

SECTION: Clinical

Procedure No. 02133v1/v1/01/2018

PROCEDURE TITLE: *Helicobacter pylori* ¹³C Urea Breath Test

Review Officer: Senior Scientist,
Gastroenterology & Hepatology

Review Summary: v1

Applicable To: All Gastroenterology &
Hepatology Laboratory Staff

Date Introduced: 01/2018

Next Review Date: 01/2021

Authority: Director, Gastroenterology &
Hepatology

Replaces: New procedure

Key Words: H pylori, urea, breath test

PURPOSE

To ensure that the urea breath test is administered correctly, thus minimising inconclusive tests

OUTCOME

The test is administered correctly and efficiently

AUTHORISED TO UNDERTAKE THE PROCEDURE

Laboratory staff at the Gastroenterology and Hepatology Department

INDICATIONS

The test is used to detect gastric urease as an aid to the diagnosis of active colonisation of *H.pylori* in the stomach

RISKS AND PRECAUTIONS

- Capsule could be stuck in the throat. Encourage patient to drink water
- Patient not following instructions

STEPS OF THE PROCEDURE

Description of Test

Helicobacter pylori (*H. pylori*), is the most common cause of histological gastritis, (inflammation of the stomach), which can lead to peptic ulcer and gastric cancer. The bacteria have very high urease levels, which is the basis of diagnostic tests for detecting abnormal gastric colonisation. After an oral dose of ¹³C-urea, ¹³CO₂ rapidly appears in the breath in *H.pylori* positive subjects.

Pre-Procedure Assessment and Care

1. Prior to the test date the patient should cease:
 - a. Antibiotics or bismuth containing products for 4 weeks
 - b. Sucralfate for 2 weeks and
 - c. Proton pump inhibitors for 1 week
2. The patient should not eat or drink anything for 1 hour prior to the test
3. Smoking should be ceased 6 hours prior to the test.

Patient Teaching

- Provide patient with written and/or verbal instructions for conduction of the test.
- Explain the purpose and length of time of the test, techniques used and the sensation the patient is likely to experience.

Equipment

- IRIS foil breath collection bags and stoppers and disposable mouthpiece (available from Wager Analysen Technik Pty Ltd; *Paul Chew*)
- Disposable drinking cup
- Tablet cup
- Stopwatch
- Diabact ¹³C Urea tablets (Diatab ¹³C Urea tablet pack, Medical Diagnostics Australasia)
- IRIS (¹³C Infra-Red isotope analysis system – Wagner Analysen Technik)

Procedure

1. The patient should be sitting at rest – check compliance with instructions.
2. Label the sections of the collection bag. Label breath collection bag. The bag has 2 sections, one for a basal breath sample and the other for the 10 min breath sample.
3. Wearing gloves, position the mouthpiece on section 1 for the basal breath sample.

4. Request the patient to take a normal breath through the nasal passage and inflate the bag.
5. Remove the mouthpiece and plug the bag. Position the mouthpiece onto the second section of the split collection bag.
6. Do not handle the capsule directly but slip it into a disposable tablet cup.
7. Place 100 mL water in the second disposable drinking cup.
8. Ask the patient to tip the capsule into the mouth and then swallow it with water.
9. Start the stopwatch.
10. At 10 minutes, collect a second breath sample as per the first. Plug this bag as per previous and dispose of the mouthpiece. The contents are now ready for analysis on IRIS.
11. The patient may now go home.

Sample Analysis: Infra-Red Isotope Analyser (Iris)

1. Ensure that the IRIS is calibrated appropriately.
2. Position bags onto ports 1 and 2 on the IRIS.
3. Initiate the sample analysis as per instructions.

Data Analysis

Print out result. The IRIS software computes positivity or negativity.

EVALUATION METHOD

The Gastroenterology and Hepatology Clinical Laboratory Scientist will monitor the procedure and keep it updated with any appropriate changes.

REFERENCES

1. Di Rienzo TA, D'Angelo G, Ojetti V, Campanale MC, Tortora A, Cesario V, Zuccalà G, Franceschi F. ¹³C-Urea breath test for the diagnosis of Helicobacter pylori infection. Eur Rev Med Pharmacol Sci. 2013;17 Suppl 2:51-8.