

# $^{14}\text{C}$ -Urea Breath Test for Presence of *H. pylori*

## User's Guide



## Kit Contents

- 1  $^{14}\text{C}$ -Urea Capsule
- 2 Breath sample collection balloons
- 2 Straws: for inflating balloons
- 2 30cc dosing cups
- 1 3-part patient data and reform form
- 1 Product package insert
- 1 Package insert summary and test procedure directions
- 1 Patient information pamphlet
- 1 Kit delivery/return box



## Completion of Forms

### The Balloon Labels

The patient's name, identification number, date of test performance, time of capsule administration, time of breath sample collection (i.e., 10 and 20 minutes), and the ordering physician's name should be clearly printed on the balloon label.

### The Report Form

The report form must be completed and sent back to Radiopharmacy with any test sample balloons. You should complete the top section only of this form. The bottom section is completed by test sample analysts at Radiopharmacy. **Please keep the pink copy** to track kits which you have returned for analysis. **Please return the white and yellow copies** with the breath sample balloons. A copy of the results will be fax'ed to you immediately after analysis is completed. The completed white copy of the form will be returned to you via U.S. mail.

Please record the following when completing the report form:

- 1. Last Name:** - Patient last name
- 2. First Name:** - Patient first name
- 3. Date:** - Date test performed
- 4. DOB:** - Patient's date of birth
- 5. SSN:** - (optional) Patient's social security number
- 6. Sex:** - male/female
- 7. Referring Dr.:** - (optional)
- 8. Phone:** - Number to call for questions regarding the test; usually the number for the department where test is performed.
- 9. Fax:** - Number where results are to be fax'ed.
- 10. Address:** - **Where *the test is being performed*.** The name of the facility, street address, city, state, zip code, and to whose attention the results should be mailed.
- 11. Patient Status:** - circle appropriate status as related to the 14C-urea breath test. Fill in the number of months since treatment (tx) for ulcer or H. pylori infection.
- 12. Confounding Factors:** - Circle all that are present. Refer to additional information on confounding factors in this Guide.

*Remember to keep the pink copy and forward the white and yellow copies to Radiopharmacy in the samples return box. If you have any questions please call 800 755-5889 or 812 421-1002.*

**13. Signed:** - Signature of the physician interpreting the results at your facility, and date of signature. Physician completes /signs **after** reviewing the returned test results.

## Frequently Asked Questions

### **Is there a difference between the blood tests for *H. pylori* and the breath tests?**

Yes. Tests on blood and serum detect antibodies to the bacterium. They do not necessarily detect active infection.

### **Are there other tests besides <sup>14</sup>C-urea breath testing that detect active infection?**

Yes. A non-radioactive urea breath test is available, but it costs about twice as much yet is no more accurate than the <sup>14</sup>C test. The only other way to detect active infection besides breath testing is biopsy of the ulcer site; an invasive and expensive procedure.

### **Are there any special preparations needed before performing <sup>14</sup>C-urea Breath testing?**

No. The medical use of <sup>14</sup>C-urea does not require a radioactive materials license. However, because <sup>14</sup>C-urea capsules are legend drugs, you must comply with applicable Food and Drug Administration or other Federal and State requirements governing receipt, administration and use of drugs.

### **How does the test work?**

To detect *H. pylori*, <sup>14</sup>C-urea in a capsule is swallowed by the patient. If the *H. pylori* bacteria are present, gastric urease that it produces will split urea into CO<sub>2</sub> and NH<sub>3</sub>. The <sup>14</sup>CO<sub>2</sub> is subsequently exhaled in the patient's breath. The breath sample is collected into a balloon and later transferred to a solution that traps the radioactive <sup>14</sup>CO<sub>2</sub>. The liquid sample is then analyzed in a liquid scintillation counter to detect the radiolabeled CO<sub>2</sub>. <sup>14</sup>C-urea that is not hydrolyzed by *H. pylori* is excreted in the urine.

### **How are the kits ordered and returned to Radiopharmacy for analysis and how soon will I get a result?**

Because of the kit's long shelf life, we recommend you maintain an inventory of <sup>14</sup>C-urea Breath Test kits. When you place an order, kits are delivered by the method of your choice (pharmacy courier, UPS, Fed-X, U.S. mail, etc.).

Kits are supplied in return delivery boxes. After completing the test, return the samples in the pre-addressed return box. Breath samples are analyzed the day received at Radiopharmacy. Results are returned via fax immediately after analysis is complete; usually the next day. Results of samples received on Fridays are returned via fax on Monday. Please keep in mind that priority mail is not guaranteed, and may therefore take more than two days for the test samples arrive at Radiopharmacy. To help speed results return, you may also return kits via UPS or Fed-X.

**What happens if the patient feels the capsule is stuck in his/her throat?**

You may give the patient an additional 20cc water immediately followed by the standard 20cc 3 minutes after capsule ingestion. Use common sense and give the patient enough water to ensure that the capsule is in the stomach, but not an entire (ex. 8 oz) glass of water. Too much water can prevent the capsule from dissolving in contact with the lining of the stomach possibly causing a false negative result.

**What are confounding factors for the <sup>14</sup>C-Urea Breath Test?**

The following items are considered confounding factors. Any of the following confounding factors could lead to a false-negative result.

**ANTIBIOTICS:** Patients should not have the test performed if they have had antibiotics in the last month.

**BISMUTH:** Patients should be off all bismuth drugs for one month prior to the breath test. The most common source of bismuth is Pepto Bismol®. Patients should not have the test performed if they have had bismuth in the last month.

**SUCRALFATE:** Patients should not have the test performed if they have had sucralfate (Carafate®) in the last 2 weeks.

**NONFASTING:** Patient should be fasting for 6 hours prior to the test. This means nothing to eat or drink.

**PROTON PUMP INHIBITORS:** Patients should not have the test performed if they have had a proton pump inhibitor in the last 2 weeks.

**What medications are considered Proton-Pump Inhibitors?**

Generic Name	Brand Name
Omeprazole	Prilosec®
Lansoprazole	Prevacid®
Rabeprazole Sodium	Aciphex®
Pantoprazole Sodium	Protonix®
Esomeprazole Magnesium	Nexium®

**Are H2 Blockers considered a confounding factor?**

No

**What medications are considered H2 Blockers?**

<b>Generic Name</b>	<b>Brand Name</b>
Cimetidine	Tagamet®
Ranitidine	Zantac®
Nizatidine	Axid®
Famotidine	Pepcid®

**Are antacids considered to be a confounding factor?**

No

**What are names of some commonly used antacids?**

Maalox®, Roloids®, Tums®, Mylanta®, Gelusil®, and many more.

**Is there someone I can call if I am unfamiliar with a particular drug the patient has taken?**

Yes, you may call a pharmacist at 800 755-5889.

**How soon can the test be repeated?**

The test may be repeated after 6 hours if the patient is fasting and has no other confounding factors.

**What should be done if the patient is unable to fully inflate the balloon with one breath?**

After the patient has partially inflated the balloon with his first breath, simply squeeze the straw to keep the breath in the balloon from escaping. Allow the patient to take another breath, hold it for 5-10 seconds and then again blow into the balloon. You should try to complete this process as soon as possible. The patient may take as many breaths as is needed to completely fill the balloon.

**What happens if the balloon is only half filled?**

One mmol of CO<sub>2</sub> is required in order to perform analysis of the breath sample. The amount of breath required to provide 1 mmol varies depending on the amount of CO<sub>2</sub> the patient is producing. A balloon which is half-full may or may not provide enough CO<sub>2</sub>. We strongly recommend the balloons be completely filled. Do not be concerned about the balloon bursting - they are *very* strong.

**What happens if the balloon has a leak?**

If you can locate the leak, seal it with a piece of adhesive tape. If the leak cannot be found, you may "rob" a balloon from another kit to be replaced later. One reason for supplying balloons for two samples with each kit is to prevent the loss of the patient study if one sample is lost.

## Interpretation and Results

### **What are the cut-off points for positive and negative results?**

< 50 DPM	=	Negative
50-100 DPM	=	Indeterminate ("Other")
>100 DPM	=	Positive

### **What causes an indeterminate result?**

An indeterminate result can be caused by random chemiluminescence of the liquid scintillation cocktail. However if results from **both** sample balloons are in the indeterminate range, the chances of the cause being chemiluminescence is small. If one result is in the indeterminate range and the other in the positive or negative range, the indeterminate sample is recounted to rule out chemiluminescence.

An indeterminate result can also be caused by a patient who actually has *H. pylori* but has a confounding factor for the test. Note that based on hundred of samples analyzed to date, less than 5% of all samples fall in the indeterminate range.

### **What is suggested for re-testing a patient with an indeterminate result?**

The indeterminate result should be evaluated by repeating the test or using an alternative diagnostic method. If you repeat the breath test, be sure to obtain a careful history to exclude confounding factors. If confounding factors are present, wait appropriate time (table below or at least 6 hours) before repeating the breath test.

<u>Confounding Factor</u>	<u>Recommended Wait to Re-testing</u>
Antibiotics	One month
Bismuth	One month
Proton-Pump Inhibitors	Two weeks
Sucralfate	Two weeks
Non-fasting	Six hours

### **Does the test result need to be confirmed by serology or other methods of testing?**

No

### **What does it mean if I discover a patient had a confounding factor and the result is negative?**

It may be a false negative result. The test should be repeated after the confounding factor has been eliminated for the appropriate amount of time.

## Radiation Safety

### **What is the risk from the $^{14}\text{C}$ ?**

The  $^{14}\text{C}$ -urea breath test gives a maximum Effective Dose Equivalent (EDE) to the patient of 0.3 mrem. This is approximately the same radiation dose as 24 hours of normal background radiation.

### **What is the dose to the people performing the test? Are they at risk?**

The Nuclear Regulatory Commission (NRC) has performed an analysis of the radiation dose estimates for personnel working the  $^{14}\text{C}$ -urea breath test and concluded that the risks to those performing the test is insignificant. The NRC has exempted the performance of this test from their regulations.

## Waste Disposal

### **What do I do with the packaging considering it was used with radioactive material?**

All references to radioactive material and the radiation symbol should be defaced prior to disposing in the regular trash.

## Billing and Reimbursement

### **Is there a CPT CODE for $^{14}\text{C}$ -urea breath testing?**

There are two CPT codes used for the two separate parts of  $^{14}\text{C}$ -urea breath testing.

**78267 Urea Breath Test, C-14; acquisition for analysis**

**78268 Breath test Analysis, C-14**

## Regulatory Issues

### **Do we have to have a CLIA license to perform this test at our site?**

No, CLIA does not consider breath a sample and, therefore, does not regulate the  $^{14}\text{C}$ -urea breath test.

**Do I need a radioactive materials license to perform this test?**

No, other than Kansas and Maryland, no other states require a radioactive materials license to perform the <sup>14</sup>C-urea breath test.

**Who do call to order the <sup>14</sup>C-urea breath test?**

Call your local nuclear pharmacy or Radiopharmacy, Inc. at (800) 755-5889 or (812) 421-1002. A pharmacist will take your order.

**Are we required to check each <sup>14</sup>C-urea capsule in a dose calibrator like we are other radiopharmaceuticals?**

No, a dose calibrator is not capable of accurately measuring this type of radioisotope. NRC regulations do not require unit dosages be assayed prior to administration to a patient.