

Instructions for Use

*This test aids in the diagnosis of
Small Intestinal Bacterial Overgrowth (SIBO)
& Intestinal Methanogen Overgrowth (IMO)*

**SIBO & IMO
6 Tube
Lactulose
Hydrogen &
Methane Breath Test
Collection Kit**

When bacteria normally found in the large intestine become present in the small intestine, the digestive system may produce excessive hydrogen and/or methane gas, which can cause many gastrointestinal symptoms such as bloating, diarrhea, and/or constipation. This condition has historically been diagnosed as **Small Intestinal Bacterial Overgrowth (SIBO)** and either classified as hydrogen-related SIBO or methane-related SIBO. However, new guidelines outlining the distinction between each classification has led to the reclassification of methane-related SIBO as **Intestinal Methanogen Overgrowth (IMO)**, since methane in the gastrointestinal tract is produced by archaea, which is actually not a bacteria.

Access instructional guides and videos at www.commdx.com/patients



QUESTIONS?

1(888)-258-5966 | info@commdx.com

Mon-Fri: 9am - 5pm ET

Your Kit Includes:

- (1) Instructions for Use
- (1) Laboratory Requisition Form
- (1) Wrapped collection straw
- (1) Lactulose substrate packet*
- (6) Collection tubes in a vacuum-sealed pack
- (1) Sample label card with 6 labels
- (1) Prepaid return shipping label
- (2) Bubble wrap bags for packaging of samples

Indications and Usage: The intended use of this device is for the collection of human breath samples to aid in the diagnosis of Small Intestinal Bacterial Overgrowth (SIBO) or Intestinal Methanogen Overgrowth (IMO).

Contraindications: Patients with a known lactulose allergy should not take this test. Patients with a low galactose diet should discuss with their healthcare provider prior to taking this test. Although lactulose is a non-absorbable synthetic sugar, patients with diabetes should consult with their healthcare provider prior to taking the test due to the fasting period required and any other impact the test may have on blood sugar levels.

Precautions: Patients with food allergies should take precaution before taking this test as most substrates do not come with food allergy labeling. Contact immediate medical assistance if you have signs of a possible allergic reaction: hives; difficulty breathing; swelling of face, lips, tongue, and throat. Any serious incident that occurs in relation to this device shall be reported to the manufacturer and the competent authority of the member state in which the patient is established.

* Please note that Lactulose is a prescribed laxative and may effect sensitive patients. Possible side effects include nausea, bloating, diarrhea, etc. Please contact your physician if unexpected or prolonged symptoms occur.


Please consult with your healthcare provider if you have any health concerns, are on a specialty diet, and/or are on prescribed medications. Please do not discontinue taking any prescribed or over-the-counter (OTC) medications, including the ones listed in the Test Restrictions section, without consulting with your healthcare provider prior to taking this test.

Substrate manufacturer's information*

Store at 20°-25°C (68°-77°F). Avoid subfreezing temperatures. Under recommended storage conditions, a normal darkening of color may occur. Such darkening is characteristic of sugar solutions and does not affect therapeutic action. Prolonged exposure to temperatures above 86°F (30°C) or to direct light may cause extreme darkening and turbidity which may be pharmaceutically objectionable. If this condition develops, do not use. Prolonged exposure to freezing temperatures may cause change to a semi-solid, too viscous to pour. Viscosity will return to normal upon warming to room temperature.

* *The substrate is provided "as is" and CDI makes no representations or warranties whatsoever, express or implied, including without limitation any implied warranty of merchantability or fitness for a particular purpose. Patients should consult with their healthcare provider before ingesting this substrate.*

Important Reminders

- 1. Be sure to check the expiration date of your test kit** which is located on the outside of your kit next to the hourglass () image displayed as YEAR/MONTH/DAY. Do not take your test if the expiration date has already passed and reach out to CDI to receive a new test kit. You may still be responsible for the cost of the test when using an expired test kit.
- 2. Samples are valid for two [2] weeks from sample collection** and must be received at CDI's lab within this timeframe. Please ship your kit back to CDI immediately after completing the test.
- 3. Failure to follow these instructions can lead to an invalid result.** You may still be billed for the test if the test is invalid due to patient error; please review all guidance carefully and reach out on any questions you may have.
- 4. Please be sure to thoroughly read the billing & insurance policies** in these instructions as well as on your requisition form. Additional information can be found here on our website, www.commdx.com/insurance.
- 5. If you have multiple test kits,** please keep in mind that the full 24-hour preparation will need to be repeated between each test. We recommend spacing tests apart by at least 24 hours.

Symbol Definitions



Consult the
Instructions For Use



Contains sufficient
for 1 test

IVD

In vitro diagnostic
medical device



Use By Date



Manufacturer



Do not use if broken

LOT

Batch Code



Caution



Do not re-use

REF

Catalog Number

Billing & Insurance

Please read prior to taking your breath test:

- CDI will submit a claim on your behalf for all commercial insurance plans. Most commercial insurance plans do not consider CDI as an in-network provider, therefore most patients will be responsible for the **maximum out-of-pocket cost of \$249 per breath test**.
- If your insurance provider is not listed on our website as an in-network provider, your claim will be billed as an out-of-network claim. It is the patient's responsibility to contact their insurance provider to determine coverage. CPT codes and other information needed to determine coverage can be found on our website. *Please note, our lab is separate from your healthcare provider, so if your healthcare provider is in-network, it does not mean that CDI is in-network. Please refer to our website for a list of in-network insurance providers.*
- CDI accepts all **Medicare, Medicare Advantage, and Tricare** government managed health insurance plans.
- CDI **does not accept Medicaid**. If you are a Medicaid patient, you will be billed for the maximum out-of-pocket cost of \$249 per breath test.
- CDI offers convenient payment plans and financial hardship programs for those who qualify. Contact CDI's customer service team at customerservice@commdx.com or visit our website for more information.
- Insurance payments are applied to the registered cost of our test, \$599. All non-covered costs are the patient's responsibility. The maximum out-of-pocket cost will not exceed \$249 per test.

Visit www.commdx.com/insurance for important information including a list of our in-network providers and billing & insurance FAQs.

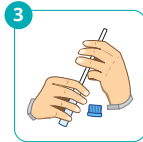
8 Simple Steps



1 Fill out the **Requisition Form**, sign and date. DO NOT fill out the Provider information section.



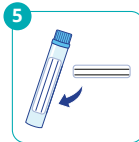
2 Mix the **substrate packet** into 8 ounces of room temperature water. DO NOT DRINK YET.



3 Collect **sample #1** - Insert straw halfway into tube, exhale normally for 5-8 seconds until condensation forms on sides of tube.



4 Screw cap back on securely - DO NOT OVERTIGHTEN. Cap should be screwed to the first point of resistance. If you see an inner dimple, loosen cap and screw again to ensure proper seal.



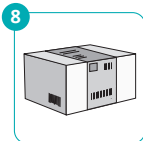
5 Label **sample #1** - Fill out the label completely and apply to the side of the tube.



6 Immediately drink the **entire substrate mixture** after collecting sample #1; then collect sample #2 exactly 20 minutes after the first sample.



7 Repeat **Steps 3-5 for all tubes**, waiting 20 minutes before sample #3, and another 20 minutes before sample #4. Before sample #5, wait only 15 minutes, and another 15 minutes before sample #6. Place labeled tubes in provided bubble wrap.



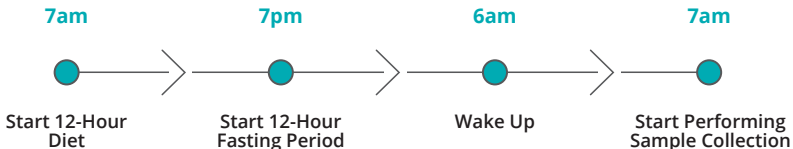
8 Ship back to CDI - Apply shipping label to box. Check label for carrier details. Samples must be received at lab within 2 weeks of collection. Shipping kit within 24 hours of taking the test recommended.



Time of Test:
SIBO & IMO 6 Tube Kit:
1 hour and 30 minutes

24 Hour Preparation Period

SUGGESTED SCHEDULE:



It may be convenient to begin the 24-hour preparation period in the morning so that you may follow the specific diet during the day, immediately followed by the fasting period during the night (which may include time spent sleeping).

TEST RESTRICTIONS*

- Please wait four weeks after the last dose of any ingested antibiotics or after having a colonoscopy.
- Discontinue the use of any laxatives and/or promotility drugs (i.e. anything that helps aid in the movement of your bowels) for 1 week prior to taking the test.
- Do not smoke or vape for at least 24 hours prior to the test, or any time during the test.
- Do not sleep or exercise for at least 1 hour prior to taking the test or at any time during the test.

* Consult with your healthcare provider prior to discontinuing any medications before taking this test.

12-HOUR DIET: PERMITTED FOODS ONLY

Visit CDI's website for a complete list of permitted foods, sample recipes, and suggested meal plans.



Olive Oil, Salt, & Pepper (*minimal seasonings*)



Plain White Bread



Baked or Broiled Seafood



White Rice



Plain Black Coffee, Plain Black or Green Tea (*no herbal teas*)



Eggs



Baked or Broiled Lean Beef & Lean Pork (*no deli meat*)



Boiled or Mashed Potatoes (no skin), Carrots & Turnips



Plain Tofu



Baked or Broiled Chicken & Turkey (*no deli meat*)

12-HOUR FASTING PERIOD

- Do not ingest anything other than water while fasting or during the test.
- You may take necessary prescribed medications cleared by your physician
- Do not take any vitamins or supplements.
- You may brush your teeth as you normally would.
- You must be awake for at least 1 hour prior to starting the test.

We encourage you to reach out to our dedicated customer service team with any questions during normal business hours (Mon-Fri: 9am - 5pm ET).



The Leader In Hydrogen and Methane Breath Testing®



Commonwealth Diagnostics International, Inc.

4 Technology Way, Salem, MA 01970

commdx.com | info@commdx.com

Phone 1-(888)-258-5966 | Fax 1-(888)-258-5973



IVD **REF**

USA-HBT-6-S-I

DO NOT USE IF PACKAGE IS DAMAGED