GENOVA DIAGNOSTICS

63 Zillicoa Street
Asheville, NC 28801

CDSA 2.0™
WITHOUT PARASITOLOGY

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

2002 CDSA 2.0 w/o Parasitology - 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 ◆	>500	> 200 mcg/g
2. Putrefactive SCFAs (Total*)	19.9	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	1.6	<= 4.6 mcg/g
4. Calprotectin ◆	46	<=50 mcg/g

Metabolic

Analyte	Result	Reference Range
5. Beneficial SCFAs (Total*)	136.1	>= 13.6 micromol/g
6. n-Butyrate	29.9	>= 2.5 micromol/g
7. pH	6.5	6.1-7.9
8. Beta-glucuronidase	<dl	337-4,433 U/g

Secondary Bile Acids

9. Lithocholic acid (LCA)	1.80	0.65-5.21 mg/g
10. Deoxycholic acid (DCA)	3.13	0.67-6.76 mg/g
11. LCA / DCA Ratio	0.58	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	4+
Bifidobacterium	3+

13. Additional Bacteria

alpha haemolytic Streptococcus	NP	1+
Staphylococcus aureus	NP	1+
Enterococcus faecalis	NP	2+
Haemolytic Escherichia coli	NP	4+
Citrobacter species	PP	4+
Enterobacter cloacae	PP	4+

14. Mycology

*NG *NG

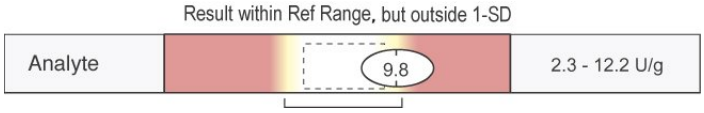
Human microflora is influenced by environmental factors and the competitive ecosystem of the organisms in the GI tract. Pathological significance should be based upon clinical symptoms and reproducibility of bacterial recovery.

*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
19. Occult Blood ◆	Negative	

Analyte	Result	Reference Range
Chymotrypsin	9.5	0.9-26.8 U/g

Fecal Fat Distribution

Triglycerides	1.5	0.2-3.3 mg/g
Cholesterol	4.4	0.2-3.5 mg/g
Long Chain Fatty Acids	5.5	1.3-23.7 mg/g
Phospholipids	<dl	0.2-8.8 mg/g
Fecal Fat (Total*)	11.4	2.6-32.4 mg/g

*Total values equal the sum of all measurable parts.

Chymotrypsin
This proteolytic enzyme is released by the pancreas and activated in the small intestine. Deficiencies of chymotrypsin are indicative of exocrine pancreatic insufficiency. Chymotrypsin may become increased with rapid transit time (i.e. diarrhea).

Fecal Fats
Global assessment of fecal fat is the sum total of triglyceride, cholesterol, phospholipids and long-chain fatty acids. Thus, total fecal fat is a representation of dietary intake, digestion and absorption. The mg fat/ gm stool % correlates with the 72 hour fecal fat study. Thus, increased fecal fat is usually representative of malabsorption. Most dietary fat comes in the form of triglyceride, which is normally 99% absorbed. Only 2/3 of dietary cholesterol is normally absorbed.

Occult blood
Fecal occult blood can be present in the stool sample because of blood loss somewhere in the gastrointestinal system. This could be caused by conditions such as ulcers, polyps, diverticulitis, inflammatory bowel disease or colorectal cancer.

Bacterial Sensitivity

Patient: **SAMPLE PATIENT**
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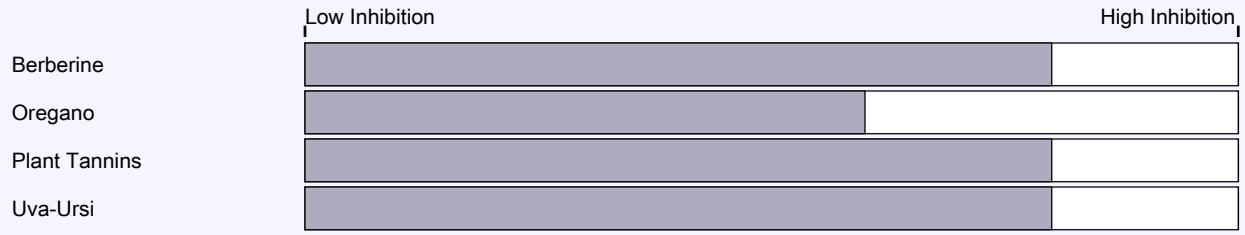
Prescriptive Agents

CITROBACTER SPECIES

	R	I	S-DD*	S	NI*
Ampicillin	R				
Amox./Clavulanic Acid	R				
Cephalothin	R				
Ciprofloxacin				S	
Tetracycline				S	
Trimethoprim/Sulfa				S	

Natural Agents

CITROBACTER SPECIES



Prescriptive Agents:
The R (Resistant) category implies isolate is not inhibited by obtainable levels of pharmaceutical agent.
The I (Intermediate) category includes isolates for which the minimum inhibition concentration (MIC) values usually approach obtainable pharmaceutical agent levels and for which response rates may be lower than for susceptible isolates.
* The S-DD (Susceptible-Dose Dependent) category implies clinical efficacy when higher than normal dosage of a drug can be used and maximal concentration achieved.
The S (Susceptible) column implies that isolates are inhibited by the usually achievable concentrations of the pharmaceutical agent.
* NI (No Interpretive guidelines established) category is used for organisms that currently do not have established guidelines for MIC interpretation.
Refer to published pharmaceutical guidelines for appropriate dosage therapy.

Natural Agents:
In this assay, inhibition is defined as the reduction level on organism growth as a direct result of inhibition by a substance. The level of inhibition is an indicator of how effective the substance was at limiting the growth of an organism in an in vitro environment. High inhibition indicates a greater ability by the substance to limit growth, while Low Inhibition a lesser ability to limit growth. The designated natural products should be considered investigational in nature and not be viewed as standard clinical treatment substances.
This test has been developed and its performance characteristics determined by Genova Diagnostics, Inc. It has not been cleared by the U.S. Food and Drug Administration.

Bacterial Sensitivity

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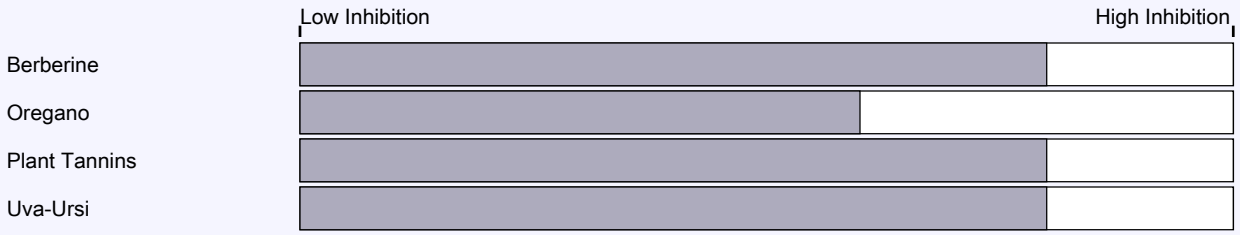
Prescriptive Agents

ENTEROBACTER CLOACAE

	R	I	S-DD*	S	NI*
Ampicillin	R				
Amox./Clavulanic Acid	R				
Cephalothin	R				
Ciprofloxacin				S	
Tetracycline				S	
Trimethoprim/Sulfa				S	

Natural Agents

ENTEROBACTER CLOACAE



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ENSURE THE FOLLOWING:

❑ **Peel and stick labels completed** with **patient's date of birth** are on all tubes as well as the test requisition form

All tubes:

❑ Are tightly closed

❑ Sealed in the biohazard bag with absorbent pad

❑ Refrigerated until packaged for shipping

All required information:

❑ **All sections of test requisition form completed either online or on the included paper form. If using the online form, the paper form must still be returned with the health care provider's signature**

❑ **Health survey** completed

❑ **Payment information provided**

❑ **All tubes and associated forms** placed back in the original Genova sample collection pack box prior to shipping

SHIP THE SAMPLE(S) TO THE LAB

Ship only Monday through Friday, and within 24 hours after final collection.
Please refer to the shipping instruction insert found in your Genova sample collection pack box.

REGISTER FOR THE PATIENT RESOURCE CENTER AT WWW.GDX.NET/PRC

- Complete health surveys
- Make payments
- Access test results

GASTROINTESTINAL 1 DAY COLLECTION

PATIENT SAMPLE COLLECTION INSTRUCTIONS FOR THE FOLLOWING PROFILE(S)

GI Effects Comprehensive Profile*	Stool	#2200
GI Effects Microbial Ecology Profile*	Stool	#2205
GI Effects Gut Pathogen Profile*	Stool	#2207
CDSA™ (Comprehensive Digestive Stool Analysis)	Stool	#2000
CDSA 2.0 without Parasitology	Stool	#2002

COLLECTION MATERIALS FOR SAMPLE

USE PEEL AND STICK LABEL | ORANGE-TOP C & S TUBE | PINK-TOP TUBE (10 % FORMALIN) | GREEN-TOP SAF TUBE | CLEAN TUBE | FECAL SWAB AND TUBE | COLLECTION DEVICE

- **CAUTION: Tubes contain poisonous liquid. KEEP OUT OF REACH OF CHILDREN.**
- Tubes are under pressure. Cover tube cap with a cloth and remove cap slowly.
- For eye contact, flush with water for 15 mins.
- For skin contact, wash with soap and water.
- For ingestion, contact poison control center immediately.

REQUIRED MATERIALS

- Disposable glove (vinyl)
- Peel and stick labels
- Black disposable bag
- Absorbent pads
- Test requisition form
- Biohazard bags
- Genova sample collection pack box
- FedEx® Clinical Lab Pak and Billable Stamp
- Health survey

IMPORTANT INFORMATION BEFORE YOU BEGIN THE COLLECTION

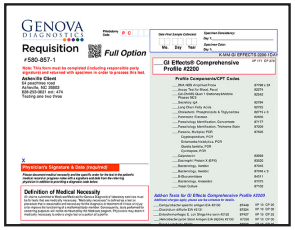
- Test not recommended for patients under 2 years of age.
- **Wait at least 4 Weeks** from colonoscopy or barium enema before starting the test.
- Please consult with your physician before stopping any medications. Certain medications and/or supplements may impact test results.
- **2 to 4 Weeks Before the Test:**
  - » Discontinue antibiotics, antiparasitics, antifungals, probiotic supplements (acidophilus, etc.).
  - » Discontinue proton pump inhibitors (PPIs), and bismuth **14 Days prior *if adding on the H. pylori test.***
- **2 Days Before the Test:**
  - » Discontinue aspirin and other NSAIDs (i.e. ibuprofen), rectal suppositories, enemas, activated charcoal, bismuth, betaine HCL, digestive enzymes, antacids, laxatives, mineral oil, castor oil, and/or bentonite clay.
- **DO NOT collect samples** when there is active bleeding from hemorrhoids or menstruation.
- Before collecting your specimen refer to the shipping instruction to determine what day you can ship. **Ship only Monday through Friday, and within 24 hours after final collection.**

* Not available in New York

If any items are missing or expired, or liquid is spilled, call Client Services at 800.522.4762 and press "1"

COLLECTION

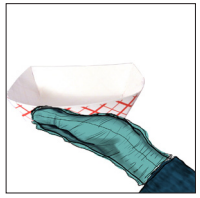
1. **Completely fill out** front and back of test requisition form using the **included form** or **online at www.gdx.net/register**. Failure to provide all information will result in delay of test processing.



2. Using the peel and stick labels provided **record** the **patient's date of birth** and **place** a label on each of the tubes and the test requisition form

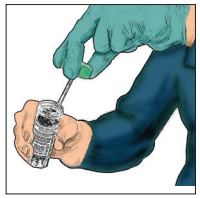
STOOL COLLECTION

3. **Put on** the glove.



4. **Collect** your stool sample using the enclosed collection container. **DO NOT contaminate** the sample with either urine or water from the toilet.

5. **GREEN-TOP TUBE: Remove** the cap. **Transfer** stool sample into the tube using the built-in scoop. **Collect** from different areas of the sample. **Mix** the sample with the liquid in the tube until it is as smooth as possible. **Make** sure that the liquid and sample do not exceed the FILL LINE. **DO NOT OVERFILL**. **Screw** the cap on tightly. **Shake** tube for 30 seconds.

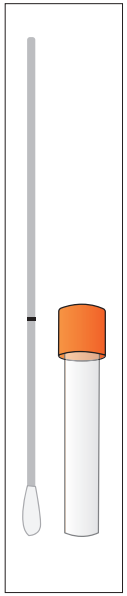


NOTE: If a worm is seen, **DO NOT place** it in tube with stool. Instead **place** it in **GREEN-TOP TUBE WITHOUT** scooping additional stool. Alternatively, a worm can be placed in a clean glass jar with rubbing alcohol, with no additional stool added to jar. Make note on requisition form that a worm was seen and write **WORM** on the tube. **Do not mix and mash** sample if there is a worm inside. **Do not shake tube** if there is a worm inside.

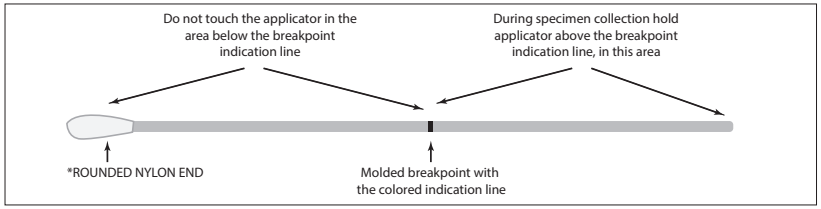
6. **Repeat STEPS 3 through 5** with **ORANGE-TOP TUBE, PINK-TOP TUBE, and the WHITE-TOP TUBE.**
Note: There is no liquid in the WHITE-TOP TUBE.

BLENDED SAMPLE & PRESERVATIVE CANNOT EXCEED THE RED FILL LINE

7. **Peel** open swab package, **remove** the tube, and place it upright. The swab should remain in the sleeve until you are ready to collect sample.



8. **Grasp** swab above the molded breakpoint which is the opposite end from the nylon applicator tip. (see diagram below)

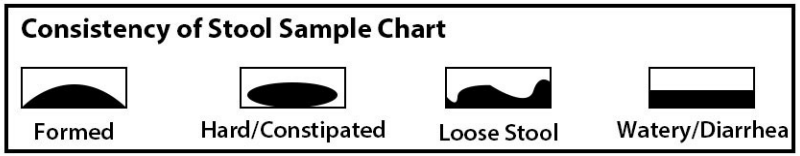


9. **Collect** sample by inserting the **ROUNDED NYLON END*** (see above) of the swab into the stool sample and **rotate** it. **Confirm** that the swab contains fecal material. If not, repeat.

10. **Open** the swab collection tube and insert the swab. **Mash** and **mix** the rounded nylon end of the swab with stool on it against the side of the tube.

11. **Break** the swab off at the break point. **Place** the screw cap on the tube and **tighten**. **Shake** the tube. Using the peel and stick label, **write** patient's date of birth on the label and apply to the swab tube.

12. **Record the date of collection, stool consistency** (refer to chart below), and **stool color** for **Day 3 Collection only**, on the Test Requisition Form in the sample consistency , sample color, and collection date areas.



13. **Dispose of remaining sample** into toilet and put collection container and glove in **black disposable bag.**

14. **Place** all tubes in the biohazard bag and refrigerate. **Refrigerate** until ready to ship. **DO NOT FREEZE.**