

# The **PYtest** – The “Cutting Edge” Urea Breath Test to detect *Helicobacter pylori*

FDA Approved



Barry Marshall



## *The “Gold-Standard” Non-invasive Diagnostic Test for The Detection of H.pylori*

*As a Healthcare Provider ...*

*Do you treat patients with ulcers?*

*Do You treat patients who suffer from pain or discomfort in their stomachs?*

*Do you treat patients who suffer from lack of appetite and weight loss?*

*Do you treat patients who suffer from nausea or vomiting?*





*Prof. Barry J. Marshall  
Nobel Laureate–Inventor  
of the PYtest®*

## Barry Marshall – Inventor of the PYtest

Tri-Med Distributors was founded in 1996 by Prof. Barry Marshall, to satisfy a need for the design, development and distribution of safe, reliable, accurate diagnostic tests to detect *Helicobacter pylori*. Subsequent to this, a new company called “*Helicobacter pylori* Diagnostic and Therapeutic Company” was created to be associated with the functions of Tri-Med Distributors.

Professor Barry Marshall and Dr. Robin Warren were jointly awarded the Nobel Prize for Medicine in December 2005 for their discovery of the bacterium *Helicobacter pylori* and its role as the causative agent of gastritis, peptic & duodenal ulcer disease.

Prof. Marshall is well known & globally respected for reversing decades of medical doctrine which held that ulcers were caused by stress, spicy foods, alcohol and too much acid. (Wikipedia)

## The PYtest

The PYtest is a Urea Breath Test which is considered to be the “gold standard”, non-invasive diagnostic for determining the presence of a current infection of *Helicobacter pylori* in the human stomach. It is highly accurate (Positive Predictive Value 100%, Negative Predictive Value 98%) and extremely reliable for pre-treatment diagnosis and post-treatment evaluation of “proof-of-cure”.

### How the PYtest works

If *Helicobacter pylori* exists in a patient’s stomach, it produces large quantities of urease which protects it against the acidic conditions in the stomach. The PYtest detects and quantifies the amount of urease in the patient’s stomach. If there is no urease present in the patient’s stomach, then the patient has no *Helicobacter pylori* infection.

### Why is it a “Cutting Edge” diagnostic test?

It is a “Cutting Edge Designed Test” because it uses microbeads (~100 Microns in diameter) made of a patented glycopolymer material surface-impregnated with <sup>14</sup>C-urea and contained within the PYtest-capsule. The capsule undergoes dissolution within 2 minutes in the stomach secretions, releasing the microbeads which penetrate the mucus layer of the stomach and lodge against the epithelial-lining of

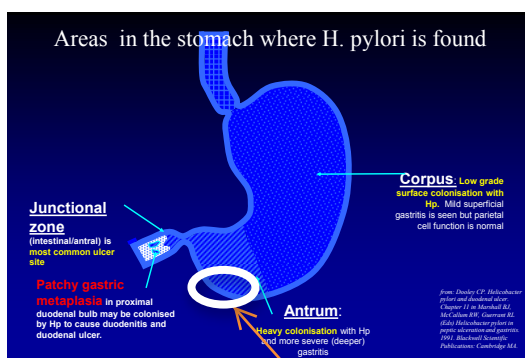
the stomach where the *H. pylori* reside. Thus the <sup>14</sup>C –urea marker is delivered directly to the site of infection. This innovative microbead system thus affords a rapid response in less than 10 minutes. A breath sample is available in ten minutes and can be analysed & the results obtained in DPM’s using the PYtest analysis machine -The microCOUNT Lite beta counter. This gives a numerical measure as to the degree or severity of the *H. pylori* infection of the patient. The greater the DPM the greater the severity of the infection.

### Also

- As the <sup>14</sup>C-urea coated microbeads are contained within a capsule, it does not interact with any urease producing bacteria in the oral cavity or oesophagus, and is only released when it enters the stomach after the capsules dissolves. This prevents occurrence of False Positives.
- The unique design of the PYtest involves microbeads surface-coated with <sup>14</sup>C –urea. These interact with the urease produced by *Helicobacter pylori* giving rise to <sup>14</sup>CO<sub>2</sub> and ammonia
- Because the PYtest beads are delivered directly to where the bacterium resides, it takes little time for a patient (less than 10 minutes) produce an analysable breath sample more than adequate to elicit a result.
- Results are obtained using the microCOUNT Lite analyser in under 5 minutes.

## The Stomach

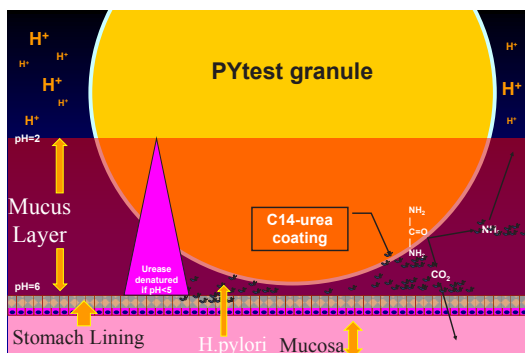
*Helicobacter pylori* tends to colonise mostly the Antral area of the stomach.



(see enlargement diagram of this section below)

## Enlargement of this Section of Stomach is shown below

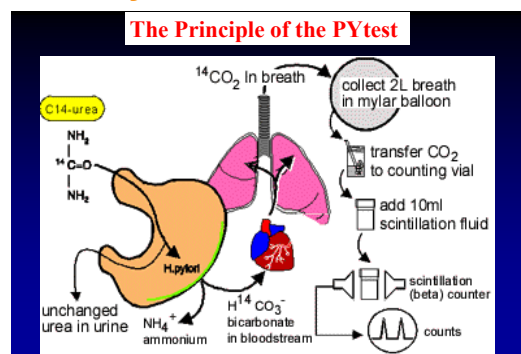
*H. pylori* resides in the area close to the epithelial cell-lining of the stomach underneath the mucus layer.



## Other Features:

- No Patient preparation apart from fasting and withholding some medications is required. Withholding certain medications is necessary because they suppress *Helicobacter pylori* activity and give lower than actual readings i.e. false negatives.
- The PYtest® is US-FDA & Australian-TGA approved and registered in many other countries internationally. The US-FDA saw no reason why it cannot be used in whole families.
- The PYtest® Comes as a self-contained kit with all components necessary to carry out the testing.
- Analysis is carried out using The microCOUNT Lite machine (MCL):
  - It is simple, robust, fool-proof and fast to use
  - It saves space as It has a small "Footprint" (36 x 25 x 19mm)
- The numerical reading displayed by the MCL gives a measure as to a patient's level of infection (i.e. higher the reading greater the infection)
- The MCL was Designed by Prof. Barry Marshall who is a world acknowledged authority on *Helicobacter pylori*.
- The PYtest capsule is manufactured in the USA under stringent US-FDA pharmaceutical regulations.

## Summary of How the PYtest Works



- $^{14}\text{C}$ -urea is found on the surface of the PYtest® microbeads.
- The density of the microbeads allows them to penetrate the mucus layer and approach the location where *Helicobacter pylori* resides (in proximity to the stomach epithelial lining.).
- The urease produced by *Helicobacter pylori* breaks down the  $^{14}\text{C}$ -urea into carbon dioxide ( $^{14}\text{CO}_2$ ) and ammonia.
- The labelled  $\text{CO}_2$  enters the blood vessels in the mucosa as bicarbonate ions, and gets carried by the circulatory system to the heart and finally to the lungs
- This labelled  $\text{CO}_2$  is exhaled in the patient's breath and collected in the metalised PYtest® balloon.
- The balloon contents are transferred to a vial with breath collection fluid (BCF) using a special electric-air-pump. Scintillation fluid is added to the BCF which is then analysed in a microCOUNT Lite beta-counter.

## How the microCOUNT Lite (PYtest analysing machine) Works



Accuracy of a microCOUNT lite.

The PYtest system is extremely accurate because it uses a “liquid scintillation system” of measurement using BETA counters (also known as Liquid Scintillation Counters) or (LSC’s). This is because BETA counters operate at a very high level of “Efficiency” not missing signals of carbon atoms disintegrating. (This is the great advantage of using a liquid scintillation system for <sup>14</sup>C-Urea Breath Test analysis)

This is important as it enables the PYtest® system to give a measure as to the level of infection a patient may have, to assist medical practitioners to determine the dosage and type of medication a patient should be prescribed.

It is also a crucial advantage where degrees of infection are at lower levels as a lower accuracy may miss a low level of infection, leading to a false negative reading.

The BETA counters used in the PYtest system (large automatic BETA counters or a microCOUNT Lite) employ scintillation fluid and Photo Multiplier Tubes (PMTs). These PMTs measure the carbon 14 in the PYtest as it degrades. As carbon 14 degrades (Disintegrates) it releases a BETA particle. The BETA particles interact with the scintillation fluid molecules causing them to emit a light particle (or Photon). Photons are detected by the photo multiplier tubes which are extremely light sensitive. These photons are recorded as Counts Per Minute (CPM) by the Photo Multiplier Tubes. The efficiency of the microCOUNT Lite or other BETA counters are assessed daily using a PYtest-Calibration-Standard-Set.

This daily calibration affords the microCOUNT Lite or larger automated BETA counters to detail a known set of parameters so the actual disintegrations per minute ( DPMs) can be calculated from the Counts Per Minute recorded by the Photomultiplier Tubes. This means the efficiency of an analyser can be calibrated to achieve “100% efficiency” for the readings given by the machine for that day

### Features of The MCL:

- Lightweight (weighs 12.5kgs)
- Footprint is 37x25x17cm
- Built in daily (Quality control) calibration procedure which ensures proper and accurate operation from day to day.
- Quick results in 5 minutes or less
- Affordable and low-cost compared to other analysis equipment
- Easy to use & “Fool-Proof”
- One touch button to obtain results
- Accurate

## PYtest Administration & Analysis in 6 Easy Steps

The patient should have fasted for 4 hours prior to completing the test. The patient should not have taken antibiotics and bismuth containing products for 1 month, proton pump inhibitors for 1 week and cyto-protective medicines such as sucralfate for 2 weeks prior to the test. This is because such medications will decrease the DPM readings and may give false-negative results.

### Step 1

The PYtest® Kit should be opened up and all components laid out.

PYtest Kit Includes:

- 2 paper cups
- PYtest® balloon
- PYtest® capsule
- A straw
- A courier/mail box for the balloon should the breath sample need to be posted or air-freighted



### Step 2

The Patient swallows a PYtest® capsule (containing a small amount of  $^{14}\text{C}$ -labelled urea) with 30mls of water using paper cup provided. Wait 3 minutes then swallow the second cup of water and wait for another 7 minutes before proceeding to Step-3. When the  $^{14}\text{C}$ -urea comes into contact with *H.pylori* in the stomach, it is hydrolyzed into  $^{14}\text{C}$ -carbon dioxide and ammonia. The  $^{14}\text{C}$ -carbon dioxide ( $^{14}\text{CO}_2$ ) enters the bloodstream and is carried to the lungs via the circulatory system and is exhaled by the patient.



### Step 3

Ten minutes after ingesting the capsule, a breath sample is collected in a special metalised mylar balloon. The balloon containing the breath sample may be analysed on-site or sent to a pathology laboratory for analysis. The balloons have been altitude tested so they can be air-freighted if required.



### Step 4

The contents of the balloon are transferred into breath collection fluid specially formulated to absorb a known quantity of carbon-dioxide, then liquid scintillation fluid is added to complete the mixture for analysis in the microCOUNT Lite machine.



### Step 5

The Tri-Med designed microCOUNT Lite Liquid Scintillation Counter analyses the breath sample. Compact in size, the microCOUNT provides results in five minutes on a LCD display panel and the printer gives a permanent record of the readings. If the breath sample contains  $^{14}\text{CO}_2$ , it indicates that the patient has an infection of *H. pylori*. If *H. pylori* is not present,  $^{14}\text{CO}_2$  does not appear in the breath sample and the  $^{14}\text{C}$ -urea is excreted in the urine of the patient, unchanged.



### Step 6

On-site test administration takes 10 minutes and analysis can be completed in less than 5 minutes. Therefore, test results can be discussed with the patient and treatment prescribed before the patient leaves the testing site.



**DPM < 50 = Confirmed Negative for *H. pylori***

**50 < DPM < 200 = Border Line Positive Indicates a low level infection)**

**(If a Borderline Positive is obtained the same breath sample should be re-counted again in the microCOUNT Lite machine after 20 minutes.**

**DPM > 200 = Confirmed Positive for *H.pylori***

The highest reading recorded was 5600 DPM. A typical infection is 900 to 1500 DPM.

## General Information on *H. pylori* Infections

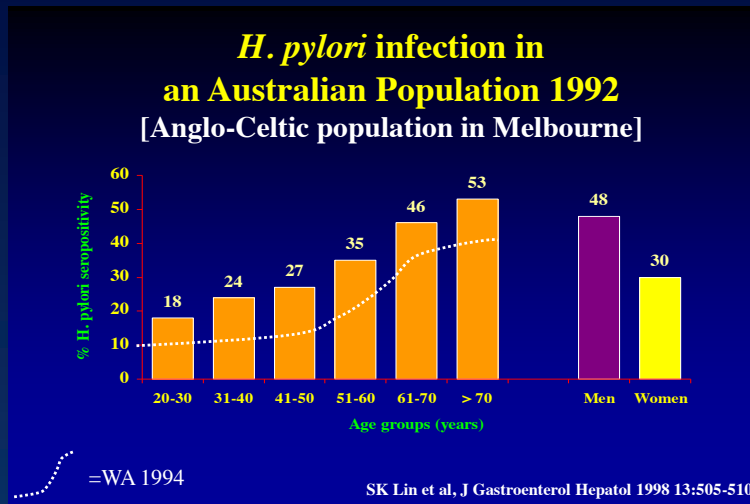
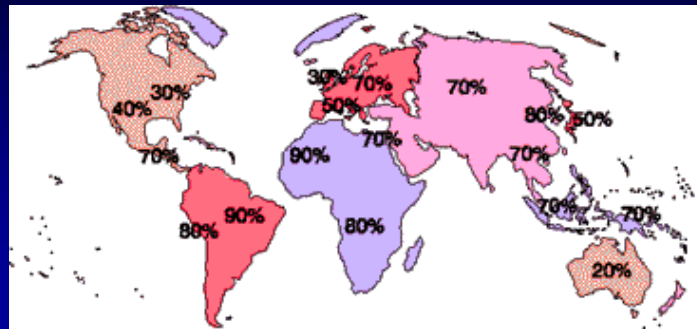


Illustration showing that *H. pylori* prevalence tends to increase with age

## Global Prevalence of *H. pylori* (Epidemiology)



Obtained from [www.helico.com](http://www.helico.com) (the Website of Helicobacter Foundation)



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