GENOVA DIAGNOSTICS

63 Zillicoa Street
Asheville, NC 28801

CDSA™

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

2000 CDSA (Comprehensive Digestive Stool Analysis) - 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

		Reference Range
Chymotrypsin	12.6	1.0-32.0 U/g
Products of Protein Breakdown (Total) (Valerate, Isobutyrate, Isovalerate)	<DL	1.8-9.9 micromol/g

	Inside	Outside	Reference Range
Meat Fibers		Rare	None
Vegetable Fibers	Few		None - Few

Absorption

		Reference Range
Triglycerides	<DL	0.3-2.8 mg/g
Long Chain Fatty Acids	2.7	1.2-29.1 mg/g
Cholesterol	2.1	0.4-4.8 mg/g
Phospholipids	<DL	0.2-6.9 mg/g
Fecal Fat (Total*)	4.8	3.2-38.6 mg/g

* Total values equal the sum of all measurable parts.

Metabolic Markers

		Reference Range
Beneficial SCFAs (Total*)	19.9	>= 23.3 micromol/g
n-Butyrate	4.3	>= 3.6 micromol/g
pH	5.2	6.1-7.9
Beta-Glucuronidase	<DL	368-6,266 U/g

* Total values equal the sum of all measurable parts.

SCFA distribution

Acetate %	53.0	48.1-69.2 %
Propionate %	25.6	<= 29.3 %
n-Butyrate %	21.6	11.8-33.3 %

Immunology

	Inside	Outside	Reference Range
Fecal Lactoferrin ◆	Negative		Negative

Macroscopic

	Inside	Outside	Reference Range
Color	Brown		Brown
Mucus	Negative		Negative
Occult blood ◆	Negative		Negative

Microbiology

Bacteriology

Beneficial Bacteria

Lactobacillus species		*NG
Escherichia coli		4+
Bifidobacterium		2+

Additional Bacteria

Klebsiella pneumoniae	PP	4+

Mycology

Candida kruseii	NP	1+
Candida tropicalis	NP	1+

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

Bacterial Sensitivity

Patient: **SAMPLE PATIENT**
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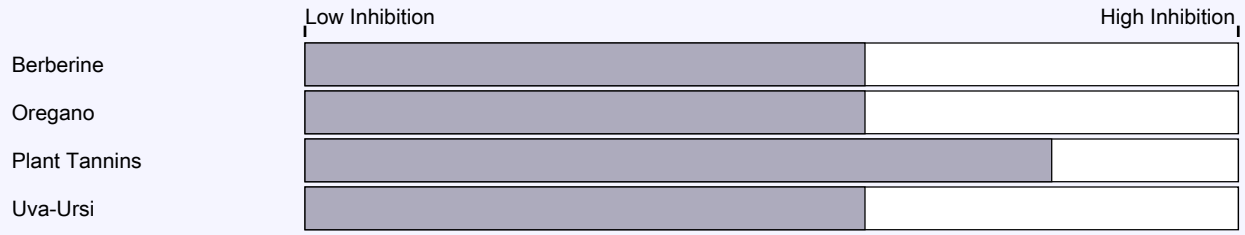
Prescriptive Agents

KLEBSIELLA PNEUMONIAE

	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



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.

Yeast Sensitivity

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

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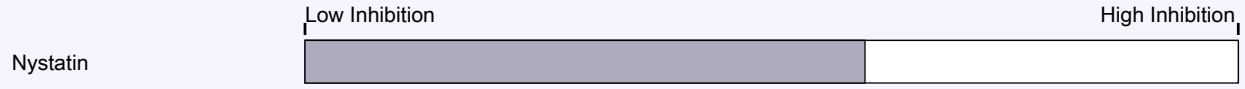
Azole Antifungals

CANDIDA KRUSEII

	R	I	S-DD*	S	NI*
Fluconazole	R				
Voriconazole				S	

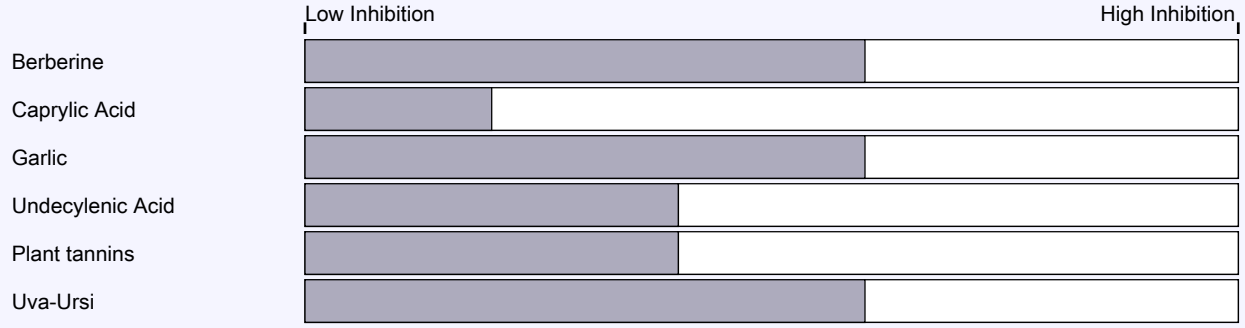
Non-absorbed Antifungals

CANDIDA KRUSEII



Natural Antifungals

CANDIDA KRUSEII



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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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Yeast Sensitivity

Patient: **SAMPLE PATIENT**
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Sex:
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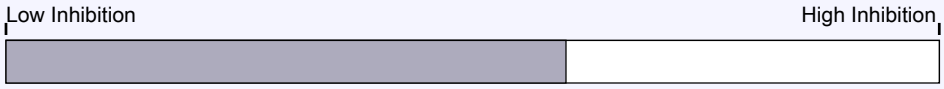
Azole Antifungals

CANDIDA TROPICALIS

	R	I	S-DD*	S	NI*
Fluconazole				S	
Voriconazole				S	

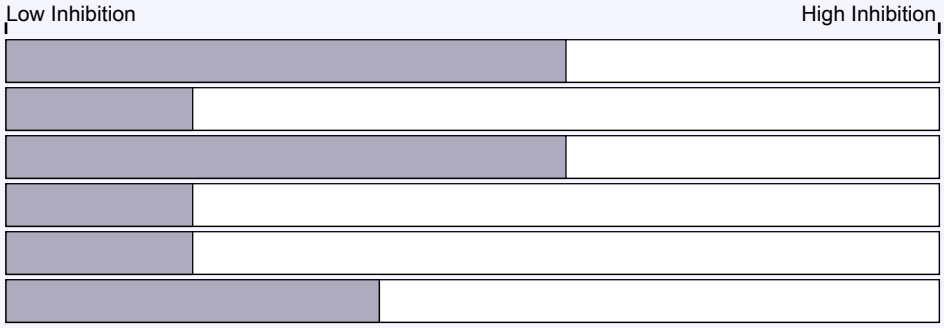
Non-absorbed Antifungals

CANDIDA TROPICALIS



Natural Antifungals

CANDIDA TROPICALIS



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Sensitivities performed by manual MIC assay.
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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

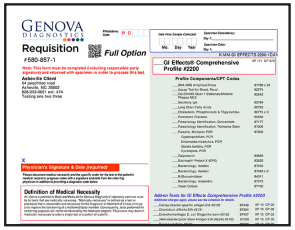
- Test not recommended for patients under 2 years of age.
- **Wait at least 4 Weeks** from colonoscopy or barium enema before starting the test.
- Please consult with your physician before stopping any medications. Certain medications and/or supplements may impact test results.
- **2 to 4 Weeks Before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

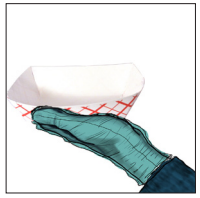
1. **Completely fill out** front and back of test requisition form using the **included form** or **online at www.gdx.net/register**. Failure to provide all information will result in delay of test processing.



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

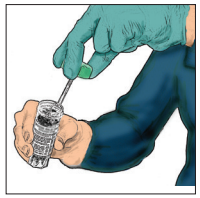
STOOL COLLECTION

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.

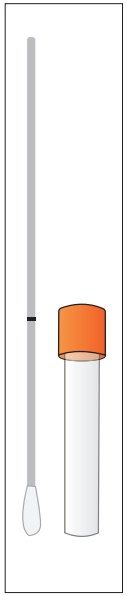


NOTE: If a worm is seen, **DO NOT place** it in tube with stool. Instead **place** it in **GREEN-TOP TUBE WITHOUT** scooping additional stool. Alternatively, a worm can be placed in a clean glass jar with rubbing alcohol, with no additional stool added to jar. Make note on requisition form that a worm 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.

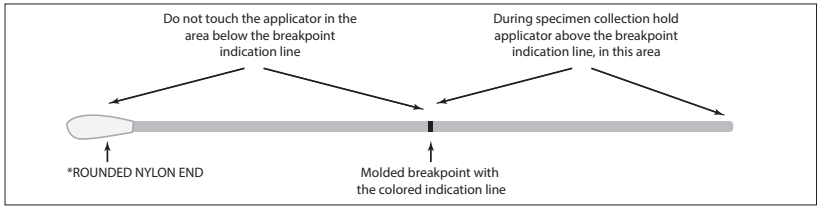
6. **Repeat STEPS 3 through 5** with **ORANGE-TOP TUBE, PINK-TOP TUBE, and the WHITE-TOP TUBE.**
Note: There is no liquid in the WHITE-TOP TUBE.

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)

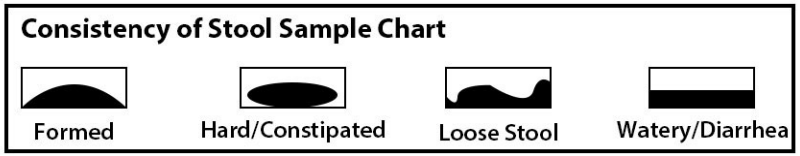


9. **Collect** sample by inserting the **ROUNDED NYLON END*** (see above) of the swab into the stool sample and **rotate** it. **Confirm** that the swab contains fecal material. If not, repeat.

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.**