GENOVA DIAGNOSTICS EUROPE
46-50 Coombe Road
New Malden
Surrey KT3 4QF

63 Zillicoa Street
Asheville, NC 28801

CDSA 2.0™

Patient: **SAMPLE PATIENT**
DOB:
Sex:
MRN:

2003 CDSA/P 2.0 - Stool

Methodology: MALDI-TOF MS, Automated and Manual Biochemical Methods, Vitek 2® System Microbial identification and Antibiotic susceptibility, Automated Chemistry, GC-FID, Microscopic Evaluation, ELISA, Ion Selective Electrode, Immunoassay, GCMS

Digestion/Absorption

Analyte	Result	Reference Range
1. Pancreatic Elastase 1 ◆	167	> 200 mcg/g
2. Putrefactive SCFAs (Total*)	1.2	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	5.2	<= 4.6 mcg/g
4. Calprotectin ◆	38	<=50 mcg/g

Metabolic

Analyte	Result	Reference Range
5. Beneficial SCFAs (Total*)	62.0	>= 13.6 micromol/g
6. n-Butyrate	11.1	>= 2.5 micromol/g
7. pH	5.9	6.1-7.9
8. Beta-glucuronidase	2,368	337-4,433 U/g

Secondary Bile Acids

9. Lithocholic acid (LCA)	2.70	0.65-5.21 mg/g
10. Deoxycholic acid (DCA)	3.65	0.67-6.76 mg/g
11. LCA / DCA Ratio	0.74	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. Fecal EPX elevations can be associated with several conditions including IBD, IgE-mediated food allergies, parasite or worm infections, and collagenous colitis. Elevated EPX requires further diagnostic testing to determine the cause. Calprotectin is a neutrophilic marker specific for inflammation in the gastrointestinal tract. It may be elevated with IBD, post-infectious IBS, infection, food allergies, neoplasia and use of nonsteroidal anti-inflammatory drugs (NSAIDs). Fecal calprotectin is FDA-cleared to differentiate between IBD and IBS. Levels 50 mcg/g are considered normal; levels between 50-120 mcg/g are considered borderline and should be re-evaluated at 4-6 weeks; levels > 120 mcg/g are considered abnormal, the source of inflammation should be determined, and levels repeated as clinically indicated; and levels > 250 mcg/g have been associated with high risk of clinical relapse in patients with IBD.

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.

Microbiology

Bacteriology

12. Beneficial Bacteria

Lactobacillus species		*NG
Escherichia coli		*NG
Bifidobacterium		4+

13. Additional Bacteria

alpha haemolytic Streptococcus	NP	4+
gamma haemolytic Streptococcus	NP	4+
Geotrichum capitatum	PP	4+

14. Mycology

Candida albicans/dubliniensis	PP	3+

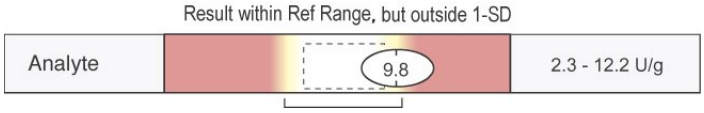
Human microflora is influenced by environmental factors and the competitive ecosystem of the organisms in the GI tract. Pathological significance should be based upon clinical symptoms and reproducibility of bacterial recovery.

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

Microbiology
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 ◆, the assay has not been cleared by the U.S. Food and Drug Administration.

Additional Tests

	In Range	Out of Range
16. Shiga toxin E. coli ◆	Negative	
17. Campylobacter ◆	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 serotypes, with 0157:H7 being the most significant, as it occurs in over 80% of all cases. Contaminated food continues to be the principal vehicle for transmission; foods associated with outbreaks include alfalfa sprouts, fresh produce, beef, and unpasteurized juices.

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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Methodology: Microscopic Examination, EIA and Macroscopic Evaluation.

Parasitology

Microscopic Exam Results:

No Ova or Parasites seen

PARASITOLOGY EIA TESTS:

	In Range	Out of Range
Cryptosporidium ♦	Negative	
Giardia lamblia ♦	Negative	
Entamoeba histolytica ♦	Negative	

Parasitology

Parasite Recovery: Literature suggests that >90% of enteric parasitic infections may be detected in a sample from a single stool collection. Increased sensitivity results from the collection of additional specimens on separate days.

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