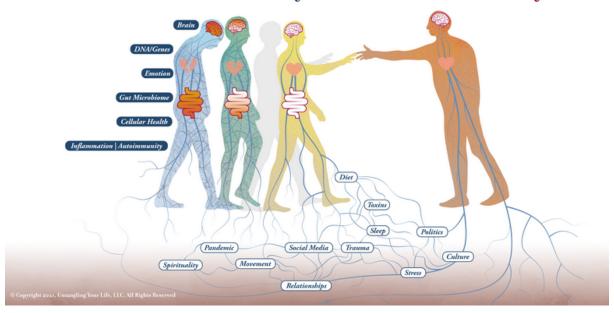


# Root Cause Psychiatry Program Guide

## Our Mental Health Ecosystem Root Cause Analysis





#### **TABLE OF CONTENTS**

Root Cause Psychiatry Program Outline

**Contact Information** 

**Care Coordination** 

**Patient Portal** 

**Overview of Required Core Diagnostic Tests** 

**Genomind Professional PGx Test** 

**Genova GI Effects Test** 

**Genova Metabolomix+ Test** 

Quest/LabCorp Laboratory Test

Overview of Optional Diagnostic Tests

**IntellxxDNA Tests** 

KBMO FIT 176

Genova SIBO Test (3 hour collection)

<u>Cunningham Panel via Moleculera Labs</u>

IncellKine via IncellDX

Vibrant America/ Vibrant Wellness

Tickborne 2.0

**Gut Zoomer** 

Wheat Zoomer

Home Collection Instructions for Required Diagnostic Tests

**Genomind Professional PGx** 

Genova GI Effects Test (3-Day Collection)

Genova Metabolomix Test

**Home Collection Instructions for Optional Tests** 

Genova SIBO Breath Test- 3 Hour

Vibrant America Gut Zoomer

Vibrant America Dried Bloodspot Collection



## Root Cause Psychiatry Program Outline

#### **Prerequisite Phase**

Initial Evaluations: \$1,235-1,735

- Complimentary 15 minute consult with Bruce Alan Kehr, MD or Rene Stokes, MD, MPH and Julie Wendt, MS, LN, CNS
- 60 minute initial evaluation with Dr. Kehr or Dr. Stokes
- 75 minute initial evaluation with Julie
- 45 minute initial evaluation with your Potomac Psychiatry treating psychiatrist if needed

#### **Discovery Phase (approximately 3-5 months)**

#### Step 1 - Create Initial Root Cause Analysis Treatment Plan - \$5,760

- Once core diagnostic test results are ready, Dr. Kehr and Julie initially meet without you for 90 minutes to review results and create the initial treatment plan.
- Dr. Kehr and Julie meet with you for 90 minutes to present the treatment plan.

#### Step 2- Initial Execution of Treatment Plan- \$3,465

- Total 120 minutes of appointments with Dr. Kehr or Dr. Stokes
  - Four 30-minute appointments
- Total 60 minutes of appointments with Julie
  - Two 30-minute appointments

#### Step 3 - Refine Treatment Plan - \$6,090

- Total 120 minutes of appointments with Dr. Kehr or Dr. Stokes
  - Four 30-minute appointments
- Total 60 minutes of appointments with Julie
  - Two 30-minute appointments
- 90 minute appointment with both Dr. Kehr/ Dr. Stokes and Julie at the end of the Discovery Phase
  - First 60 minutes: Dr. Kehr and Julie to revise treatment plan, review what approaches are working, and to determine which symptoms are resolving and which aren't
  - Last 30 minutes: You will join and be presented the revised treatment plan

#### **Maintenance Phase (approximately 9-12 months)**

#### Step 4- Maintenance of Treatment Plan- \$1,750 per month

- Total 60 minutes of appointments monthly with Dr. Kehr or Dr. Stokes
  - Two 30-minute appointments per month
- Total 60 minutes of appointments monthly with Julie Wendt
  - Two 30-minute appointments per month



- Repeat diagnostic testing
  - Repeat Genova NutrEval/Metabolomix and GI Effects tests (usually after 6 months)
  - Repeat Labcorp/Quest laboratory tests (after 6 months and 12 months if abnormal)

**Reports and Treatment Planning** - All initial and revised treatment plans created by Dr. Kehr or Dr. Stokes and Julie, throughout the course of the program will be available to the patient for downloading and printing through their Patient Portal.

<u>Weekly Team Meetings</u> - Throughout the program, Dr. Bruce Kehr, Dr. Rene Stokes, Julie Wendt, and the program coordinator will have a care coordination meeting every week to review any questions or concerns that you may have raised to enable a prompt, team-based response.

#### **Additional Services**

Additional Charges will be incurred for the following services:

- · Meetings with outside doctors who are involved in your care
- · Additional appointments with our clinicians outside these Program Steps

### **Contact Information**

Please contact Dana Schwartz for any administrative questions regarding scheduling appointments, billing or payment, diagnostic testing questions, etc.

- Email: info@potomacpsychiatry.com

- Phone number: 301-984-9791, option 5

Please contact Dr. Bruce Kehr/ Dr. Rene Stokes or Julie Wendt regarding clinical questions (not acute) related to your treatment plan, medications, supplements, etc.

- Leave them a voicemail by calling 301-984-9791, option 2, option 1, then enter the prompt for Dr. Bruce Kehr, Dr. Stokes, or Julie Wendt
- During the weekly meeting, they will collect all the questions from the week, review them in the meeting, and form a response.



Please contact your treating/prescribing psychiatrist (if different from Dr. Kehr) regarding any acute medical or medication issue.

- Leave him/her a voicemail by calling 301-984-9791, option 2, option 1, then enter the prompt for his/her name

## **Care Coordination**

If you would like your healthcare provider(s) outside of Potomac Psychiatry to coordinate your treatment with Dr. Bruce Kehr, Dr. Rene Stokes, Julie Wendt, and/or your Potomac Psychiatry treating doctor, please contact Dana Schwartz. We will send you an Authorization to Release Health Information form electronically via PandaDoc to complete. Then, we will contact your healthcare provider directly to schedule a complimentary 15-minute meeting to discuss your treatment and coordinate care.

#### **Patient Portal**

All of your Root Cause Psychiatry treatment plans, nutrition care plans, and diagnostic test results will be available for you to view and download on our patient portal.

When you first register as a patient, you will be sent an activation link from HF Alert NextGen. Please follow the link to create a patient portal account. If you have Google Chrome, use this browser to create the account, as our patient portal works the best on this browser. The link will expire after 3 days so please make sure that you create your account within 3 days of receiving it.

If your link expired or you are having difficulty logging into your account, please contact Emily Wang and she will send you another activation link or reset your password for you. If you already have an account and you forgot your password, please click "Forgot Password."

#### Instructions:

- 1. Log in here.
- 2. Click "Review Medical Record."
- 3. On the lefthand side, click the "Documents" tab then click "Patient Documents."
- 4. You will find the results there and you can click "view" to download them.



## Overview of Required Core Diagnostic Tests

The following tests provide your Root Cause Analysis team with a core biological baseline from which we can begin to build your desired mental health outcomes. Each provides critical information your team will need to move forward—and thus we require them of each of our Root Cause Psychiatry patients:

#### Genomind Professional PGx Test

- This test analyzes 24 genes to inform treatment for psychiatric conditions. The results will show which medications will be most effective for your genetic profile specifically. Please review the Genomind <a href="https://www.webpage">webpage</a> for more information.
- Cost:
  - For patients with commercial insurance: \$399 maximum out-of-pocket copay
  - For patients with Medicare or Tricare: \$0
  - Self-pay cost: \$599
- Process:
  - 1. We will order the test electronically in our system.
  - 2. You will receive an email from Genomind with a link to fill out an online order form with your address, insurance info, and payment info.
  - 3. Once you submit the order form, the test kit will be shipped directly to your house via FedEx in 3 days. Please follow the instructions on the test kit carefully to collect your cheek swab sample.
  - 4. When you are done, you can either drop the sample off at a FedEx location yourself or arrange for a FedEx pickup to your house. (Please note that it MUST be FedEx that delivers your sample.)
  - 5. If Genomind requires additional information from you once the lab receives your sample, they will contact you via phone call.
- Administration: Buccal swab
- Turnaround time for results: ~5 days

#### Genova GI Effects Test

- This test analyzes your digestive function, intestinal inflammation, and intestinal
  microbiome to manage your gastrointestinal health. Please review the Genova webpage
  for more information.
- Cost:



- For patients with commercial insurance: \$204 initial out-of-pocket payment with additional bill of up to \$221 from insurance. Potential total of \$425
- For patients with Medicare or Tricare: \$0
- o For patients with Medicaid and patients without insurance: \$424

#### Process:

- 1. Once we order the test electronically in our system, the test kit will be shipped directly to your house in a few business days to your shipping address. It will arrive in the same package with the other Genova test(s).
- 2. Once you receive the test kit, please register and pay for the kit online.
- 3. Please follow the instructions in the test kit very carefully to collect your **3-day** stool sample and ship the sample back to the lab. There are also detailed instructions and an instructional video in this Quick Start Guide.
- Administration: 3-day stool collection
- Turnaround time for results: ~17 days

#### Genova Metabolomix+ Test

- This test analyzes key nutritional biomarkers to assess your functional need for antioxidants, B-vitamins, minerals, digestive support, fatty acids, and amino acids. Please review the Genova webpage for more information.
- Cost:
  - For patients with commercial insurance: \$190 initial out-of-pocket payment with additional bill of up to \$200 from insurance. Potential total of \$390
  - For patients with Medicare or Tricare: \$0
  - o For patients with Medicaid and patients without insurance: \$419

#### Process:

- 1. Once we order the test electronically in our system, the test kit will be shipped directly to your house in a few business days to your shipping address. It will arrive in the same package with the other Genova test(s).
- 2. Once you receive the test kit, please register and pay for the kit online.
- 3. Please follow the instructions in the test kit very carefully to collect your urine sample and do a blood spot fingerstick. You may disregard the cheek swab collection. Then, ship the samples back to the lab. There are also detailed instructions and an instructional video in this Quick Start Guide.
- Administration: urine collection and bloodspot fingerstick
- Turnaround time for results: ~14 days



## Quest/LabCorp Laboratory Test

- These laboratory tests provide a variety of information to help your clinicians treat you such as whether a medication is working properly, rule out underlying conditions, give information on your body's metabolism, inflammation levels, electrolytes balance, etc.
- Cost: Depends on your insurance
- Process:
  - 1. We will order and send the tests electronically to Quest or LabCorp. The lab will already have your order in their system, but we will still email you a copy of the requisition form just in case.
  - 2. You can go to any Quest or LabCorp location (depending on which lab your clinician ordered the tests) to get your blood drawn. Please fast for 12 hours before the blood draw.
- Administration: Blood draw
- Turnaround time for results: ~10-14 days



## **Overview of Optional Diagnostic Tests**

#### IntellxxDNA Tests

- This test analyzes over 700 genes to guide the use of supplements and nutrition. Please review the <a href="Intellexedna">Intellexedna</a> webpage for more information.
- Cost:
  - Mental Wellness Panel: \$900
  - Mental Wellness + Brain Optimization Panels: \$1400
  - Mental Wellness + Brain Optimization + Medical Overview Panel: \$1700
- Process:
  - 1. We will order the test electronically in our system and pay for it using the credit card you provide.
  - 2. The test kit will be shipped directly to your shipping address in 5-7 days. Please follow the instructions we email you to activate your test kit, collect your cheek swab sample, and ship it back to the lab.
    - The instructions we email you will have your username and password to activate the barcode on your kit. Feel free to change your password by clicking the "Forgot Password?" button on patientdnadashboard.com login page.
- Administration: Buccal swab
- Turnaround time for results: 4-8 weeks

#### KBMO FIT 176

- This test analyzes your sensitivity to 176 different foods, coloring, and additives, identifying dietary sources of systemic and brain inflammation that cause chronic emotional distress. Please review the KBMO webpage for more information.
- Cost: \$375
- Process:
  - 1. Click <u>here</u> to fill out the order form on the KBMO website:
    - You may also call the lab directly at 617-933-8130 to place the order.
  - 2. Enter your physician reference #: C-1902607
  - 3. Fill out the rest of the online order form with your contact info, address, payment info, etc.
    - The test that you need is FIT 176. You may use your HSA card if you have one.



- 4. The test kit will be shipped directly to your house via USPS in about 1 week. Please follow the instructions to do the finger prick at home then ship your sample back to the lab.
- Administration: Blood spot fingerprick
- Turnaround time for results: 7-10 business days
- For a video of collection instructions, click here.

## Genova SIBO Test (3 hour collection)

- Purpose: This test captures exhaled hydrogen and methane gasses following patient ingestion of a lactulose solution to evaluate bacterial overgrowth of the small intestine.
- Administration route: breath sample
- Cost:
  - For patients with commercial insurance: \$85 initial out-of-pocket payment with additional bill of up to \$159 from insurance. Potential maximum total of \$244.
  - For patients with Medicare and Tricare: \$0
  - For patients with Medicaid and patients without insurance: \$195
- Process:
  - The order will be placed electronically in our system, then the test kit will be shipped directly to your house in a few business days.
  - Once you receive it, please register and pay for the kit online.
  - Please follow the instructions carefully to collect your breath samples (it requires some preparation in advance.) Then, you can ship the samples back to the lab yourself.
- Turnaround time for results: 7 days
- For more information on this test:
   <a href="https://www.gdx.net/product/bacterial-overgrowth-of-the-small-intestine-sibo-test">https://www.gdx.net/product/bacterial-overgrowth-of-the-small-intestine-sibo-test</a>

## Cunningham Panel via Moleculera Labs

- Purpose: This panel consists of a series of high complexity blood tests that assists clinicians in diagnosing infection-triggered autoimmune neuropsychiatric syndromes.
  - To learn more about the panel, please click here:
     https://www.moleculeralabs.com/cunningham-panel-pandas-pans-testing/



- Administration route: blood draw (inside elbow)
- Cost: The cost of this panel is a maximum of \$925. As you have commercial insurance, an upfront deposit of \$425 is required, then Moleculera Labs will submit a claim to your insurance for you. The potential cost of the panel would be \$425-\$925 depending on your insurance plan and the outcome of this claim.
  - To learn more about the ordering process, insurance, and payment information, please click here:

https://www.moleculeralabs.com/cunningham-panel-ordering-process-patients/

#### Process:

- The order is placed through our prescriber portal with Moleculera Labs, and you
  will receive an automated email from Moleculera Labs to provide payment and
  insurance information in their online portal.
- The test kit (containing specimen collection supplies) will be shipped directly to your house in 2-3 business days.
- Once the test kit arrives, please contact mobile phlebotomist, Brenda Simms, to go to your house and draw your blood for the test. She will ship the samples back to the lab for you.
  - Her cell phone # is 443-535-7737, office phone # is 443-850-9278, and email is bfs1061@gmail.com. Please try calling first. Her fee is \$150, which includes mileage, centrifuging, freezing, specimen handling, packaging, and shipping. However, there may be an extra mileage fee of up to \$50 depending on where you live.
  - If you live outside the MD/DC/VA area, please contact us for other mobile phlebotomy resources
- The results will be uploaded to our Moleculera prescriber portal when they are ready. Then, I will upload them to your patient portal for you to view and notify you.
- Turnaround time for results is about 2 weeks

#### IncellKine via IncellDX

- Purpose: IncellDx has developed a test for cytokine storm-related cytokines, which it said are elevated in COVID-19 patients who experience long-term symptoms.
- Cost: The entire lab test cost is \$360. It covers:
  - The blood draw kit you will be sent
  - The airfare to send the test to you and back to the lab
  - The running of the assay which produces 15 results



- The report for you and your MD
- It does not cover the actual blood draw
- Process: You will need to order this test yourself. To do so, go to the "For Patients" section of the website below:
  - <a href="https://www.covidlonghaulers.com/you">https://www.covidlonghaulers.com/you</a>
- After results are available, we recommend a consult together with your Potomac Psychiatry clinician and the IncelIDX team. Here is the information on that consultation:
- The entire video consult cost is \$199 It covers:
  - The 20-minute video consult please include your MD/DO on the call if possible by sharing the link
  - Full review of your data, your clinical symptoms currently and your clinical history
     this review includes you, your MD and our CCTC physician
  - o A therapeutic pathway is established
  - The report for you and your MD which describes what was discussed include the therapeutic pathway
  - Our CCTC physician will then communicate with your MD and answer any questions over time that is needed
- Please note: If you register today or over the weekend, you will hear from one of the labs by next Monday or Tuesday end of day. Look for one of two email domains:
   @innovativebioanalysis.com or @radiancediagnostics.com.

#### Vibrant America/ Vibrant Wellness

Tickborne 2.0

Purpose: A test for detection of tickborne disease and other tickborne diseases

Cost: **\$900** 

#### **Gut Zoomer**

Purpose: A unique opportunity to take a close look at the microbial world that exists in our gut, and how it affects our daily functions.



Cost: **\$478.80** 

#### Wheat Zoomer

Purpose: For the detection of wheat and gluten-related disorders, intestinal permeability, celiac disease, and gluten-related autoimmunity

Cost: **\$238.80** 

\*Insurance does not cover any portion of these tests.

#### Process:

- The test will be ordered. You should receive an email from the company within a day or two to provide payment so they can ship your kit to your house.
- The test involves a finger prick and/or a stool or urine sample, depending on the test. All materials you need, including instructions, will be shipped directly to you.
- We will send a PDF of all the information about the test after it is ordered.
- Results should be available within 7-10 business days after the test is completed.



## Home Collection Instructions for Required Diagnostic Tests

#### Genomind Professional PGx

#### **Included in Your Test Kit:**







#### **Step-by-Step Instructions:**

- 1. Check that you Provided your Insurance Information
  - If you did not send a front and back image of your insurance card prior to us sending you the test, you must include a copy when returning your sample. Not providing your insurance information will slow down the process.
- 2. Collect your Buccal (Cheek) Swab Sample
  - Read and follow the instructions for using the Buccal (Cheek) Swab that were provided on the Swab Envelope
- 3. Write the Required Information on the Swab Envelope
  - Write your full name, date of birth and email on the Barcode located on Swab
     Envelope. Please provide the date the sample was collected under the Barcode.
- 4. Prepare to Ship Back. Please ensure you have all of the below in your Swab Return Envelope before sending:
  - A clear front and back image of your insurance card (if you did not previously provide it in the online order form)
  - Sealed Swab Envelope with your Buccal (Cheek) Swab
  - Name, date of birth and email on Barcode on the Swab Envelope
  - Add the collection date on the Swab Envelope
  - Place the sealed Swab Envelope in the Return Envelope, seal, and place the FedEx Return Label on the outside



- Send the Return Swab Envelope
  - Find a FedEx drop off location at fedex.com/en-us/shipping/dropbox.html
  - ii. Call our customer service line at 877-895-8658, press 2 for a complimentary pick up

If you have questions, call Genomind's customer service line to assist with testing process: 877-895-8658

## Genova GI Effects Test (3-Day Collection)

#### **Included in Your Test Kit:**

- Disposable gloves (3) (vinyl)
- Peel and stick labels
- Black disposable bag
- Absorbent pads
- Test requisition form
- Biohazard bags
- FedEx® Clinical Lab Pak and Billable Stamp
- Health survey
- Genova sample collection pack box:



#### **DISCLAIMERS:**

- DO NOT collect sample 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.
- Test is NOT recommended for patients under 2 years of age.
- Certain medications, supplements, and/or foods may impact test results. Please note that reference ranges were established based on patients who were taking no



- medications or supplements. In some instances, it is unknown what potential impact a medication may have on test results.
- Please consult with your healthcare provider before stopping any prescription or over-the-counter medications or dietary supplements. We never recommend that patients discontinue medically necessary medication or supplements in order to complete testing.
  - There may be times when your healthcare provider prefers that you stay on a medication or dietary supplement during testing in order to evaluate its effectiveness.

#### **Test Prep Timeline:**

- 1. Register your test online at gdx.net/register.
- 2. Use a calendar to plan for sample collection.
  - a. Do not collect samples while experiencing active bleeding from hemorrhoids or menstruation.
  - b. It is okay if the samples are not collected on consecutive days. However, the samples must be shipped within 7 days of the first collection and within 24 hours of the final collection.
- 3. **4 weeks** before the test- Wait at least 4 weeks from colonoscopy or barium enema before beginning the test.
- 4. **2-4 weeks** before the test- If taking antibiotics, antiparasitics, antifungals, or probiotic supplements (acidophilus, etc.), please wait at least 14 days after your last dose before beginning the test. 28 days may be preferred after antibiotics have been used.
- 5. **2 days** before the test- Discontinue the following substances 2 days prior unless directed otherwise by your physician: aspirin and other NSAIDs (i.e. ibuprofen), rectal suppositories, enemas, activated charcoal, bismuth, betaine HCL, digestive enzymes, antacids, laxatives, mineral oil, castor oil, and bentonite clay

#### **3-Day Sample Collection Timeline:**

- 1. **Day 1** of the test- Follow collection instructions and place the sample in 1 green-top tube only. Refrigerate until ready to ship.
- 2. **Day 2** of the test- Follow collection instructions and place the sample in 1 green-top tube only. Refrigerate until ready to ship.
- 3. **Day 3** of the test- Follow collection instructions and place samples in each of the remaining green-top, orange-top, pink-top, and white-top tubes. Refrigerate until ready to ship.
- 4. Within 24 hours of final collection- Follow collection instructions and ship samples Monday thru Friday only.



#### **Sample Collection Instructions**

1. Completely fill out the front and back of the 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.

#### \* Click here for collection instructional video.

#### DAY 1

- 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:

a. Remove the cap and transfer stool sample into the tube using the built-in scoop.



- b. Collect from different areas of the sample. Mix the sample with the liquid in the tube until it is as smooth as possible.
- c. Make sure that the liquid preservative and sample mixture do not exceed the RED FILL LINE. DO NOT OVERFILL.





- d. Screw the cap on tightly.
- e. Shake tube for 30 seconds.
- f. NOTE: If a worm is seen, DO NOT place it in a 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 the jar. Make note on the 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 the tube if there is a worm inside.
- 6. Place in a biohazard bag and refrigerate. Refrigerate tube until ready to ship. DO NOT FREEZE.
- 7. Dispose of the remaining sample into the toilet and put the collection container and glove in black disposable bag.

#### DAY 2

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

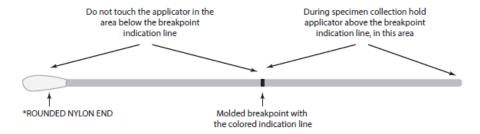
#### DAY 3

- 10. Repeat Steps 3 through 6 with GREEN-TOP TUBE, ORANGE-TOP TUBE, PINK-TOP TUBE, and the WHITE-TOP TUBE.
  - a. Note: There is no liquid in the WHITE-TOP TUBE.
- 11. Peel open fecal swab/tube 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 the 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.

#### Consistency of Stool Sample Chart



- 17. Dispose of the remaining sample into the toilet and put the 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.

#### Final Checklist (Before You Ship Out Sample):

- 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 (can be completed online or using included paper forms):
  - All sections of test requisition form completed
  - Health survey completed
     Payment information provided
- All tubes and associated forms are placed back in the original Genova sample collection pack box prior to shipping.



- 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: <a href="www.gdx.net/prc">www.gdx.net/prc</a> to complete health surveys, make payments, and access test results.

#### Genova Metabolomix Test

#### Included in Bag One (bloodspot collection materials):

- Alcohol prep pads (2)
- Adhesive bandage
- Absorbent pad
- Resealable plastic bag with desiccant/moisture absorbent pack
- Foam insulator box
- Freezer brick
- Biohazard bags with absorbent material
- Rubber band
- Test requisition form
- Peel and stick labels
- Vial sleeve
- FedEx® envelope
- Billable stamp
- Patient bloodspot collection materials:





Lancets (2)

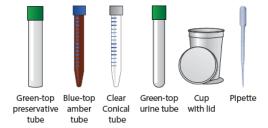
Bloodspot card

#### Included in **Bag Two** (urine collection materials):

- Alcohol prep pads (2)
- Adhesive bandage
- Absorbent pad
- Resealable plastic bag with desiccant/moisture absorbent pack
- Foam insulator box



- Freezer brick
- Biohazard bags with absorbent material
- Rubber band
- Test requisition form
- Peel and stick labels
- Vial sleeve
- FedEx® envelope
- Billable stamp
- At-home urine collection materials



<sup>\* &</sup>lt;u>Disregard</u> the cheek swab collection materials. You will not be doing this portion of the test.

#### **DISCLAIMERS:**

- DO NOT collect sample when there is active bleeding from hemorrhoids or menstruation.
- Plan to complete the urine collection <u>the day before</u> your bloodspot collection. You will need to fast overnight before your urine collection.
- 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.
- Abnormal kidney function or use of diuretics may influence test results.
  - Valproic acid, acetaminophen, and berberine HCL are direct assay interferants for certain analytes.
- Certain medications, supplements, and/or foods may impact test results. Please note
  that reference ranges were established based on patients who were taking no
  medications or supplements. In some instances, it is unknown what potential impact a
  medication may have on test results.
- Please consult with your healthcare provider before stopping any medications or supplements. We never recommend that patients discontinue medically necessary medication or supplements in order to complete testing.
  - There may be times when your healthcare provider prefers that you stay on a medication or dietary supplement during testing in order to evaluate its effectiveness.



#### **Test Prep and Sample Collection Timeline:**

- 1. Register your test online at gdx.net/register.
- 2. Use a calendar to plan for sample collection.
  - a. Plan to complete the urine collection the day before your bloodspot collection.
  - b. Do not collect samples while experiencing active bleeding from hemorrhoids or menstruation.
  - c. It is okay if the samples are not collected on consecutive days. However, the samples must be shipped within 7 days of the first collection and within 24 hours of the final collection.

#### 3. **24 hours** before urine collection:

- a. Eat your usual diet. Avoid over-consuming any single food or extreme diets.
- b. Freeze the provided freezer brick.
- c. Limit fluid intake to six 8-ounce glasses of fluid.

#### 4. **1 night** before urine collection:

- a. Fast overnight and leading up to urine collection. Water is okay.
- 5. **Day of** urine collection (and 24 hours before blood spot collection):
  - a. If you wake up during the night within 6 hours of your morning urination, collect urine and refrigerate. Upon waking up in the morning, collect your urine into the same container.
  - b. Transfer urine from the collection container into the provided tubes, following the kit instructions.
  - c. Place tubes in the freezer with the provided freezer brick until you complete your blood spot collection. Tubes must be frozen for a minimum of 2 hours.
  - d. Fast overnight and leading up to your bloodspot collection tomorrow. Water is okay.

#### 6. **Morning of** bloodspot collection:

a. Continue to fast before your blood spot collection. Water is okay.

#### 7. **Immediately after** blood spot collection:

a. Pack your frozen specimens and blood spot collection. Follow instructions to ship your completed collection pack Monday thru Friday only.

#### **Sample Collection Instructions**

1. Completely fill out the front and back of the test requisition form using the included form or online at www.gdx.net/register. Both methods require the paper form to be returned with the pack.





2. Fill out all the peel and stick labels with ONLY your date of birth (mm/dd/yyyy) and apply to all the tubes and requisition form. <u>Do not write on the tubes.</u> (There may be extra labels left over.)

#### \* Click here for urine collection instructional video.

#### **URINE COLLECTION**

- 3. If you wake up during the night, within 6 hours of your morning urination, collect that urine into the cup and refrigerate it. Upon waking in the morning, collect your urine into the same cup.
- 4. Use the pipette to transfer urine from the cup into the green-top preservative tube, blue-top amber tube, clear conical tube, and green-top urine tube until all are nearly full.



- a. Avoid contact with the skin and eyes. For eye contact, flush with water thoroughly for 15 minutes. For skin contact, wash thoroughly with soap and water. If ingested, contact poison control center immediately.
- 5. Recap the tubes tightly and shake.
- 6. Place a peel and stick label on all the tubes and the test requisition. Make sure your date of birth (mm/dd/yyyy) is filled out.
- 7. Place the tubes into the biohazard bag labeled BAG ONE and freeze for a minimum of 2 hours.





#### **BLOODSPOT COLLECTION**

- 8. Write first and last name and date of collection on the blood spot card.
  - a. Patients must fast overnight prior to collection the bloodspot.
- 9. Wash hands with warm water for a minimum of 20 seconds. Dry hands.
- 10. To improve circulation:



- a. Hold your hand lower than heart level and gently massage the entire length of the middle finger for 30 seconds.
- b. Firmly grasp the top knuckle of the middle finger for a few seconds to restrict return circulation.
- c. Hang your arm down and gently shake your fingers for a few seconds to increase blood pools in the finger.
- 11. Clean the tip of your finger with the alcohol pad.



- 12. Remove the clear cover from the lancet. One end of the lancet has a small hole in the center; this will be the end that you press firmly against your finger to engage the lancet.
- 13. Locate the appropriate site on the middle fingertip (see image).



14. Place the hole-end of the lancet firmly against your fingertip to depress the tip and release the lancet. The lancet will immediately retract safely after depression.

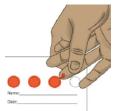




15. Using your thumb, gently massage the entire length of the pricked finger to form repeated blood drops. As each drop forms, touch the tip of the drop to a circle on the collection card. Do not smear. **Do NOT touch your fingertip to the card**!



16. Repeat until blood has soaked to the border of the circle on the collection card. Continue this procedure for all four circles.



- a. If you are unable to get enough blood from the first collection, repeat this procedure with a different finger.
- b. If necessary, use the absorbent pad to dry the site on your finger after your collection. Use the enclosed adhesive bandage as needed.
- 17. Allow absorbent collection card to air dry overnight, approximately 24 hours, before placing in the resealable plastic bag with desiccant/moisture absorbent pack for shipping. If the card is not completely dry, your sample may be unusable.

CONFIRM:	AVOID:
Blood should saturate through both sides of the card	Layering blood on a previously dried spot
Requisition is properly completed and signed	Smearing blood onto the card
Dried card is in zip lock bag with desiccant	Touching the surface of the card with fingers
ACCEPTABLE COLLECTION CARD EXAMPLE	UNACCEPTABLE COLLECTION CARD EXAMPLE:
	(a) (b) (b) (c) (c) (d)

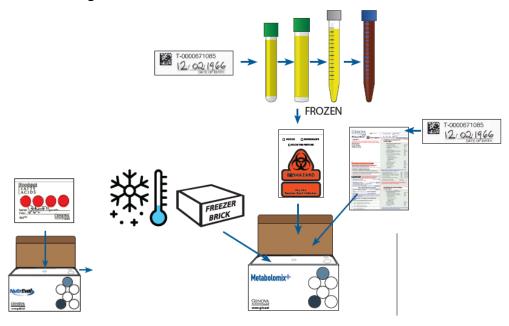


#### **Final Prep and Shipping**

- Place the biohazard bag with frozen urine tubes, frozen freezer brick, and absorbent material in the foam insulator box inside the outer collection box.
- Place the bloodspot card into the plastic bag with the desiccant pack inside the outer collection box.
- Disregard the envelope with cotton swabs.

#### Return Checklist (Before You Ship Out Sample):

- All tubes with peel and stick panels with patient's date of birth
- Frozen green-top urine tube
- Frozen green-top preservative tube
- Frozen blue-top amber tube
- Frozen clear conical tube
- Blood spot card
- Test requisition
- All frozen urines inside biohazard bag with absorbent pads
- All materials including urine tubes and frozen freezer brick inside Genova box



<sup>\*</sup> Specimen must be returned in the Genova Diagnostics box. Please refer to the shipping instruction insert found in your collection box.



## Home Collection Instructions for Optional Tests

#### Genova SIBO Breath Test- 3 Hour

Click HERE for a video walk-through of these steps.

- 1. Stir the Lactulose solution into 8 ounces of water. Set aside until after you have completed your first breath collection. Brush your teeth and tongue (including the back of your tongue) without using toothpaste or mouthwash. Rinse your mouth with water.
- 2. Take the first collection tube and apply the label to the tube. Be sure to record the time and date of collection to the label and the collection time on the Breath Collection Table (located on the paper requisition OR online as part of the test registration).
- 3. Pick up the mouthpiece/plastic bag in one hand and Tube 1 in your other hand. Breathing normally, inhale and hold for 5 seconds. Then close your mouth tightly around the mouthpiece and exhale normally into the plastic bag until it fills completely. Do not blow hard.
- 4. Continue to exhale normally with the bag expanded, and press the specimen tube into the side part of the mouthpiece. The needle will puncture the tube's self-sealing membrane allowing air to fill the tube. Do not inhale at any point.
- 5. Remove the tube within 2 seconds of puncturing. You may stop exhaling into the mouthpiece. Do not unscrew the cap on the collection tube. Place the tube in the bubblewrap bag.
- Immediately drink the Lactulose solution before continuing with the rest of the breath test. Drink the entire amount within 5 minutes. Do not drink water for 1 hour after you drink the solution.
- 7. Repeat steps 2-5 for each breath collection, using the remaining tubes and labels 2-6, in order and according to the collection schedule. Record times on Collection Schedule found on the Test Requisition. (see image)
- 8. Repeat steps 2-5 for each breath collection, using the remaining tubes and labels 7-8 in order and according to the collection schedule.



#### Vibrant America Gut Zoomer

- PLEASE FILL ONLY UP TO THE FILL LINE INDICATED ON THE COLLECTION TUBE. SAMPLE WILL BE REJECTED IF OVERFILLED.
- ENSURE THAT THE SAMPLES ARE LABELED APPROPRIATELY WITH NAME, DATE OF BIRTH AND DATE OF SAMPLE COLLECTION. SAMPLES WITH INSUFFICIENT LABELING WILL BE REJECTED.
- IMMEDIATE SHIPPING OF SAMPLES RECOMMENDED AFTER COLLECTION. DO NOT STORE SAMPLES IN DIRECT SUNLIGHT OR TEMPERATURES ABOVE 18\* C.
- WELL FORMED AND DIARRHEAL COMPONENTS OF STOOL ARE RECOMMENDED TO BE COLLECTED TO GUARANTEE RESULT OF ASSAYS. (DIARRHEAL COMPONENTS ARE RECOMMENDED FOR PATHOGEN ASSAYS AND WELL FORMED COMPONENTS ARE RECOMMENDED FOR PROTEOMIC ASSAYS SUCH AS PANCREATIC ELASTASE).

#### Step 1

Open the kit and spread out the contents.

#### The contents include:

- 1 sampling sheet
- 1 pair of disposable gloves
- · 1 MCC C & S Medium (orange top)
- 1 MCC Clean Vial (clear top)
- 2 blank identification labels
- 1 bubble mailer with return label
- · 1 small box

#### Step 2

Label all collection tubes appropriately with your name, date of birth and date & time of sample collection. Only the additional stickers provided need to be filled and stuck on the tube.

#### Step 3

Put on disposable gloves. Unfold the sampling sheet containing 2 flaps and orient as shown in the figure.



#### Step 4

Remove the protective covering from the tape and adhere the sampling sheet onto the toilet seat.

Note: The sampling sheet should not touch the surface of the water.

#### Step 5

Have a bowel movement.

Note: Make sure stool does not come in contact with the toilet water or urine. Slowly drain urine away from bowel movement before collecting a sample if necessary.

Please fill & label both tubes

#### Step 6

Collect stool sample well formed & diarrheal using the scoop provided in the respective tubes and add specimen upto the fill line. Both MCC C & S Medium (yellow top) and MCC Clean Vial(clear top) need to be filled.

Note: DO NOT dispose of the liquid inside the vials. Add specimen to the red fill line but do not overfill. Recap the vial and make sure that the container is properly sealed.

#### Step 7

Remove sampling sheet flaps from toilet. Flush both the sampling sheet and excess stool down the toilet.

Note: When using water saving toilets use a full flush. Repeat if necessary.

#### **Step 8** (\*required)

Place ALL sample containers into the biohazard bag with absorbent material and store in the refrigerator prior to shipment.

#### Step 9

Remove gloves and properly dispose of the material.

Wash hands to prevent contamination.



#### Step 10

Keep the biohazard bag inside the small box provided and place it into the bubble mailer along with all documents. Mail the package as soon as possible.

Note: SEND OUT VIA FEDEX and we must receive the sample within 5 days of collection. Ensure name and date of birth are mentioned on both tubes prior to shipment.

## Vibrant America Dried Bloodspot Collection

#### Materials in Your Kit:

- Blood specimen collection cards
- Safety Lancet
- Alcohol Pads
- Silica Gels
- Bandage
- Gauze Pad
- Biohazard Bags
- Return Bubble Mailer





#### Step 1:

Before you begin, make sure you will have at least 15 minutes of uninterrupted time. First, find a clean, open space to work on. Open the DBS collection kit and lay out all of your materials on the placemat (the last page) provided. Please wear appropriate PPE ( personal protective equipment) while collecting the specimen from the patient.

- \* You will be given as many Blood specimen collection cards as required by your lab order.
- \* All DBS cards need to be filled for testing. Failure to complete all cards will result in the test not being performed.

#### Step 2:

Write the name and Date of Birth on the card. Write the date and time on the blood specimen collection card.

#### Step 3:

Open the alcohol wipe.

#### Step 4:

Wash your hands with warm water (not hot), then dry with a clean towel.

#### Step 5:

Choose a finger to poke on your non-dominant hand.

- If you are right-handed, choose your left hand.
- If you are left-handed, choose your right hand.

#### Step 6:

Choose an area on the side of your finger to poke.

#### Step 7:

Pick up your lancet and twist the cap off.

#### Step 8:

Rub your finger from base to tip.



#### Step 9:

Put the lancet down and wipe the tip of your finger with the alcohol wipe.

#### **Step 10:**

With your palm facing up, press the lancet to your finger until you hear a click and feel a slight pinch.

#### **Step 11:**

Wipe the first drop of blood away with the gauze pad

#### **Step 12:**

Milk your finger from base to tip to produce more blood.

#### **Step 13:**

Allow blood drop to form. If you are not getting enough blood, try standing up and milking your finger below your waist.

#### Step 14:

Let the blood drop fall from your fingertip into the collection circle.

- DO NOT touch your finger to the card.
- Fill the circle as full as possible, but do not add a second drop of blood. If necessary, use the second lancet.

#### Step 15:

After filling in all of the collection card circles, use your gauze pad to wipe the blood, apply pressure and apply a bandage.

#### **Step 16:**

Please discard the bio waste, including the used lancet, alcohol pads, and gauze sponge, in an appropriate biohazard waste container.

#### Step 17:

Let your collection card sit for at least 2 hours to dry before sending it back to Vibrant.

- Keep the collection card in a cool, dry place away from sunlight.



- Do not add additional blood drops after blood spots have dried.
- Blood spots will darken as they dry.

#### **Step 18:**

After the blood spots have dried for at least 2 hours, fold the collection card, place it in the biohazard bag along with the humidity indicator and silica gel packs, and seal tightly.

#### **Step 19:**

Place the biohazard bag into the bubble mailer. Wash hands to prevent contamination. Please schedule Fedex pick up or take it to a local Fedex office to mail.