

7 SIMPLE STEPS

Hydrogen & Methane Breath Test for SIBO & IMO

This document is only a summary of the Instructions for Use that are included in your test kit. Be sure to read all instructions prior to taking your test.

Time of Test:

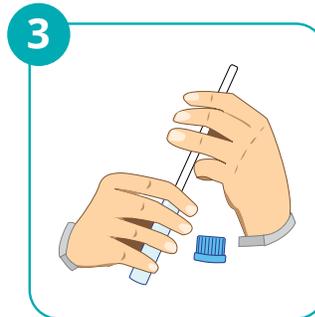
SIBO & IMO 10 Tube Kit
2 hours and 15 minutes



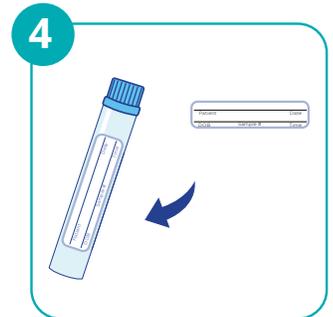
1
Fill out the Requisition Form, sign and date. DO NOT fill out the Provider information section.



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



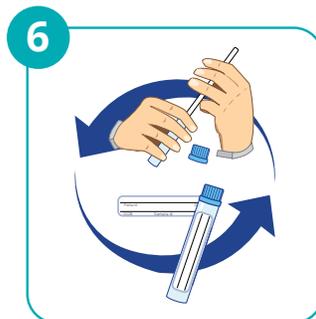
3
Collect sample #1 - Insert straw halfway into tube and exhale normally for 5 seconds. Screw cap back on securely. Do not over-tighten.



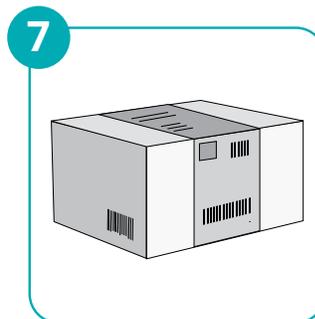
4
Label sample #1 - Fill out the label completely and apply to the side of the tube.



5
Drink the substrate mixture immediately following the collection of sample #1 and wait 15 minutes before collecting sample #2.



6
Repeat Step 3 and 4 for all tubes every 15 minutes until all tubes are used. Place labeled tubes in provided bubble wrap.



7
Ship back to CDI - Apply the provided shipping label to the box, and ship. Samples must be received at our lab within 2 weeks of collection. We recommend shipping your kit within 24 hours of taking the test.

QUESTIONS?

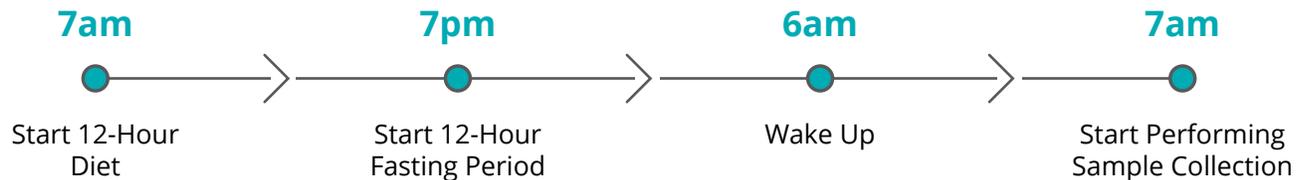
Phone: 1(888)-258-5966
info@commdx.com

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MM-079 Rev A

24-HOUR PREPARATION PERIOD

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).

Suggested Schedule:



TEST RESTRICTIONS

- Discontinue the use of any antibiotics for 4 weeks prior to taking the test.
- Discontinue the use of any laxatives and/or promotility drugs 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.

12-HOUR DIET *(only the foods listed below are permitted during the diet)*

 Olive Oil, Salt, & Pepper (Minimal)	 Eggs	 White Rice	 Chicken & Turkey	 Lean Beef & Lean Pork	 Seafood	 Plain Coffee, Tea or Water
Baked, Boiled, Broiled, Grilled, or Pan Seared only						

12-HOUR FASTING PERIOD

Please do not ingest anything other than water while fasting or during the test. You may brush your teeth as you normally would. Please note that you must be awake for at least 1 hour prior to starting your breath test. Prior to taking your test, we encourage you to reach out to our dedicated customer service team with any questions during normal business hours at **888-258-5966** or **customerservice@commdx.com**.

SIBO 10 Tube (Lactulose or Glucose)

Hydrogen and Methane Breath Test Collection Kit

Instructions for Use

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

When bacteria normally found in the large intestine become present in the small intestine, a condition called Small Intestinal Bacterial Overgrowth may occur. These bacteria feed on undigested food and produce hydrogen and/or methane gas which can cause many gastrointestinal symptoms such as bloating, diarrhea, and/or constipation.

Watch the SIBO instructional video at www.commdx.com

Any Questions? Phone:

(888)-258-5966

info@commdx.com

CDI[®]
Commonwealth
Diagnostics
International
INC.

SIBO 10 Tube Lactulose Kit

Your Kit Includes:

- (1) Instructions for Use
- (1) Laboratory Requisition Form
- (1) Wrapped collection straw
- (1) Lactulose substrate packet*
- (10) Collection tubes in a vacuum-sealed pack
- (1) Sample label card with 10 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).

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. Patients with diabetes should not use this test due to the amount of absorbable sugar and fasting required. Patients should discuss with their healthcare provider prior to ingesting the substrate.

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, or throat.

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 between 59°F-86°F. Store according to label and/or product insert information. Store away from oxidizing agents and acids. 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 86F (30C) or to direct light may cause extreme darkening and turbidity which may be pharmacologically 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.

SIBO 10 Tube Glucose Kit

Your Kit Includes:

- (1) Instructions for Use
- (1) Laboratory Requisition Form
- (1) Wrapped collection straw
- (1) Glucose substrate packet
- (10) Collection tubes in a vacuum-sealed pack
- (1) Sample label card with 10 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).

Contraindications: Patients with a known glucose allergy should not take this test. Patients with diabetes should not use this test due to the amount of absorbable sugar and fasting required. Patients should discuss with their healthcare provider prior to ingesting the substrate.

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, or throat.

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.

Patients should consult with their healthcare provider prior to taking this test

It is okay to drink water while fasting and during the 2-hour and 15 minute testing period.

If you are taking more than one breath test, you must perform the preparation prior to each test.



1. TEST RESTRICTIONS

- Discontinue the use of any antibiotics for 4 weeks prior to taking the test.
 - Discontinue the use of any laxatives and/or promotility drugs 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.
-

2. 24-HOUR PRERARATION PERIOD

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).

2A. 12-HOUR DIET

Only the foods listed below are permitted during the diet.



- Baked or Broiled: chicken, turkey, lean beef, lean pork, or seafood
- Eggs
- White rice
- Water, plain coffee, or tea
- Minimal fats and seasoning (i.e. salt, pepper, cooking oil)

2B. 12-HOUR FASTING PERIOD

Please do not ingest anything other than water while fasting or during the test. You may brush your teeth as you normally would. Please note that you must be awake for at least 1 hour prior to starting your breath test.

Performing Sample Collection

Carefully open the substrate and mix the substrate with 8oz of room temperature water. **DO NOT DRINK YET**

START

Collect Sample #1

Drink the substrate immediately after you collect sample #1. Please drink quickly to make sure your next sample is collected within 15 minutes of your first sample

Wait 15 minutes

Collect Sample #2

Wait 15 minutes

Collect Sample #3

Wait 15 minutes

Collect Sample #4

Collect the remaining samples every 15 minutes until all 10 tubes are used.

FINISH



Once collected, your breath samples are only valid for 2 weeks so please return your completed samples back as soon as possible.

How You Collect a Breath Sample

1. Carefully open the sealed pack of collection tubes using a pair of scissors.

2. Unscrew the blue cap from a collection tube.

3. Unwrap the collection straw and insert the straw about halfway into the tube.

4. Inhale normally (do not inhale deeply) and then exhale normally through the straw for 5 seconds. You may see condensation on the inside of the tube indicating the presence of your breath.

5. Remove the straw and immediately screw the blue cap back on the top of the tube securely *but do not over-tighten*. The blue cap has a rubber piece which is for laboratory extracting purposes only; it is not for patient use.

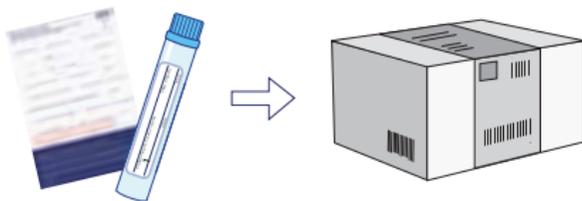
6. Complete and apply the included sample labels with your full name, date of birth, and the date and time the sample was collected.

7. Fully complete the Laboratory Requisition Form by filling in the patient information as well as the insurance/credit card information. **Please note if your kit was directly shipped to you, CDI has your provider's signature and information on file and it does not need to be included on the Laboratory Requisition Form.**



After completing your test, place all the labeled collection tubes into the provided bubble bags. Place the filled bubble bags and your completed Laboratory Requisition Form into the kit box, then seal the kit box with the prepaid return shipping label.

You can either take your kit to the nearest drop box or arrange to have your kit picked up by the carrier on the return shipping label.



If there are any issues with your kit, or any of its components, contact CDI with your kit's unique number for assistance. The number is printed on the side of the kit box next to the "SN" symbol.

PAYMENT GUIDELINES: Prior to returning your test kit, please review the test payment guidelines that are included on the Laboratory Requisition Form. For a list of in-network insurance carriers visit www.commdx.com/insurance.



Commonwealth Diagnostics International, Inc.
39 Norman Street, Salem, MA 01970
(888) 258-5966
MM-078 Rev A
12/16/2020



IVD

DO NOT USE IF PACKAGE IS DAMAGED OR EXPIRED.