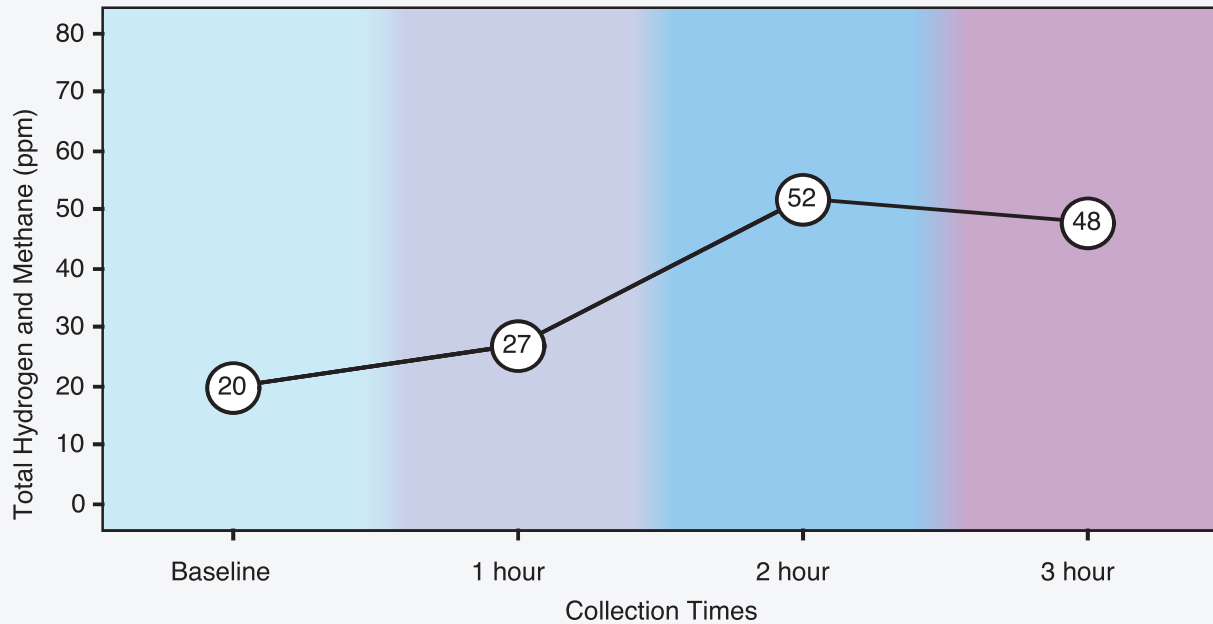


Patient: SAMPLE
PATIENT

Age:
Sex:
MRN:

SAMPLE REPORT

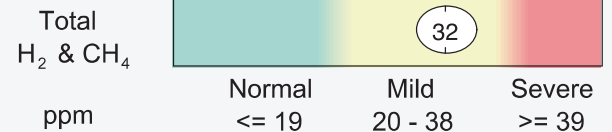
Total Hydrogen & Methane Breath Gases



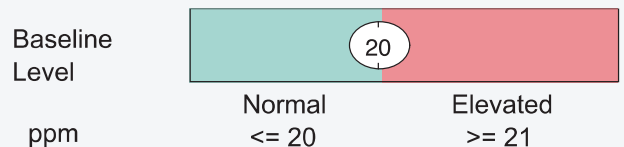
Hydrogen & Methane (ppm)

Hours	Base-line	1	2	3
Hydrogen (H ₂)	10	12	15	17
Methane (CH ₄)	10	15	37	31
Total	20	27	52	48

Change from Baseline



Baseline Evaluation



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

Commentary

Lactose Intolerance Lactose, or "milk sugar", is a disaccharide that is normally hydrolyzed by lactase, producing glucose and galactose. This enzyme, along with other disaccharidases, is secreted by the microvilli of the small intestine. Deficiency of the enzyme may result from damage to the microvilli, or may be inherited (more commonly in African, African-American, Asian, Hispanic, Native American, Mediterranean, and Jewish individuals). Whether acquired or inborn, lactase deficiency leads to incomplete digestion of lactose.

When lactase is deficient, the undigested lactose in the challenge drink will be fermented by colonic bacteria, producing hydrogen and/or methane gases, which are absorbed into the bloodstream and then released into the breath. Generally, the higher the level of breath gases, the greater the degree of lactose intolerance.

Your results: Your breath test for lactose intolerance showed a net increase in total breath gases of 20-38 ppm. This represents mild lactose maldigestion and malabsorption. Lactose malabsorption may feature intestinal cramping, gas and bloating, diarrhea, and eventually lead to bacterial overgrowth of the small intestine as bacteria feed on the undigested carbohydrate. Lactase deficiency may, in some cases, result from intestinal parasitic infection. Avoidance of lactose (see sources of lactose below) or supplementation with lactase preparations can help to minimize symptoms.

False positive results are possible (especially for elevated hydrogen) with incomplete avoidance of high-fiber foods, exposure to tobacco smoke or napping during collection.

Sources of lactose: Milk, cream, cheese, butter, many margarines, yogurt, artificial sweeteners containing lactose, baked goods made with milk, breadings on fried foods, breakfast and baby cereals containing milk solids, buttered or creamed foods, cake and pudding mixes, many frostings, milk chocolate, hot dogs, luncheon meats, sausage, hash, processed and canned meats, creamy salad dressings, nondairy creamers (except for Coffee Rich), weight reduction formulas, many prescription drugs, many types of vitamins, foods containing whey, casein, caseinate, and sodium caseinate.

Step 3:

Ship the specimen to the lab

Specimen must be returned in the Genova Diagnostics kit box for correct delivery to the lab. Please refer to the shipping instruction insert found in your kit box.



Lactose Intolerance Breath Test

IS-1050

Patient Instructions



Check Your Kit

- A - LacTest powder (25gm)
- B - 4 Vacuum-sealed collection tubes
- C - 4 Labels
- D - Mouthpiece/plastic bag
- E - 1 Bubblewrap Bag
- F - 1 Requisition (to be completed and signed)
- G - 1 Mailing envelope

- If any items are missing or expired, call Client Services at 800.522.4762 and press "1".
- Keep the kit box for shipping your specimen to the lab.



63 Zillicoa Street
Asheville, NC 28801
800.522.4762
Fax: 828.252.9303
www.gdx.net

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IS-1050.g-pi,b-124-b,010214

Step 1:

Important things to know and consider

- **Caution:** This test uses lactose as its testing agent, and is not recommend for individuals who are diabetics with a fasting urine glucose concentration >105mg/dl.
- **Caution:** Do not open, remove, or loosen tops of collection tubes—this will break the vacuum and make it impossible to perform your test. Do not stick your finger into the mouthpiece/plastic bag – there is a sharp needle inside.
- Keep collected specimens at room temperature.
- We do not suggest collecting during an acute infectious illness. Wait at least **4 weeks** from colonoscopy or barium enema before beginning the test. If you are using antibiotics, antifungals or Pepto-Bismol, wait at least **2 weeks** from your last dose before beginning the test.
- 1 week before the test: Avoid the use of laxatives, stool softeners and/or stool bulking agents (Ex-Lax, Colace, Metamucil®, Fibercon).
- **2 days before the test:** Stop eating high-fiber and lactose-containing foods for a full 36 hours before specimen collection. This usually means starting with the dinner meal two nights before doing the test. Refer to the enclosed diet instructions for a list of allowed / non-allowed foods and a sample diet. **The night before the test:** Eat a light dinner from the attached list of allowed foods, concentrating on the foods in the “A” list. **Stop eating and drinking** anything other than water at least **12 hours** before the specimen collection.
- **The day of the test:** Do not drink anything for the first hour of collection. After the first hour you may drink water only. Continue fasting until you complete the entire test. Do not chew gum or tobacco, smoke, eat breath mints or candy, use toothpaste, nap, or exercise vigorously for at least 30 minutes before or at any time during the test. Do not take the test in a location where you are exposed to tobacco smoke.

Schedule & Prepare for Collection

- It is important that you collect breath specimens during the specified time frame.
- **Number the labels 1-4** on the line “Sample ID”. Write the patient’s name, the healthcare provider’s name, and the date of collection on each label. Stir the LacTest powder 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.
- **Special Instructions for Children under 56 pounds**
Stir LacTest powder into 8 oz of warm water until dissolved.
Give child 1 ounce of dissolved LacTest for every 7 pounds of body weight.
- **Plan for Monday-Friday collection only:** Specimens must be received in the laboratory within 8 days of collection.
- **Refer to the shipping instruction insert for specimen shipment instructions.**
- **Complete the Requisition Form** with all patient and billing information. Be sure it is signed by the Patient/Responsible Party and the healthcare provider.

Breath Collection Schedule:

Use	Tube #	Time of collection
appropriate labels for each tube	1	before drink
	2	1 hour after drink
	3	2 hours after drink
	4	3 hours after drink

Step 2:

Breath Collection Steps

Not following these instructions may affect your test results.



- 1** Write the patient’s name and the time and date of collection on each collection tube and transfer tube. Select an empty tube and label number 1.



- 2** Pick up the mouthpiece/plastic bag in one hand and Tube 1 in your other hand.



- 3** 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 properly fill the tube.



- 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. Record the time under “Schedule”.



- 6** Drink the LacTest 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. Record the time you drink the solution here: _____.



- 7** Repeat steps 1-6 for each breath collection, using the remaining tubes and labels 2-4, in order and according to the collection schedule.

Consult your healthcare provider if you have any questions at any time during this test.