C-14 UREA BREATH TEST FOR HELICOBACTER PYLORI (PYTEST)

Clearwater Imaging Associates Protocol

INDICATIONS:
Document eradication of HP infection after therapy
Suspected or proven gastritis
Suspected or proven gastric ulcer disease
Suspected or proven duodenal ulcer
Gastric adenocarcinoma
Gastric lymphoma

SCHEDULING:

1. Instructions to Patients:
   a. Confirm that patient is being referred for one of the indications above. **DO NOT SCHEDULE THIS TEST FOR PREGNANT WOMEN OR CHILDREN WITHOUT CLEARANCE BY THE NUCLEAR MEDICINE PHYSICIAN.**
   b. Patient should remain NPO overnight, including water (or for a minimum of six hours prior to testing).
   c. Patient must be off all antibiotics for one month prior to the exam.
   d. Patient must be off Pepto-Bismol or any other bismuth-containing remedies for one month.
   e. Patient must be off proton-pump inhibitors, including Prilosec (omeprazole), Prevacid (lansoprazole) and Carafate (Sucralfate) for two weeks prior to the test.
   f. The procedure is quite simple, requiring the patient to swallow a single capsule, and exhale into a balloon ten minutes later. The entire procedure should take less than 30 minutes. There are no risks and no side effects.

2. Lab:
   No laboratory data necessary.

3. Image Correlation:
   If the patient has had an upper GI or upper endoscopy at Morton Plant Mease, please obtain the reports. It is not necessary to have reports sent in from referring doctor’s offices.

RADIOPHARMACEUTICAL:

1 μCi C-14 PYtest capsule po.
PATIENT PREPARATION:

The patient is given a (gelatin) PYtest capsule, to be taken orally, containing 1 µCi of C-14 labeled urea absorbed on sugar beads, and colored yellow with fluorescein. The patient should understand that there is no external radiation hazard, that no special “radiation” precautions need to be taken, and that there is a minimal amount of low energy exposure.

EQUIPMENT AND PREPARATION:

The PYtest kit (C-14 Urea Breath Test kit) containing one PYtest capsule, two 30 ml disposable cups, one Mylar breath collection balloon, one patient breath straw, one Tri-Med breath test form, and one breath collection balloon transport container with prepaid shipping.

PROCEDURE:

1. Before the test:
   a. Label the balloon completely, and fill in breath test report form.
   b. Check that all materials are present.
   c. Open the package containing the C-14 urea capsule; tip the capsule into the empty 30 ml cup. Do not handle the capsule directly. Hand the cup to the patient, and fill the second cup with 20 ml of lukewarm water. Do not hold capsule in mouth.

2. a. Ask patient to tip the capsule directly into his/her mouth and swallow it with the 20 ml of lukewarm water.
   b. Start the stopwatch when the patient swallows the capsule.
   c. Remove the cup, discard the waste.

3. At 3 minutes, ask the patient to drink another 20 ml of lukewarm water.

4. a. At 10 minutes, push the drinking straw into the neck of the balloon; ask the patient to hold his/her breath for 5-10 seconds and blow up the balloon with a single breath through the straw, filling the balloon completely.
   b. Tie the neck of the balloon into a tight knot.
   c. Check that the balloon label and breath test report form are completed and correct, to be mailed to Tri-Med.

   Note: There is no physician interpretation of this exam. When results are received, they are mailed to the referring physician with a form letter. A copy of indications for indeterminate results is also sent.

Precautions:
1. No special precautions are necessary; the patient should not directly handle the C-14 capsule, but reassure the patient that there is an extremely low radiation dose, much smaller than most of the procedures done in Nuclear Medicine or Radiology.

2. Potential sources of error include:
   a. contamination with oral flora (difficulty swallowing capsule)
   b. antibiotics or Bismuth within 30 days
   c. Sucralfate or proton-pump inhibitors (see p. 1) within 14 days
   d. non-fasting
   e. achlorhydria
   f. uremia
   g. H2 receptor antagonists
   h. Resective gastric surgery

REFERENCES:


ATACHMENT

List of and Further Information on Confounding Factors

Below is a list of all PYtest confounding factors:

1. Antibiotics taken within the last 30 days. There are too many to list...
2. Bismuth taken within the last 30 days (i.e., Pepto-Bismol).
3. Sucralfate taken in the last 2 weeks. This is also called Carafate.
4. Proton-pump inhibitors:
<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Brand Name</th>
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<tbody>
<tr>
<td>Omeprazole</td>
<td>Prilosec</td>
</tr>
<tr>
<td>Lansoprazole</td>
<td>Prevacid</td>
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5. Non-fasting (eating or drinking within 6 hours of the test).
6. Sample time: missing or incorrect. When the sample time is not indicated.

7. Insufficient sample: this is when the balloon does not have sufficient breath (CO2) to turn the color from blue to clear.

Things that are **NOT** a confounding factor:

1. Antacids.

2. H2 blockers:

<table>
<thead>
<tr>
<th>Generic Name</th>
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<tbody>
<tr>
<td>Cimetidine</td>
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<tr>
<td>Ranitidine</td>
<td>Zantac</td>
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<tr>
<td>Nizatidine</td>
<td>Axiv</td>
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<tr>
<td>Famotidine</td>
<td>Pepcid</td>
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</table>

3. OK: Maalox  
     Tums  
     Gelusil  
     Rolaids  
     Mylanta