

### **BEFORE YOU START THE TEST**

Please read all directions and familiarize yourself with the test procedures.  
The test results will be useful only if the samples are properly collected.



**Do not insert your finger into the tube holder of the EasySampler at any time; it contains a sharp needle.**



**Do not loosen or remove the tops of the vacuum-sealed collection tubes; this will destroy the vacuum and make the tubes useless for this test.**

### **KIT CONTENTS**

- EasySampler™ with tube holder
- Labels for the collection tubes
- 4 - Vacuum-sealed collection tubes
- Lactose sugar for testing



### **TIME NEEDED FOR TESTING**

- This test will take 3 hours to complete.
- After collecting a baseline sample and drinking the solution, each breath sample will be collected in 60 minute intervals throughout the test period.
- Please schedule your time appropriately.

## **PREPARATION FOR THE TEST**

### **Review the enclosed *Preparation Guidelines* prior to performing this test!**

**It is recommended to avoid performing this test within 14 days of any of the following conditions or consult a physician prior:**

**Recent antibiotic treatment, barium study, or colonoscopy.**

- No smoking, including second-hand smoke, for at least 1 hour before or at any time during the test.
- No sleeping or vigorous exercise for at least 1 hour before or at any time during the test.
- With the exception of water, do not eat/drink anything while fasting or during the test! This can cause inaccurate readings or cause your test to be unreadable.
- Suggested meals prior to fasting are located in the *Preparation Guidelines* sheet.
- 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.

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## **Prepare Test Solution - DO NOT DRINK YET!**

***If you are unable to determine your dosage amount, consult your physician.***

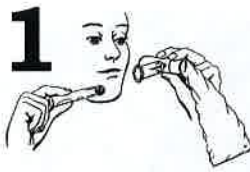
- If you weigh 50 lb (23 kg) or more, mix the packet of the enclosed substrate into 8 oz. (250 ml) of water. Set drink aside.
- If you weigh less than 50 lb (23 kg), mix 1 gram of substrate for each 2.2 lb (1 kg) of weight into 6 ounces of water. Set drink aside.

**SAMPLE CHART**

<b>Sample</b>	<b>Collection Time</b>
Baseline	Before drinking
#1	60 min. after drink
#2	120 min. after drink
#3	180 min. after drink

## **PERFORMING THE TEST (Collection Steps)**

Collect your baseline sample following steps 1-4.



Hold the EasySampler device in one hand and a collection tube in the other hand.

**You will only exhale once per each sample collection.**

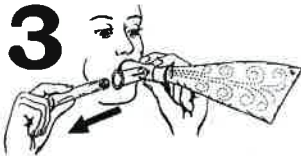
Take a normal breath in (do not take a deep breath) close your mouth around the mouthpiece then blow out normally.



As you exhale, the bag fills with air. Keep it inflated.

During your same exhalation, insert the test tube into the needle holder completely so the stopper on the tube is punctured.

Remove the tube after 1-2 seconds and stop exhaling.



**Keep the bag inflated until after the test tube is removed from the test tube holder.**



Complete the tube label provided.

**Make certain you label the Sample # correctly or your results will be inconclusive.**

After collecting your baseline sample, drink the test solution you prepared.

After drinking the solution, collect one sample every 60 minutes.

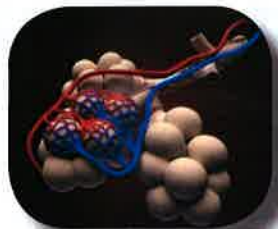
Collect all samples following the *Sample Chart* and *Collection Steps 1-4*.

Put collection test tubes in the bubble bag(s). Place the bubble bag(s), any paperwork, and the EasySampler back in the cardboard container, and return to the laboratory for analysis immediately.

**Return the kit immediately, it must be analyzed within 14 days!**

# Breath-Tests and Digestive Problems

When some bacteria digest (or ferment) food substances, they produce acids, water and gases. The major gases which are produced by bacteria include, primarily, carbon dioxide ( $\text{CO}_2$ ), hydrogen ( $\text{H}_2$ ), methane ( $\text{CH}_4$ ) and small concentrations of aromatic gases. Carbon dioxide is produced by all cells during metabolism, but only bacteria can produce  $\text{H}_2$  and  $\text{CH}_4$  as metabolic by-products, and this is accomplished primarily by bacteria which thrive in the absence of oxygen (called anaerobic bacteria). So, if either  $\text{H}_2$  or  $\text{CH}_4$  are produced biologically, it tells us that some food substance is exposed to bacterial fermentation.



In the digestive tract, bacteria are normally limited to the colon. Most of the bacteria contained in food are killed by the acidity of the stomach, so the small intestine usually has few bacteria. In some conditions, called “bacterial overgrowth”, bacteria exist in high concentrations in the small intestine. Their presence in that area can interfere with the absorption of some vitamins and other essential foodstuffs, so it is important to diagnose the condition.



The colon is concerned with conserving water and salt by reabsorbing them from the luminal contents. However, the colon is involved in other functions, some of which depend on having a high bacterial-count. Fiber, very popular in breakfast cereals, is not digested in the small intestine, so it undergoes bacterial fermentation in the colon. Short-chain fatty acids (SCFA) produced by that process are absorbed in the colon, and are beneficial to health. It is becoming apparent that substantial amounts of starch (10-20% of foods like legumes) escape digestion in the small intestine and are broken down in the colon, thus, adding to the efficiency of energy production by such food-stuffs.

In addition, colonic bacteria contribute to fecal bulk, and the short-chain fatty acids mentioned above reduce colonic pH. These factors may reduce the likelihood of diarrhea, confer some degree of protection against other severe colon problems, and enhance the colonic absorption of metal ions like calcium, magnesium and zinc. Thus, fermentation in the colon is normal, and it is important.

Gases which are produced in the colon are reabsorbed and equilibrated with the blood leaving that area. They appear in the lung and cross the capillary membrane into the alveoli, from which they are expired during breathing. The alveolar air can be collected with QuinTron collection devices and analyzed on BreathTracker or MicroLyzer instrument.

**QUINTRON**  
The Global Standard in Breath Testing

[www.BreathTests.com](http://www.BreathTests.com)

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EasySampler™ Device - US Patent # 5,467,776  
QT02070 Rev G

# Patient Preparation Guidelines for all Hydrogen/Methane Breath Tests

Any questions related to preparation should be discussed with a medical professional.

QuinTron is unable to provide medical advice.

If you (the patient) are not able to comply with these guidelines for testing, then you may not be a candidate for a breath test and your medical professional can assist you in determining if another test without these preparation limits is more suitable.

- No smoking, including second-hand smoke, for at least 1 hour before or at any time during the breath test.
- No sleeping or vigorous exercise for at least 1 hour before or at any time during the breath test.
- Wait at least 14 days before beginning your breath test if you recently had antibiotic therapy, runny diarrhea, colonoscopies, barium studies or enemas.

**Before you start the breath test, a 24 hour preparation is required consisting of a 12 hour restricted diet and a 12 hour fasting period.**

If you are uncertain if something will affect the test, **AVOID** the product or consult your physician prior to starting the test.

1. The **first 12 hours** is the restricted diet. Limit your foods to those below.

You may drink plain water, coffee, tea (no sugar/artificial sweeteners or cream added)

- Baked or broiled chicken, fish or turkey. (Salt and pepper only)
- Plain steamed white rice
- Eggs
- Clear chicken or beef broth
- White bread (only)

2. The **second 12 hours** DO NOT eat or drink anything, except water.

*These guidelines are adapted from various hospital organizations and studies.*

QuinTron did **not** exclusively develop these preparations or protocols for Hydrogen/Methane Breath Tests; medical professionals have ultimate authority as to how they choose to prepare their patient for the breath test in accordance with their own interpretation guidelines.



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QT1.0010 Rev C1

# LacTest® - Lactose

## Catalog #: QT02425-S

### Description:

Lactose is a disaccharide composed of glucose and galactose. It is a white powder with a sweet taste. It is found in milk and milk products. Its molecular weight is 342.30 and its empirical formula is  $C_{12}H_{22}O_{11}$ . LacTest is a powdered form of lactose.

### Storage:

LacTest should be stored at 60° to 85°F.

### Clinical Pharmacology:

The disaccharide, lactose is hydrolyzed by the enzyme, *lactase*, in the small intestine. Lactase splits lactose into its two monosaccharide sugars, glucose and galactose. These simple sugars are then directly absorbed by the small intestine and enter the blood stream.

The absorption of the monosaccharides is the basis for the lactose tolerance blood test. By measuring the rise of serum glucose after the ingestion of lactose, a determination of the degree of digestion and subsequent absorption of lactose component sugars can be made. Thus, lactose tolerance test indirectly measures the amount of lactase present in the small intestine. If lactose is not digested and absorbed, it enters the colon where fecal bacteria degrade it into water, metabolic gases, and small-chain fatty acids that may produce clinical complaints of flatulence, borborygmus, diarrhea, or bloating. Thus, the lactose tolerance test can also assess the degree of lactose intolerance.

### Indications:

LacTest is used as the challenge dose for the lactose tolerance test for detecting a deficiency of *lactase*. The test is used to detect the presence of milk intolerance in patients with clinical complaints of flatulence, borborygmus, diarrhea or bloating. The lactose tolerance test has been performed extensively in infants and children; no untoward symptoms have been reported.

### Contraindications:

There is no known contraindication to the use of LacTest for the lactose tolerance test. In diabetic patients, blood sugar levels should be monitored during the test, and appropriately controlled. A subsequent glucose-galactose tolerance (BBTT) may need to be performed.

### Warnings:

Adequate reproduction studies have not been performed in animals to determine whether this drug affects fertility in males or females, has teratogenic potential, or has other adverse effects on the fetus. Adverse reaction reports have not revealed evidence of fetal injury. As with all drugs, LacTest should be used in women who are or may become pregnant *only* when clearly needed.

### Adverse Reactions:

The recommended dose of LacTest may cause nausea, abdominal bloating, borborygmus, cramps, and/or diarrhea in patients with severe lactose malabsorption. No other adverse effects have been reported.

### Precautions:

Interpretation of the results of testing for lactose tolerance with LacTest requires (1) Close attention to technical details, (2) awareness of "false positives" that may occur with vomiting or severe diarrhea, (3) awareness of "false negative" in the presence of diabetes.

### How Supplied:

In powder form sealed in foil packets (pouches) containing 25 grams of lactose ( $\pm 5\%$  tolerance). For oral administration only.

### Dosage and Administration:

1. The test is performed in the morning, in a fasting state.
2. The selected dose of LacTest is given orally after being dissolved in 6-8 ounces of water. Because of the relative insolubility of lactose, mix frequently during ingestion if necessary. If any sugar remains in the glass, swirl with a small amount of additional water and drink.
3. Serum glucose specimens or breath samples are obtained in the usual manner on the schedule listed herein, and analyzed by the usual method for the laboratory.

Examples of the various methods of performing the lactose tolerance test are as follows.

(Please note: the following doses incorporate the additional weight of the LacTest overfill tolerances.)

1. 25 gram BREATH Hydrogen/Methane test:  
A more widely used test for lactose malabsorption/intolerance depends on measuring the appearance of hydrogen and/or methane concentrations in expired alveolar air following administration of 25 grams of lactose dissolved in water.
  - a. Dissolve one 25 gram packet of LacTest or dissolve 25 grams of lactose in 8 ounces (approximately 240cc) of water. Mix thoroughly.
  - b. Obtain a fasting alveolar air breath sample.
  - c. Have the patient ingest the LacTest solution after it has been thoroughly mixed.
  - d. Obtain additional alveolar air samples at **60, 120 and 180 minutes** after the ingestion of LacTest.
  - e. Note: For pediatric use, dissolve 1 gram of LacTest for every 1kg (2.2 lbs) of the patient's body weight in 6-8 ounces of water.
  - f. Contact QuinTron Instrument Company, Inc. for more detailed instructions on breath tests, or review the breath test instructions contained in each breath test kit.
2. 50 gram BLOOD test:
  - a. Dissolve two 25 gram packets of LacTest or dissolve 50 grams of lactose in 8 ounces (approximately 240cc) of water. Mix thoroughly.
  - b. Obtain a fasting venous glucose specimen.
  - c. Have the patient ingest the LacTest solution after it has been thoroughly mixed.
  - d. Obtain venous glucose specimens **15, 30, 60, 90 and 120 minutes** after the ingestion of LacTest.
3. 100 gram BLOOD test:
  - a. Dissolve four 25 gram packets of LacTest or dissolve 100 grams of lactose in 8 ounces (approximately 240cc) of water. Mix thoroughly.
  - b. Obtain a fasting venous glucose specimen.
  - c. Have the patient ingest the LacTest solution after it has been thoroughly mixed.
  - d. Obtain venous glucose specimens **15, 30, 60, 90 and 120 minutes** after the ingestion of LacTest.

### Interpretations:

#### Blood Test:

1. Using venous blood samples, a peak (maximal) rise of 25 mg/dl in blood glucose signifies normal lactase activity. A peak rise less than 20 mg/dl strongly suggests lactase deficiency.

#### Breath Test:

(There are three different methods to review depending on what type of gas productions are measured in an expired alveolar air sample. Review each method below to determine how to interpret each individual patient.)

1. A peak delta increase of at least 20 parts per million (ppm) of Hydrogen from the lowest preceding Hydrogen value in the breath test, may suggest lactase deficiency.
2. A peak delta increase of at least 12 ppm of Methane from the lowest preceding Methane value in the breath, test may suggest lactase deficiency.
3. A combined (add the two values together) increase of both Hydrogen and Methane of at least 15 ppm from the lowest preceding combined value within the breath test, strongly suggests lactase deficiency.



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