

[¹⁴C]Urea Breath Test brochure

[¹⁴C]-Urea breath test (UBT) is used for the detection of the presence of 'Helicobacter Pylori' in the human stomach.

Helicobacter Pylori

It is a gram negative, spiral shaped, urease producing bacterium that lives in the stomach and duodenum. It is mainly responsible for peptic ulcer and gastritis in human beings.

Principle of the test

There is an abundant supply of urea in stomach but there is no natural urease enzyme in the human body. Urease is secreted by H. Pylori which converts urea into carbon dioxide and ammonia. By taking advantage of this reaction, ¹⁴C- urea is given to the patient in the form of capsule and the ¹⁴C- labelled carbon dioxide exhaled by affected patient is monitored to confirm the infection. The amount of radioactivity present in each sample represents the amount of ¹⁴C- carbon dioxide exhaled which is proportional to the amount of ¹⁴C- urea metabolized by the bacteria

How is the test done ?

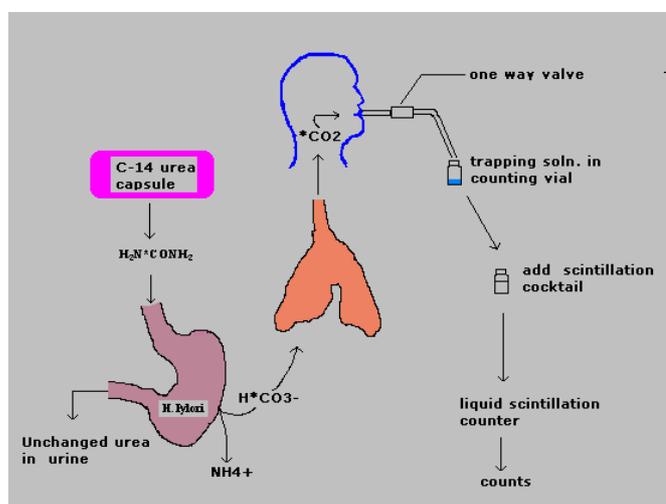
It involves three steps-

- 1] Patient takes the capsule.
- 2] Patient blows air as bubbles in the trapping solution.
- 3] Radioactivity in breath sample is quantified using liquid scintillation counter.

How does the test work ?

¹⁴C- urea in the capsule is split into ammonium and ¹⁴C-labelled bicarbonate ions in the stomach by urease produced by 'H. Pylori'. ¹⁴C- bicarbonate anions reach blood stream, get transported to the lungs and are subsequently exhaled as ¹⁴C-labelled carbon dioxide into breath. It is

absorbed in the trapping solution and later quantified using liquid scintillation counter.



Data on ¹⁴C – urea

Carbon-14 is a pure beta emitter with a physical half-life of 5730 years and maximum energy of 156 KeV. Measurement of beta emissions from ¹⁴C is carried out in a liquid scintillation counter.

The effective dose from an administered activity of 37 KBq (1 microcurie) ¹⁴C – urea is extremely low, about 0.3 millirems. This is roughly equivalent to a sixtieth of that from a chest X-ray and less than daily background exposure.

Composition of Capsule

Form	:-	Gelatin capsule containing ¹⁴ C – urea adsorbed on 350 mg of NPS
Radioactivity	:-	1 μCi (37 KBq)
Gelatin Capsules (size 1)	:-	77 mg (average)
Cap / Body colour	:-	Black / Orange
NPS (filler)	:-	Cellulose / Lactose / Talc / Starch
Radiochemical Purity	:-	Greater than 99%.
Specific activity	:-	1 μCi (37 KBq) / mg of urea.
Storage	:-	Stored under a silica gel desiccant.
Expiry period	:-	Stable at least for six months

Limitations of the test

1] The test has been evaluated in patients attending for elective endoscopy.

2] Test results should be evaluated with clinical signs and patient history when diagnosing H. Pylori infection.

3] The performance characteristics of the test have not been established for monitoring the efficacy of antimicrobial therapies for the treatment of H. Pylori infection.

4] A false positive test could occur in patients who have achlorhydria.

5] Very rarely, a false positive test may occur due to urease associated with Helicobacters other than H. Pylori (i.e. Helicobacter heilmann)

6] A negative result does not completely rule out the possibility of H. Pylori infection. If clinical signs and patient history suggest H. Pylori infection, use of an alternative diagnostic method can be adopted.

Trapping Solution

It contains 2 ml of 0.5 M hyamine hydroxide in methanol corresponding to 1mM of hyamine hydroxide solution with a trace amount of thymolphthalein blue indicator. The solution is blue in colour and turns to colourless after trapping 1mmole of carbon dioxide in breath test.

Caution :

1] Hyamine is a corrosive and caustic alkali. While collecting breath directly into the trapping solution, one must supervise the patient and ensure that unidirectional valve and safety trap are used.

2] The amount of hyamine (1 mmole) is not sufficient to cause serious poisoning. Local irritation to skin or mucous membranes is likely when the solution is blue. After collecting the breath, the collection fluid is clear and it is less dangerous as the pH is near neutral.

3] If the collection fluid splashes onto the skin or eyes, wash immediately with water. If the collection fluid is accidentally ingested, wash the mouth with water and have the patient drink 250 ml of water immediately. Consult the doctor immediately.

Breath collection assembly

It is a simple disposable system to collect the breath sample where a piece of plastic tubing is used to bubble the patient breath through a trapping solution in a scintillation vial . An unidirectional valve and a safety trap are used to prevent the back suction of the trapping solution.



Advantages of ¹⁴C- urea breath test over conventional test

In histological method , the presence of H. Pylori in the biopsy specimen is demonstrated by Warthin Starry Silver method of staining. In rapid urease test generally known as ‘clo’ test , biopsy specimen is placed in a medium that contains urea . Urease secreted by H. Pylori converts urea into ammonia which changes the pH of the medium as indicated by the change in colour. In microbial culture, the biopsy specimens are grown in micro - aerophilic conditions.

Since all these invasive methods require endoscopic biopsy, these are not only expensive and time consuming but also require an experienced practitioner.

In non – invasive methods , the serology test is done by ‘ELISA’ method where the antibody responsible for H. Pylori is detected. The method is accurate but the disadvantage of the method is that it cannot

be used to confirm the eradication of the pathogen after the treatment, since the antibodies are likely to be present in the body for quite a long time.

Considering all the disadvantages of the above conventional methods, the ^{14}C -urea breath test is preferred because of its simplicity, accuracy, less time consumption and cost effectiveness. Above all, the importance of this method is that it is not only used to diagnose the H. Pylori infection alone but also to confirm the eradication of the pathogen in post treatment. It is a versatile nuclear medicine test employed widely all over the world.
