.	Negative	Negative

Campylobacter
Campylobacter jejuni is the most frequent cause of bacterial-induced diarrhea. While transmission can occur via the fecal-oral route, infection is primarily associated with the ingestion of contaminated and poorly cooked foods of animal origin, notably, red meat and milk.

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2131 Clostridium difficile EIA

Methodology: EIA

	Results	Expected Value
1. Clostridium difficile	Negative†	Negative

Clostridium difficile
Clostridium difficile is an anaerobic, spore-forming gram-positive bacterium which can be part of the normal intestinal flora. Disruption of the normal gut flora via antibiotic use (especially those with broad spectrum activity) may result in overgrowth of Clostridium difficile. Symptoms may range in severity from mild diarrhea to life-threatening colitis.

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2132 Shiga toxin E. coli EIA

Methodology: EIA

	Results	Expected Value
1. Shiga toxin E. coli	Negative†	Negative

Shiga toxin E. coli
Shiga toxin-producing Escherichia coli (STEC) is a group of bacterial strains that have been identified as worldwide causes of serious human gastrointestinal disease. The subgroup enterohemorrhagic E. coli includes over 100 different stereotypes, with 0157:H7 being the most significant, as it occurs in over 80% of cases. The pathogen is transmitted primarily by food, in particular dairy and beef cattle.

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Reference #:		Date of Report:	01/08/2014
Patient:	**Jeffrey Epstein**		
Date of Birth:	01/20/1953	Telephone:	5616275816
Age:	60	Fax:	5616275895
Sex:	Male		
Reprinted:			
Comment:			

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U.S. patent pending 2008

2133 Helicobacter pylori Stool Antigen EIA (HpSA)

Methodology: EIA

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