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GLOSSARY

PI Sheet

Product Name:

PYtest (14C-urea Capsules)

Manufacturer Name:

Ballard Medical Products A wholly-owned subsidiary of Kimberly-Clark Corporation,
Draper, Utah 84020 USA,

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Z0394, U4791

Protection. For life.

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 $^{14}\text{CO}_2$ 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 $1\mu\text{Ci}$ of ^{14}C labeled urea. The urea is adsorbed on sugar spheres and colored yellow with fluorescein.

Data on ^{14}C -urea:

Structural Formula (^{14}C -urea): $\text{NH}_2\ ^{14}\text{CONH}_2$

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 ^{14}C is swallowed by the patient. If gastric urease from *H.pylori* is present, urea is split to form CO_2 , and NH_3 at the interface between the gastric epithelium and lumen and $^{14}\text{CO}_2$ is absorbed into the blood and exhaled in the breath.

Following ingestion of the capsule by a patient with *H.pylori*, ^{14}C excretion in the breath peaks between 10 and 15 minutes and declines thereafter with a biological half-life of about 15 minutes. ^{14}C -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 ^{14}C remains in the body at 72 hours and is gradually excreted with a biological half-life of 40 days.

Clinical Trial Results:

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 ten 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**	96%	82%
Specificity**	88%	96%
Positive Predictive Value	86%	100%
Negative Predictive Value	99%	98%

* 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

Commitment to Excellence:

If, for any reason, our products do not meet your expectations, please let us know your comments or suggestions for improvement. Your input will result in a concerted effort on our part to meet your requirements. Our goal is to provide quality products that completely meet your needs time after time.

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

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 heilmannr).

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 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 (1 µCi ¹⁴C) is about 0.3 mrem.

Carcinogenesis Mutagenesis:

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

Impairment of Fertility:

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

Pediatric Use:

Clinical studies in children have not been conducted. However, PYtest is expected to work the same in children as in results. 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.

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.

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.

Warnings:

None

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.

Dosage and Administration:

Administration & Analysis in 5 Easy Steps:

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

Step 1:

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

**Step 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 Kimberly-Clark/Ballard for analysis.

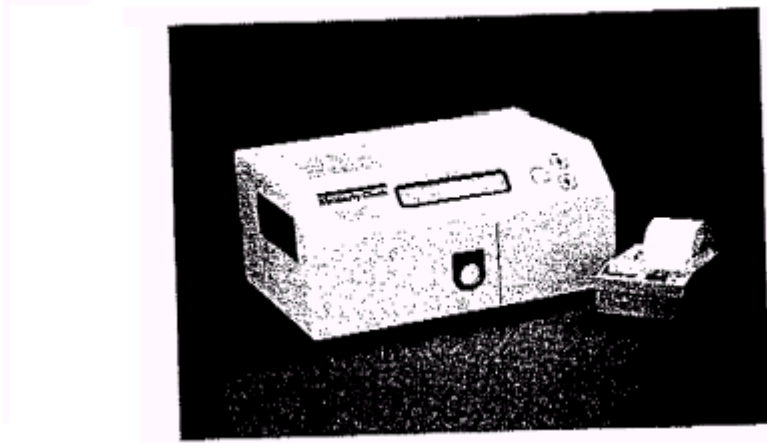
**Step 3:**

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

**Step 4:**

The KIMBERLY-CLARK microCOUNT Life Liquid Scintillation Counter analyzes the breath sample.

Compact in size, the microCOUNT provides results in five minutes on a 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 hydrolyzed and is excreted in the urine.



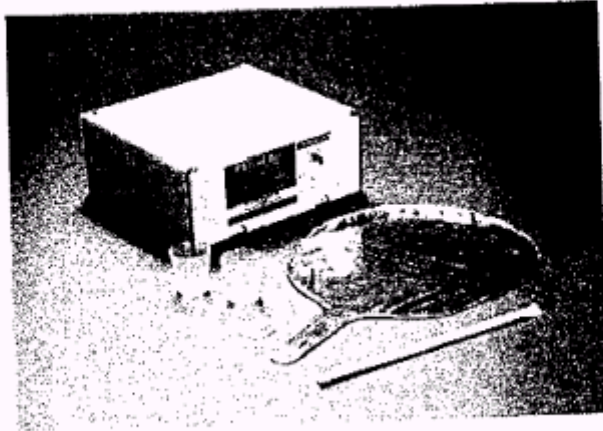
Step 5:

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.



Analysis of the breath sample is also available at Kimberly-Clark/Ballard 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 Kimberly-Clark/Ballard for analysis. Results are typically available within 24 hours of receipt.

PYtest[®] Kit Program

**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.