



H. PYLORI QUICK BREATH TEST

Clinician and Patient Information Sheet

INTRODUCTION

Diabect 13 C Quick Breath Test is a breath test that can be used in patients over the age of 18 to determine whether or not there is infection in the stomach caused by the bacterium *H. pylori*. This test is not currently licensed for use on children and antigen testing from stool samples is recommended for children.

Infection with *H. pylori* is one of the world's most common human bacterial infections. The strong correlation between the presence of *H. pylori* and historically confirmed gastritis, peptic ulcer disease and gastric carcinoma, as well as disease resolution after *H. pylori* eradication, indicates a causative relationship. Enough is now known that to cure peptic ulcer disease with antimicrobial therapy is more effective and cheaper than to put patients on long term acid suppressive therapies. Detection of *H. pylori* has become a key step in the management of patients with gastric symptoms.

The benefit from testing for *H. pylori* antigen from breath or stool samples for active infection as opposed to serum antibody testing is well documented and universally accepted. Breath testing has become established as gold standard with high specificity and sensitivity (sensitivity of 96.1% and specificity of 95.7%). Breath testing for *H. pylori* is not designed to replace serological assessment which measures the presence of antibodies; instead, it is very appropriate non-invasive diagnostic and treatment management tool for active infection in the gastric mucosa, either for first line diagnosis or post treatment/eradication monitoring.

The introduction of Quick Breath Testing for *H. pylori* with the ¹³C-Urea in tablet form uses blow bags instead of breath collection tubes and straws. The principle remains the same: active *H. pylori* produces excess quantities of carbon dioxide. Capture of breath in blow bags compares identically in performance to conventional breath testing.

BENEFITS

- 1 This method condenses the procedure from approximately 40 minutes to 10 minutes.
- 2 The procedure can easily be incorporated into a consultation as a practice procedure.
- 3 Patients need to fast for only 6 hours.
- 4 It is less expensive than conventional breath sampling, serum antibody, or stool antigen testing.
- 5 Testing in the laboratory is performed daily.

The tablet, which is for oral administration, contains the active substance ¹³Carbon (¹³C)-urea.

The diagnostic kit contains the following:

Component	Quantity
¹³ C-urea tablet, 50 mg (blister packed)	1
2 blow bags for pre and post blow bags	2
Doctor / Patient Information sheet	1
Bag 1 and Bag 2 patient name labels	2

BEFORE USING THE DIABECT BREATH TEST

- The patient should have fasted for at least 6 hours before the test is performed.
- The test should not be used until at least 4 weeks after using antibiotics.
- The test should not be used until at least 14 days after using proton pump inhibitors.
- The test should not be used until at least 3-4 days after using H2 antagonists and other peptic ulcer treatments.

EXPLANATION OF INHIBITORY DRUGS

Antibiotics, proton pump inhibitors, and H2 antagonists must not have been taken for specified periods before the test is performed. False negative results could be obtained due to suppression of *H. pylori*.

Proton Pump Inhibitors

Common Proton Pump Inhibitors:

Omeprazole	(Losee)	Esomeprazole	(Nexium)
Lansoprazole	(Zoton)	Pantoprazole	(Protium)
Rabeprazole sodium	(Pariet)		

H2 Antagonists

Common H2 Antagonists:

Cimetidine	(Tagamet, Dyspamet)	Famotidine	(Pepcid)
Nizatidine	(Axid)	Ranitidine	(Zantac)
Ranitidine bismuth citrate	(Pylorid)		

Patients should not undertake the diabect UBT test if there is a documented or suspected gastric infection or atrophic gastritis, as this may interfere with the urea breath test. As the diabect UBT may be affected by other medicine that you are currently taking or have been taking within the last 28 days. It is not expected that performing the breath test during pregnancy or lactation has a damaging effect.

TESTING YOUR PATIENT FOR H. PYLORI WITH DIABECT UBT

The test should be performed in the presence of a qualified person. It is important to follow the instructions in order to obtain the correct result. The test should be performed after 6 hours fasting.

- 1 Please complete the patient labels provided with the kit. Bag 1 is for the **pre-dose** sample. Bag 2 is for the **post-dose** sample. Stick the labels on the bags before testing.
- 2 Begin the procedure by taking Bag 1, the **pre-dose** blow bag 00 minutes and remove the yellow stopper.
- 3 The patient needs to take a deep breath, blow out a small amount of air, pause, and then continue to capture the rest of the breath in Bag 1; making sure the bag is well filled.
- 4 Pinch the stopper and seal the bag by replacing the yellow stopper.
- 5 **Swallow the tablet WHOLE** with a glass of water and wait for 10 minutes.
NB: If the tablets are chewed the test must be performed again as the risk of false positive results increases. A new test may be performed the following day. It is not possible to overdose with diabet UBT 50 mg tablets ¹³Carbon (¹³C)-urea.
- 6 Repeat instruction 3 and blow into Bag 2 in the same way as described in point 3.
- 7 After the test has been performed, the two full bags need to be sent to the laboratory for analysis. Please ensure the patients' request form is enclosed in the sample bag.

Side Effects

The tablet contains ¹³C-urea which is a harmless substance that occurs naturally in the body. On rare occasions a sour taste in the mouth may be reported.

Storing diabet UBT

Keep out of the reach and sight of children. Store in the original packaging.

Do not store above 25°C.

Do not use after the expiry date stated on the tablet wrapping.