

PYTEST*

¹⁴C-Urea Breath Test



H. PYLORI DIAGNOSTICS MADE SIMPLE FOR YOU, EASY FOR PATIENTS



FROM THE LEADER IN H. PYLORI DIAGNOSTICS



Barry Marshall, M.D.

H. pylori and Gastric Ulcers

PYtest* was developed by Barry Marshall, M.D., who, along with Robin Warren, M.D., was the first to discover the correlation between **H. pylori** and gastric ulcers. Dr. Marshall also developed the CLOtest* Rapid Urease Test. Today, it has become the most widely used rapid urease test worldwide for the diagnosis of **H. pylori** and is recognized globally by medical professionals as the "Gold Standard."

One of the most common chronic infections worldwide, **H. pylori** is associated with 95% of duodenal ulcers and 80% of gastric ulcers. Clinical studies have shown that eradicating **H. pylori** is effective in eliminating or reducing the recurrence of ulcers and may also lower the risk of gastric cancer. The National Institutes of Health recommends testing for **H. pylori** in all patients with gastric or duodenal ulcers.

Simple for you. Easy for Patients.

Halyard Health is a leader in Helicobacter pylori (**H. pylori**) diagnostics. The PYtest* ¹⁴C-Urea Breath Test is the first and only currently approved ¹⁴C-UBT in the U.S. market for the diagnosis of H. pylori. Utilizing ¹⁴C-labeled urea in breath samples to identify the presence of the H. pylori bacterium, PYtest* features:

Accuracy

- Up to 96% sensitivity and 96% specificity
- Active infection determination versus the presence of antibodies, as measured by serology

Convenience

- Non-invasive, easy-to-swallow gelatin capsules
- On-site test administration and analysis that can be completed in less than 20 minutes
- Testing not regulated by CLIA†

Reimbursement

- Reimbursement by Medicare and many other carriers†

† Applies to U.S. only

PYTEST*

¹⁴C-Urea Breath Test

PRODUCT ORDERING INFORMATION

HALYARD* PYTEST* ¹⁴C-UREA BREATH TEST CAPSULES

Stock #	Description	Packaging
60442	PYtest* Capsules	10 Each
60443	PYtest* Capsules	100 Each
60437+	PYtest* Capsules	1000 Each

HALYARD* PYTEST* ¹⁴C-UREA BREATH TEST ACCESSORIES

Stock #	Description	Packaging
60404	PYtest* Patient Brochure	50 Each
60444	Air Pump	1 Each
60445	PYtest* Breath Collection Fluid, 250ml	1 Each
60446	PYtest* Breath Collection Fluid, 1000ml	1 Each
60447	PYtest* Breath Collection Vials, 200ml	100 Each
60449	PYtest* Medicine Cups	400 Each
60450	PYtest* Needles	100 Each
60452	PYtest* Reagent Dispenser, 1- 5ml, for Breath Collection Fluid	1 Each
60453	PYtest* Reagent Dispenser, 1- 10ml, for Scintillation Fluid	1 Each
60454	PYtest* Breath Collection Balloons, Straws	100 Each
60455	Scintillation Fluid, 4 Liters	1 Each
60456	PYtest* Standards Set, Background and ¹⁴ C	1 Each
60494	PYtest* Validation Package, 3- Collection Balloons, 3- Straws 3- Results Forms, 3- Return Cartons	1 Each

HALYARD* PYTEST* ¹⁴C-UREA BREATH TEST START-UP PACKAGE

Provides supplies (except capsules and liquid scintillation counter equipment) to perform 100 tests on site. The smallest container of Scintillation Fluid available provides a supply to perform 400 tests.

Includes:

- 1 – Air Pump
- 200 – Needles
- 100 – Collection Vials
- 1 – Stopwatch
- 1 – Bottle Collection Fluid, 250ml
- 100 – Balloons|100- Straws
- 1 – Bottle Scintillation Fluid, 4 Liters
- 100 – Patient Brochures
- 1 – Sample Breath Test Report Form
- 400 – Medicine Cups
- 1 – Validation Package: 3- Balloons, 3- Straws, 3- Return Cartons, 3- Patient

Results Forms

Stock #	Description	Packaging
60439	PYtest* Start-Up Package	1 Each

HALYARD* PYTEST* ¹⁴C-UREA BREATH TEST PROVIDER PURCHASE KITS

Facility purchases kit and test analysis, then bills insurance carrier and/or patient for test administration and analysis. Note: Medicare does not allow certain facilities to bill for services that they do not perform. Check with local carrier for details.

Includes:

- 1 – PYtest Capsule
- 1 – Balloon
- 1 – Straw
- 2 – Medicine Cups
- 1 – Results Form
- 1 – Directions For Use
- 1 – Alert Form
- 1 – Return Carton
- 1 – Prepaid Shipper Label
- 1 – Alert Form

Stock #	Description	Packaging
60461	PYtest* Provider Purchase Kit, UPS Return	1 Each
60470	PYtest* Provider Purchase Kit, U.S. Priority Mail Return	1 Each
60462	PYtest* Provider Purchase Kit, UPS Return	10 Each
60471	PYtest* Provider Purchase Kit, U.S. Priority Mail Return	10 Each

HALYARD* MICROCOUNT* LITE LIQUID SCINTILLATION COUNTER

Stock #	Description	Packaging
60495	MICROCOUNT* Lite, Single-Sample Liquid Scintillation Counter, Weight: 25 lbs., Size: 14½" x 6½" x 10"	1 Each
60496	MICROCOUNT* Lite Printer, Miniature Continuous-Feed Dot Matrix Serial Interface Printer	1 Each

+ For International sale only

ADMINISTRATION AND ANALYSIS IN 5 EASY STEPS

1



The patient swallows a PYtest capsule containing a small amount of ^{14}C -labeled urea. If the ^{14}C -Urea comes into contact with **H. pylori** in the stomach, it is hydrolyzed into ^{14}C -carbon dioxide and ammonia. The carbon dioxide enters the bloodstream and is exhaled by the patient.

2



Ten minutes after ingesting the capsule, a breath sample is collected in a mylar balloon. The breath sample collection balloon may be analyzed on site or sent to Halyard Health for analysis.

3



The contents of the balloon are transferred into a breath collection fluid, then liquid scintillation fluid is added to complete the solution.

4



The MICROCOUNT[®] Lite Liquid Scintillation Counter analyzes the breath sample. Compact in size, it provides results in five minutes on an LCD display panel. (A compatible printer or software for outputting results in hard copy is also available.) If the breath sample contains ^{14}C , the patient has **H. pylori**. If **H. pylori** is not present, the ^{14}C -Urea is not hydrolyzed and is excreted in the urine.

5



On-site test administration and analysis can be completed in less than 20 minutes. Therefore, test results can be discussed with the patient and treatment prescribed before he or she leaves the office.

PYtest[®] products include test capsules as well as supplies and equipment necessary for on-site administration and analysis.



PYTEST[®] KIT PROGRAM

Analysis of the breath sample is also available at Halyard Health via the PYtest[®] Kit Program. The PYtest[®] Kit contains all supplies needed to complete a single test administration. After the test is administered, the PYtest[®] balloon is sent to Halyard Health for analysis. Results are typically available within 24 hours of receipt.

PRODUCT SPECIFICATIONS

PYtest* (¹⁴C-urea Capsules)

DESCRIPTION

PYtest* (¹⁴C-Urea) capsules is intended for use in the detection of gastric urease as an aid in the diagnosis of **Helicobacter pylori (H.pylori)** infection in the human stomach. The test utilizes a liquid scintillation counter for the measurement of ¹⁴CO₂ in breath samples. The capsules are to be used when analysis is planned at the site where the sample is taken.

PYtest* capsule is a gelatin capsule for oral administration containing 1μCi of ¹⁴C-labeled urea. The urea is adsorbed on sugar spheres and colored yellow with fluorescein.

Data on ¹⁴C-Urea:

Structural Formula (¹⁴C-Urea): NH₂ ¹⁴CNH₂

Radiation emission: beta-emission, 49 keVmean, 156 keVmax, no other emissions

External emission: No external radiation hazard. Low-energy beta emissions only.

Maximum range of 0.3 mm in water.

Radiological half-life: 5730 years

Maximum effective dose equivalent (EDE): 0.3 mrem/μCi

CLINICAL PHARMACOLOGY

The urease enzyme is not present in mammalian cells, so the presence of urease in the stomach is evidence that bacteria are present. The presence of urease is not specific for **H. pylori**, but other bacteria are not usually found in the stomach.

To detect **H. pylori**, urea labeled with ¹⁴C is swallowed by the patient. If gastric urease from **H. pylori** is present, urea is split to form CO₂ and NH₃ at the interface between the gastric epithelium and lumen and ¹⁴CO₂ is absorbed into the blood and exhaled in the breath.

Following ingestion of the capsule by a patient with **H. pylori**, ¹⁴CO₂ excretion in the breath peaks between 10 and 15 minutes and declines thereafter with a biological half-life of about 15 minutes. ¹⁴C-Urea that is not hydrolyzed by **H.pylori** is excreted in the urine with a half-life of approximately 12 hours. About 10% of the ¹⁴C remains in the body at 72 hours and is gradually excreted with a biological half-life of 40 days.

CLINICAL STUDIES

Two studies were performed. In both studies, patients with gastrointestinal symptoms underwent the breath test and an endoscopy. During the endoscopy, biopsy samples were taken from the antral gastric mucosa for histological analysis (2 samples, Giemsa stain) and rapid urease test (1 sample, CLOtest). Breath samples were mailed to the TRI-MED lab where they were read in a liquid scintillation counter.

Results were reported as disintegrations per minute (DPM). Analysis for accuracy used the 10 minute breath sample. A breath sample DPM <50 was defined as a negative result. DPM ≥200 was defined as a positive result. DPM in the range of 50-199 was classified as indeterminate.

	Study 1 (n=186)	Study 2 (n=76)
Sensitivity ^a	96%	82%
Specificity ^a	88%	96%
Positive Predictive Value	86%	100%
Negative Predictive Value	99%	98%

^a Compared with agreement of CLOtest* and Histology

* Including indeterminates. If an indeterminate result (50-199 DPM) occurs, repeat testing is recommended

** Using community hospitals for study patients

INDICATIONS AND USAGE

PYtest* (¹⁴C-urea) breath test is indicated for use in the detection of gastric urease as an aid in the diagnosis of **H. pylori** infection in the human stomach. The test utilizes a liquid scintillation counter for the measurement of ¹⁴CO₂ in breath samples.

CONTRAINDICATIONS

None

WARNINGS

None

PRECAUTIONS

General: After the patient ingests the ¹⁴C-Urea capsule, the sample collected for test purposes is for in vitro diagnostic use only.

A false positive test could occur in patients who have achlorhydria. Very rarely, a false positive test may occur due to urease associated with Helicobacters other than **H. pylori (i.e., Helicobacter heilmanni)**.

LIMITATIONS OF THE TEST

- The test has been evaluated in outpatients before elective endoscopy.
- Test results should be evaluated with clinical signs and patient history when diagnosing **H. pylori** infection.
- The performance characteristics of the test have not been established for monitoring the efficacy of antimicrobial therapies for the treatment of **H. pylori** infection.
- A negative result does not completely rule out the possibility of **H. pylori** infection. If clinical signs and patient history suggest **H. pylori** infection, repeat the PYtest* or use an alternative diagnostic method.

RADIOACTIVITY

Persons concerned about very low doses of radioactivity may postpone the test or may decide to use an alternative means of diagnosis. The test produces radiation exposure equal to 24 hours of normal background. In animal experiments, such low doses of radiation do not carry measurable risk.

Preclinical studies were not conducted on ¹⁴C-Urea. The estimated dose equivalent received from a single administration of PYtest* (1μCi ¹⁴C) is about 0.3 mrem.

INFORMATION FOR PATIENTS

It is necessary for the patient to fast for 6 hours before the test. The patient should also be off antibiotics and bismuth for 1 month, and proton pump inhibitors and sucralfate for 2 weeks prior to the test. Instruct the patient not to handle the capsule directly as this may interfere with the test result. The capsule should be swallowed intact. Do not chew the capsule.

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT FOR FERTILITY

No studies have been conducted with ¹⁴C-Urea to evaluate its potential for carcinogenicity, impairment of fertility, or mutagenicity.

DRUG INTERACTIONS

Antibiotics, proton pump inhibitors, sucralfate, and bismuth preparations are known to suppress **H.pylori**. Ingestion of antibiotics or bismuth within 4 weeks and proton pump inhibitors or sucralfate within 2 weeks prior to performing the test may give false negative results.

PREGNANCY

Pregnancy category C. animal reproduction studies have not been conducted with PYtest* (¹⁴C-Urea). It is also not known whether PYtest* can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. PYtest* should be given to a pregnant woman only if clearly needed.

NURSING MOTHERS

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when PYtest* is administered to a nursing woman.

PEDIATRIC USE

Clinical studies in children have not been conducted. However, PYtest* is expected to work the same in children as in adults. While the dose (1 capsule) does not need to be adjusted, the child must be able to swallow the intact capsule and blow into a straw.

ADVERSE REACTIONS

No adverse reactions were reported in clinical trials.

OVERDOSAGE

Risk from radiation is negligible even with a 1000 capsule overdose (0.3 rem). If overdose occurs, the patient may drink one glass of water (150 mL) every hour to hasten excretion of the isotope. Maximum excretion of urea is achieved at a urine output of ≥2.0 mL/min.



KNOWLEDGE NETWORK* Accredited Education
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Commitment to Excellence

For more information, please visit:
www.halyardhealth.com/digestivehealth

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in the United States and Canada.

www.halyardhealth.com



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DH59 C14134