

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, and 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*

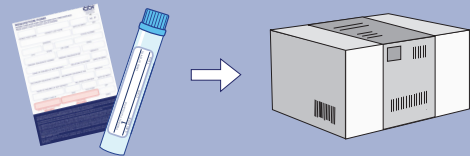
Store between 59°F-86°F. Store according to label and/or product insert information. Store away from oxidizing agents and acids. Under recommended storage conditions, a normal darkening of color may occur. Such darkening is characteristic of sugar solutions and does not affect therapeutic action. Prolonged 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.

How to Return Your Samples

After completing your test, place all the labeled collection tubes into the provided bubble bags. Place the filled bubble bags and your completed 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.



Commonwealth Diagnostics International, Inc.
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LA-013 Rev G
02/11/2018



DO NOT USE IF PACKAGE IS DAMAGED.



SIBO 10 Tube Lactulose Hydrogen and Methane Breath Test Collection Kit

Instructions for Use

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

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



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. 12-HOUR DIET

Only the foods listed below are permitted during the diet.

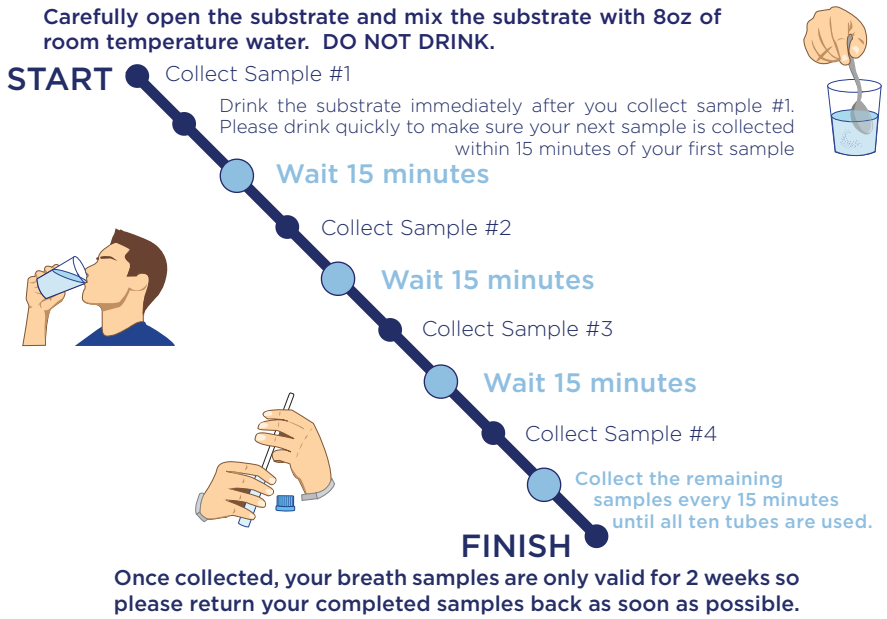


- Baked or Broiled: chicken, turkey, lean beef, lean pork, or seafood
- Eggs
- White rice
- Plain coffee or tea
- Minimal fats and seasoning (i.e. salt, pepper, cooking oil)

3. 12-HOUR FASTING 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). 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



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 will 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. 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 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.

