

63 Zillicoa Street Asheville, NC 28801 © Genova Diagnostics



Patient: SAMPLE

PATIENT

DOB:

Sex:

MRN:

2001 CDSA/P (Comprehensive Digestive Stool Analysis/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 Absorption Digestion **Reference Range Reference Range** 4.2 1.0-32.0 U/g <DL 0.3-2.8 mg/g Triglycerides Chymotrypsin Long Chain Products of Protein 0.4 3.1 1.2-29.1 mg/g 1.8-9.9 micromol/g Fatty Acids Breakdown (Total) (Valerate, Isobutyrate, Isovalerate) Cholesterol 0.5 0.4-4.8 mg/g **Reference Range** Inside Outside Phospholipids <DL 0.2-6.9 mg/g None Meat Fibers None Fecal Fat 3.6 3.2-38.6 mg/g (Total*) Vegetable Fibers Rare None - Few * Total values equal the sum of all measurable parts. Metabolic Markers Microbiology **Reference Range** Beneficial Bacteriology 48.5 >= 23.3 micromol/g SCFAs (Total*) **Beneficial Bacteria** n-Butyrate Lactobacillus species 〔12.8 〕 >= 3.6 micromol/g Escherichia coli N Bifidobacterium 6.3 pН 6.1-7.9 Additional Bacteria Beta-999 Klebsiella pneumoniae PP 368-6,266 U/g Glucuronidase Enterobacter cloacae PP PP Klebsiella oxytoca * Total values equal the sum of all measurable parts. Enterococcus durans NP SCFA distribution Mycology Acetate % 63.3 48.1-69.2 % Candida species NP (1+) Propionate % (10.2 <= 29.3 % n-Butyrate % 26.4 11.8-33.3 % Immunology Inside Outside **Reference Range** Fecal Negative Negative Lactoferrin + Macroscopic Color Brown Brown *NG NP PP Р Negative Negative Mucus NG Negative Occult blood Negative No Growth Possible Pathogen Non-Pathogen Pathogen

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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	Not 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	
odamoeba 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		



Additional Tests (if indicated)

Parasitology EIA Tests			
Methodology: EIA	Result	Expected Result	
Cryptosporidium	Negative	Negative	
Giardia lamblia ◆	Negative	Negative	
Entamoeba histoytica ◆	Negative	Negative	

Bacterial Sensitivity

Patient: SAMPLE PATIENT DOB: Sex: MRN:



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Prescriptive Agents					
KLEBSIELLA PNEU	IMONIAE				
	R	I.	S-DD*	S	NI*
Ampicillin	R				
Amox./Clavulanic Acid				S	
Cephalothin				S	
Ciprofloxacin				S	
Tetracycline				S	
Trimethoprim/Sulfa				S	

Natural Agents

KLEBSIELLA PNEUMONIAE				
	Low Inhibition			High Inhibition
Berberine				
Oregano				
Plant Tannins				
Uva-Ursi				

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

Patient: SAMPLE PATIENT DOB: Sex: MRN:



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Prescriptive Agents					
ENTEROBACTER (CLOACAE				
Ampicillin	R		S-DD*	S	NI*
Amox./Clavulanic Acid	R				
Cephalothin	R				
Ciprofloxacin				S	
Tetracycline				S	
Trimethoprim/Sulfa				S	

Natural Agents

ENTEROBACTER CLOACAE				
	Low Inhibition		High Inhibition	
Berberine				
Oregano				
Plant Tannins				
Uva-Ursi				

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.

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Bacterial Sensitivity

Patient: SAMPLE PATIENT DOB: Sex: MRN:



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Prescriptive Agents					
KLEBSIELLA OXYT	OCA				
	R	I	S-DD*	S	NI*
Ampicillin	R				
Amox./Clavulanic Acid				S	
Cephalothin				S	
Ciprofloxacin				S	
Tetracycline				S	
Trimethoprim/Sulfa				S	

Natural Agents

KLEBSIELLA OXYTOCA				
	Low Inhibition		Higl	n Inhibition
Berberine				
Oregano				
Plant Tannins				
Uva-Ursi				

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.

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Yeast Sensitivity

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Azole Antifungals				
CANDIDA SPECIES				
Fluconazole Voriconazole		-DD* S NI* NI NI		
	Non-absorbed Antifu	ingals		
CANDIDA SPECIES	Low Inhibition	High Inhibition		
	Natural Antifunga	als		
CANDIDA SPECIES	Low Inhibition	High Inhibition		
Berberine				
Caprylic Acid				
Garlic Undecylenic Acid				

Prescriptive Agents:

Plant tannins Uva-Ursi

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.

Nystatin and Natural Agents:

Results for Nystatin are being reported with natural antifungals in this category in accordance with laboratory guidelines for reporting sensitivities. In this assay, inhibition is defined as the reduction level on organism growth as a direct result of inhibition by a natural 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.

Sensitivities performed by manual MIC assay.

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Administration.

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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



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#2200GI Effects Microbial Ecology Profile*Stool#2205GI Effects Gut Pathogen Profile*Stool#2207CDSA with ParasitologyStool#2001

COLLECTION MATERIALS FOR SAMPLE

CDSA 2.0



Stool

#2003

• 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

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.*

Biohazard bags

Health survey

· Genova sample collection pack box

FedEx[®] Clinical Lab Pak and Billable Stamp

- 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.

COLLECTION

- 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

- 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 Place in biohazard bag and refrigerate. Refrigerate tube until ready to ship. DO NOT FREEZE.
- Dispose of remaining sample into toilet and put collection container and glove in black disposable bag.

BLENDED SAMPLE & PRESERVATIVE **CANNOT EXCEED** THE RED FILL LINE

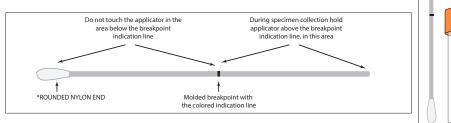
STOOL COLLECTION DAY TWO

- Follow Steps 3 through 6 using the contents of the DAY 2 bag including the **GREEN-TOP TUBE**.
- Dispose of remaining sample into toilet and put collection container and glove in black disposable bag.

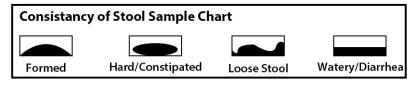
STOOL COLLECTION DAY THREE

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.

- 1 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)



- 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.
- 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.
- **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.



- **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.













