GENOVA DIAGNOSTICS
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 ◆	>500	> 200 mcg/g
2. Products of Protein Breakdown (Total) (Valerate, Isobutyrate, Isovalerate)	<DL	1.8-9.9 micromol/g

Gut Immunology

Analyte	Result	Reference Range
3. Eosinophil Protein X	0.3	<= 4.6 mcg/g
4. Calprotectin ◆	<16	<=50 mcg/g

Metabolic

Analyte	Result	Reference Range
5. Beneficial SCFAs (Total*)	46.6	>= 23.3 micromol/g
6. n-Butyrate	11.9	>= 3.6 micromol/g
7. pH	4.7	6.1-7.9

Secondary Bile Acids

9. Lithocholic acid (LCA)	2.06	0.65-5.21 mg/g
10. Deoxycholic acid (DCA)	2.96	0.67-6.76 mg/g
11. LCA / DCA Ratio	0.70	0.39-2.07

*Total values equal the sum of all measurable parts.

Digestion/Absorption
Pancreatic Elastase 1 is a marker of exocrine pancreatic function. Products of Protein Breakdown reflect undigested protein reaching the colon.

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, infection, 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 by colonoscopy or evaluation by a gastroenterologist.

Metabolic
GI metabolic biomarkers provide information regarding the health, function, and diversity of the commensal bacteria. They indicate how well the microbiome is performing the metabolic functions that are shared with the human host. Abnormalities may reflect underlying commensal bacterial imbalance.

Microbiology

Bacteriology

12. Beneficial Bacteria

Lactobacillus species		*NG
Escherichia coli		4+
Bifidobacterium		3+

13. Additional Bacteria

alpha haemolytic Streptococcus	NP	3+
Enterococcus faecalis	NP	4+
Citrobacter freundii	PP	4+
Klebsiella oxytoca	PP	4+

14. Mycology

*NG *NG

*NG
*NG
No Growth

NP
Non-Pathogen

PP
Potential Pathogen

P
Pathogen

Microbiology

Human microflora is influenced by environmental factors and the competitive ecosystem of the organisms in the GI tract.

Beneficial bacteria

Lactobacillus, Escherichia coli, and Bifidobacterium are known to exert positive local and systemic effects in the microbiome. Lower levels of these beneficial bacteria have been associated with disease.

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: 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.

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: Yeast present in culture may constitute part of the normal colonic flora. Pathogenic significance should be based upon clinical symptoms.

Additional Tests

	Result	Expected Result
19. Occult Blood ◆	Negative	Negative

Analyte	Result	Reference Range
Chymotrypsin	0.6	1.0-32.0 U/g

Fecal Fat Distribution

Triglycerides	1.0	0.3-2.8 mg/g
Cholesterol	1.5	0.4-4.8 mg/g
Long Chain Fatty Acids	3.3	1.2-29.1 mg/g
Phospholipids	0.6	0.2-6.9 mg/g
Fecal Fat (Total*)	6.4	3.2-38.6 mg/g

*Total values equal the sum of all measurable parts.

Metabolic Products

Acetate %	62.2	48.1-69.2 %
Propionate %	12.3	<= 29.3 %
n-Butyrate %	25.5	11.8-33.3 %

Occult blood
The occult blood test is a screening method for detecting fecal blood that may be indicative of gastrointestinal disease. The test is not specific for colorectal cancer or any other disease. Due diligence to assess the underlying cause is recommended.

Chymotrypsin
Chymotrypsin is a protein-digesting enzyme secreted by the exocrine portion of the pancreas. Decreased values may reflect pancreatic insufficiency, inadequate stomach acid for enzyme activation, or prolonged transit time. Since levels are influenced by transit time, an elevated level usually suggests rapid transit or excessive pancreatic enzyme supplementation.

Fecal Fats
The total fecal fats are calculated as the sum of fecal triglycerides, phospholipids, cholesterol, and long chain fatty acids (LCFAs). Elevated levels can be seen with high dietary fat intake. They may also reflect maldigestion from pancreatic or bile salt insufficiency, malabsorption, or both. Low fecal fat levels may indicate normal fat absorption or inadequate dietary fat intake.

Short Chain Fatty Acid Distribution
Beneficial (Total) short chain fatty acids (SCFAs) include acetate, propionate, and n-butyrate. They are the end products of anaerobic microbial fermentation of dietary fiber. Levels thus reflect the abundance of intestinal flora as well as the intake of dietary fiber and resistant starch. The SCFA Distribution reflects the relative proportions of the beneficial SCFAs providing an indirect measure of balance among the anaerobic organisms in the colon. These beneficial SCFAs help to maintain intestinal barrier function and regulate colonic absorption of water, provide fuel for colonocytes, and support commensal bacteria.

Parasitology

Microscopic O&P Results

Microscopic O&P is capable of detecting all described gastrointestinal parasites. The organisms listed in the box represent those commonly found in microscopic stool analysis. Should an organism be detected that is not included in the list below, it will be reported in the Additional Results section. For an extensive reference of all potentially detectable organisms, please visit www.gdx.net/product/gi-effects-comprehensive-stool-test

Genus/species	Result
Nematodes - roundworms	
Ancylostoma/Necator (Hookworm)	Not Detected
Ascaris lumbricoides	Not Detected
Capillaria philippinensis	Not Detected
Enterobius vermicularis	Not Detected
Strongyloides stercoralis	Not Detected
Trichuris trichiura	Not Detected
Cestodes - tapeworms	
Diphyllobothrium latum	Not Detected
Dipylidium caninum	Not Detected
Hymenolepis diminuta	Not Detected
Hymenolepis nana	Not Detected
Taenia spp.	Not Detected
Trematodes - flukes	
Clonorchis/Opisthorchis spp.	Not Detected
Fasciola spp./ *Fasciolopsis buski*	Not Detected
Heterophyes/Metagonimus	Not Detected
Paragonimus spp.	Not Detected
Schistosoma spp.	Not Detected
Protozoa	
Balantidium coli	Not Detected
Blastocystis spp.	Not Detected
Chilomastix mesnili	Not Detected
Cryptosporidium spp.	Not Detected
Cyclospora cayetanensis	Not Detected
Dientamoeba fragilis	**Many Detected**
Entamoeba coli	Not Detected
Entamoeba histolytica/dispar	Not Detected
Entamoeba hartmanii	Not Detected
Entamoeba polecki	Not Detected
Endolimax nana	Not Detected
Giardia	Not Detected
Iodamoeba buetschlii	Not Detected
Cystoisospora spp.	Not Detected
Trichomonads (e.g. *Pentatrichomonas*)	Not Detected
Additional Findings	
White Blood Cells	Not Detected
Charcot-Leyden Crystals	Not Detected
Other Infectious Findings	

Parasitology EIA Tests

Methodology: EIA

	Result	Expected Result
Cryptosporidium ◆	Negative	Negative
Giardia lamblia ◆	Negative	Negative
Entamoeba histoytica ◆	Negative	Negative

Macroscopic/Direct Exam for Parasites

Methodology: Macroscopic Evaluation

No human parasite detected in sample.

Bacterial Sensitivity

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

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Prescriptive Agents

CITROBACTER FREUNDII

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

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.

Bacterial Sensitivity

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

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Prescriptive Agents

KLEBSIELLA OXYTOCA

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

Prescriptive Agents:
The R (Resistant) category implies isolate is not inhibited by obtainable levels of pharmaceutical agent.
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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

GENOVA DIAGNOSTICS

Call **800.522.4762** or visit our website at **www.gdx.net**

GASTROINTESTINAL 3 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 with Parasitology	Stool	#2001
CDSA 2.0	Stool	#2003

COLLECTION MATERIALS FOR SAMPLE

- **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 gloves (3) (vinyl)
- Peel and stick labels
- Black disposable bags
- 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

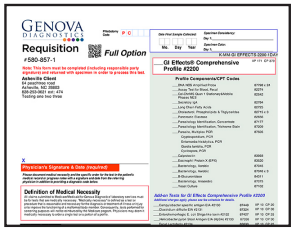
- Test not recommended for patients under 2 years of age.
- **Wait at least 4 Weeks** from colonoscopy or barium enema before starting the test.
- Please consult with your physician before stopping any medications. Certain medications and/or supplements may impact test results.
- **2 to 4 Weeks Before 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

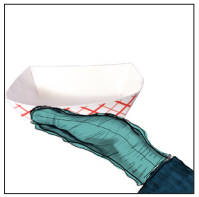
1. **Completely fill out** front and back of test requisition form using the **included form** or **online at www.gdx.net/register**. Failure to provide all information will result in delay of test processing.



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.

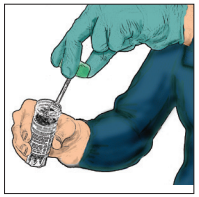
STOOL COLLECTION DAY ONE

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.

BLENDED SAMPLE & PRESERVATIVE CANNOT EXCEED THE RED FILL LINE

6. **Place** in biohazard bag and refrigerate. **Refrigerate** tube until ready to ship. **DO NOT FREEZE.**

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

STOOL COLLECTION DAY TWO

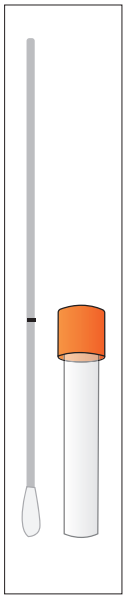
8. **Follow Steps 3 through 6** using the contents of the DAY 2 bag including the **GREEN-TOP TUBE**.

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

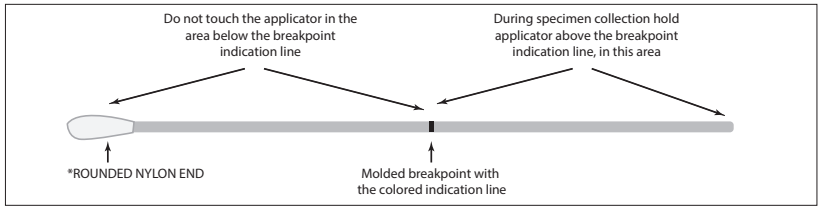
STOOL COLLECTION DAY THREE

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

11. **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.



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



13. **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.

14. **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.

15. **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.

16. **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.

Consistancy of Stool Sample Chart

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

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