

## 1. COLLECT BASELINE SAMPLE

After finishing your test preparation, but before drinking any testing solution, collect a baseline (control) sample (Sample #1).

- Hold the EasySampler device with one hand and an unused collection vial in the other.
- Take a normal breath in, then hold it for three (3) seconds.
- Exhale into the mouthpiece and continue to keep the bag inflated.
- While still exhaling, fully insert the collection vial into the needle holder on the EasySampler.
- After two (2) seconds, remove the collection vial, stop exhaling, and remove your mouth from the EasySampler.
- Fill out one vial label and affix it to the collection vial.

## 2. PREPARE & INGEST LACTOSE SOLUTION

After collecting your baseline sample, prepare the test solution as follows:

- Mix the provided lactose substrate into 8 oz (236 ml) of water.
- Drink the entire 8 oz (236ml) solution within five (5) minutes.
- After drinking the entire solution, set a timer for 60 minutes.

## 3. COLLECT REMAINING SAMPLES

After 60 minutes have passed since you finished drinking the lactose solution, you are ready to collect Sample #2. Follow steps 1-6 outlined previously to collect and label Sample #2. Once you have finished collecting and labeling Sample #2, set your timer for another 60 minutes. Repeat the sample collection process using a new vial, continuing this process at 60-minute intervals until all samples are collected.

Sample	Collection Time
#1	Baseline (no drink)
#2	60 min. after drink
#3-4	Continue to collect one (1) sample every 60 min until remaining samples are collected.

## 4. PACK & RETURN

Insert four (4) vials into the bubble bag. Peel the liner off the bubble bag and fold over to seal the bubble bag pouch. Place the bubble bag, any paperwork, and the EasySampler back into the kit container, seal the kit and return to the laboratory for analysis immediately. Return the kit promptly as samples remain viable up to 14 days after collection.

\* The substrate is provided "as is" and QuinTron 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.



QuinTron Instrument Company, Inc.  
2855 South James Drive  
New Berlin, WI 53151 USA



Emergo Europe  
Westervoortsedijk 60  
6827 AT Arnhem  
The Netherlands  
EasySampler © - US Patent # 5467776, 1869434

Emergo Australia  
201 Sussex Street  
Darling Park, Tower II,  
Level 20  
Sydney, NSW 2000  
Australia

Japan-MAH  
Star Medical, Inc.  
5F, Taiyo Bldg., 5-14-12,  
Nishi-Nippori  
Arakawa-ku, 116-0013  
Japan



## INSTRUCTIONS FOR USE

Please read all directions carefully and familiarize yourself with the test procedure before proceeding. This test takes about 3 hours to complete. Proper sample collection is important for accurate test results. For a demonstration on sample collection, visit [www.BreathTests.com](http://www.BreathTests.com).

**Indications and Usage:** The intended use of the patented EasySampler® collection device is to collect and store human breath specimens from individuals that weigh 50 lb (23kg) or greater for further analysis using QuinTron breath analyzers. The purpose is to aid medical professionals in diagnosing lactose malabsorption.

**Contraindications:** Individuals with a known lactose allergy should avoid taking this test. Those following a low galactose diet should consult their healthcare provider before proceeding with this test. Individuals with diabetes should consult their healthcare provider beforehand due to the amount of absorbable sugar and fasting involved.

**Precautions:** Individuals with food allergies should exercise caution before taking this test, as most substrates do not come with food allergy labeling. If you experience signs of a possible allergic reaction, such as hives, difficulty breathing, or swelling of the face, lips, tongue, or throat, seek immediate medical assistance. Any serious incidents related to this device should be reported to both the manufacturer and the competent authority of the member state in which the individual is established. Please note that pregnant women should consult their healthcare provider prior to undergoing this test, although lactose is generally considered safe for use during pregnancy, there may be specific considerations for this test to be aware of such as fasting and discomfort.

## KIT CONTENTS

(1) Instructions for use

(1) EasySampler® breath collection device

*(Note: There is a small hole in the bag attached to the mouthpiece - this is normal. Do not tamper with or insert your finger into the EasySampler, it contains a needle which is covered by a rubber sheath.)*

(1) Lactose powder (25g packet)\*

(4) QuinTron vials for breath collection

(4) Labels for vials

(1) Bubble bags for packaging of vials












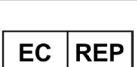
Please consult with your healthcare provider if you have any health concerns, are on a specialty diet, and/or are taking prescribed medications that may interfere with this test. Do not discontinue taking any prescribed or over-the-counter (OTC) medications, including those listed in the Test Restrictions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

4 Sample - Lactose  
Malabsorption  
Hydrogen & Methane  
Breath Test

## IMPORTANT REMINDERS

1. Ensure you verify the expiration date on your test kit, which can be found on the exterior of the kit next to the hourglass (🕒) symbol, formatted as YEAR-MONTH-DAY. Do not proceed with your test if it has expired.
2. Samples remain viable for up to 14 days from the date of collection and should be analyzed within this timeframe.
3. Not adhering to these guidelines may result in an invalid test outcome.
4. For those with multiple test kits, it is important to note that the complete 24-hour preparation process must be redone for each test. It is advisable to space each test at least 24 hours apart.
5. Please note that this test will take approximately three (3) hours to complete. After collecting a baseline sample and drinking the solution, subsequent breath samples will be collected at 60-minute intervals throughout the test period. It is essential to schedule your time accordingly to ensure accurate and timely sample collection.

## SYMBOL DEFINITIONS

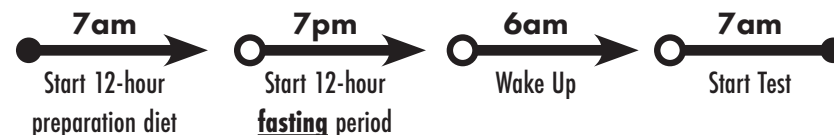
	Consult the instructions for use		Do not use if broken
	Manufacturer		Use By
	Caution		<i>In vitro</i> diagnostic medical device
	Not Sterile		Batch Code
	Contains sufficient for 1 test		Catalog Number
	Do not reuse		Authorized Representative in the European Community

## TEST RESTRICTIONS











- Complete any antibiotic treatments at least four (4) weeks before the test.
- Discontinue using laxatives and/or promotility drugs that promote bowel movement one (1) week before the test.
- Do not smoke or vape at least 2 hours before and throughout the test.
- Do not sleep or exercise for at least one (1) hour before and throughout the test.
- If you are on any medication or special diets that conflict with these test instructions, it is recommended to speak with your physician before performing this test.

## TEST PREPARATION

For this test, you will need to go through a 24-hour preparation process. This starts with eating a restricted diet for the first 12 hours, followed by a 12-hour fasting period where you should only consume water. Starting this prep in the morning might make things easier, as it allows the fasting period to overlap with your sleep. Below is a suggested schedule to guide you through this process.



## 12-HOUR DIET (PERMITTED FOODS)

	Olive Oil, Salt, & Pepper (minimal seasonings)		Plain White Bread		Baked or Broiled Seafood		Baked or Broiled Chicken & Turkey (no deli meat)
	Steamed White Rice		Plain Tofu		Baked or Broiled Lean Beef & Lean Pork (no deli meat)		Boiled or Mashed Potatoes (no skin), Carrots & Turnips
	Plain Water, Plain Black Coffee, Plain Black or Green Tea (no herbal teas)		Eggs	Only consume foods on this permitted list. For preparation recipe examples, visit <a href="http://www.BreathTests.com">www.BreathTests.com</a> .			

## 12-HOUR FASTING PERIOD

- Consume only water during the fasting period and throughout the test.
- Continue taking prescribed medications as approved by your doctor.
- Avoid vitamins and supplements during fasting and throughout the test.
- Brush your teeth as usual.
- Ensure you are awake for at least one (1) hour before beginning the test.