WHEN READY TO SHIP, ENSURE THE FOLLOWING:

Tubes:

- Tightly closed
- □ Marked with first and last name, date of birth, and date of collection.
- □ Sealed in biohazard bag with absorbent pad.
- Biohazard bag with tubes placed inside the flexfoil pack with the frozen Gel Freezer Pack
- □ All sections of **requisition form completed**.
- Dependence of the second secon
- □ All specimens in flexfoil pack with gel freezer pack placed back in original box.

SHIP THE SPECIMEN(S) TO THE LAB

Please refer to the shipping instruction insert found in your sample collection pack.

VISIT YOUR PATIENT RESOURCE CENTER AT WWW.GDX.NET/PRC

- Access test results
- Make payments
- Complete health surveys





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

GASTROINTESTINAL

PATIENT URINE COLLECTION INSTRUCTIONS FOR THE FOLLOWING PROFILE

Intestinal Permeability Assessment	Urine	#2305

COLLECTION MATERIALS FOR SPECIMEN



CAUTION: Tubes contain poisonous liquid. KEEP OUT OF REACH OF CHILDREN.
For eye contact, flush with water for 15 mins. For skin contact, wash with soap and water. For ingestion, contact poison control center immediately.

ADDITIONAL MATERIALS

- Gel Freezer Pack
- Flexfoil Pack
- Test requisition form
- Biohazard bag with side pocket with absorbent pad

- Specimen collection pack
- FedEx[®] Clinical Lab Pak and Billable Stamp

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

IMPORTANT PREP BEFORE PATIENT TAKES TEST

For full details and explanations refer to: www.gdx.net/tests/prep

- Tell your healthcare professional if you have an abnormally high glucose level; this will interfere with testing. We cannot perform this test on diabetics with >105mg/dl fasting urine glucose concentration. If you have had allergic reactions to foods (including sugar-free foods, beverages, candies, gum and mints), dietary supplements, dental products or medicines (prescription and over-the-counter) containing sugar alcohols like sorbitol or xylitol, you should NOT take this test. It is also NOT recommended for individuals who have had allergic reactions to lactulose or are on lactose-restricted diet.
- **Certain medications** such as aspirin, other anti-inflammatory drugs, antacids containing aluminum or magnesium hydroxide (eg, Maalox liquid, Equate, Milk of Magnesia, Rolaids, Mylanta) as well as drugs that contain sorbitol and/or mannitol may affect your test results.. Please let your healthcare professional know about any medications or supplements you are using before taking this test. It is recommended that you avoid the use of these medicines for at least 72 hours before taking this test.

THE NIGHT BEFORE THE TEST: Do not eat or drink

anything for at least eight hours before beginning this test.

DAY OF THE TEST: Do not eat or drink for two hours after taking the test drink. At two hours, drink a glass of water. Drink at least a cup of water every hour until you finish your test. You may eat and drink as usual two hours after taking the test drink; however, you MUST avoid certain foods or beverages, especially those containing fructose (fruit sugar), during the test. Please read all labels to double-check. These include:

- Fruits, fruit juices, jams, jellies, etc.
- Soft drinks and foods sweetened with high fructose corn syrup
- Any dairy products
- Dietetic chocolate
- Honey
- Mushrooms, beans (legumes including peanuts), celery
- Chewing gum

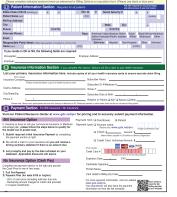
At least 4 hours prior to shipping: Gel Freezer Pack must be frozen a minimum of 4 hours before shipping.

- Completely **fill out** front and back of test requisition form. Failure to provide all information will result in delay of test processing. Write **patient's first and last name, date of birth, gender** and **date of collection** on the Test Requisition Form
- 2 After your overnight fast (of at least 8 hours), **collect** your first morning urine in the small plastic cup. (Note: If you wake up to urinate during the night within six hours before your rising time, **collect** your urine and refrigerate it; then add that refrigerated sample to the urine you collect when you rise for the day.)



3 Using the pipette, fill the white-top tube to 1cm below the top of the tube with the urine collected in Step 2. Screw the cap tightly on the tube and invert several times. Write your name, the time, and date of collection on the tube label. Place tube in Biohazard bag and refrigerate. Discard remaining urine and pipette. Rinse collection cup and let air-dry.





- Open the Lactulose/Mannitol drink mix. Fill bottle up to the fill line with water. Replace bottle lid and close bottle. Mix drink by shaking bottle vigorously.
- 5 Drink all the Lactulose/ Mannitol solution.
- 6 Note the time here: _____
- Collect all of your urine for six hours after taking the test drink. Use the small plastic cup to collect your urine and pour it into the large container. Keep refrigerated.
- 8 Five to six hours after drinking the test drink, collect a final urine sample and **pour** it into the large container. (*Note: Do not collect any urine after the 6 hour time frame. Doing so may compromise the test results.*)





- **9 Cap** the container securely. **Place** the container on a flat surface and read the amount of urine in the container.
- Write the total amount of urine in the container on the requisition form in the space labeled "Total Urine Volume." The analysis cannot be completed without this information.
- Make sure cap is on tight and shake large container vigorously at least 10 times to mix urine with sugars that settle to the bottom.



Using the other pipette, fill the purple-top tube to 1cm below the top of the tube with urine from the large collection container. Tightly screw cap on tube and invert several times. Write your name, the time, and date the specimen was collected on the tube label. Discard the pipette, the remaining urine, and the large container. Place tube in the biohazard bag and keep the tubes refrigerated until shipment.



Place refrigerated tubes in biohazard bag inside the flexfoil pack with frozen Gel Freezer Pack just prior to shipping.





Intestinal Permeability (Urine)

63 Zillicoa Street

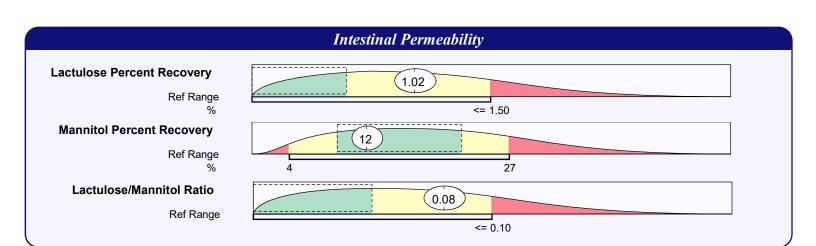
Asheville, NC 28801 © Genova Diagnostics



Patient: MALE TEST DOB: February 02, 1991 Sex: M MRN: 0001558065

Order Number: K8260251

Completed: April 26, 2017 Received: April 26, 2017 Collected: April 26, 2017 Test Office Test (PROD) Test MD, DO, ND 84 Peachtree Rd Asheville, NC 28803



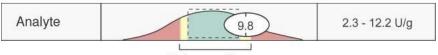
Commentary

This test has been developed and its performance characteristics determined by Genova Diagnostics, Inc. It has not been cleared or approved by the U.S. Food and Drug Administration.

Methodology: Enzymatic

The **Reference Range** is a statistical interval representing 95% or 2 Standard Deviations (2 S.D.) of the reference population.

One Standard Deviation (1 S.D.) is a statistical interval representing 68% of the reference population. Values between 1 and 2 S.D. are not necessarily abnormal. Clinical correlation is suggested. (See example below) Result within Ref Range, but outside 1-SD





Commentary is provided to the practitioner for educational purposes, and should not be interpreted as diagnostic or treatment recommendations. Diagnosis and treatment decisions are the responsibility of the practitioner.

Results are dependent on renal function. The mannitol determination has been corrected for concentration variability in the pre and post challenge urine collections by determining the creatinine concentrations and relating these to the mannitol determinations. In circumstances of significant renal insufficiency with low urinary creatinine concentrations in both the pre and post urine specimens, corrections for mannitol concentration variability using

Commentary

creatinine determinations cannot be done.

Lactulose and mannitol recoveries are both within the reference range, indicating normal intestinal permeability both through and between the cells.