ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Pylobactell, 100 mg, Soluble Tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance	Quantity per tablet
^{13}C-urea	100 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Soluble tablet
A white, biconvex tablet.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

This medicinal product is for diagnostic use only.
For *in vivo* diagnosis of gastroduodenal *Helicobacter pylori* infection.

4.2 Posology and method of administration

Pylobactell is not recommended for use in children below the age of 18 years due to insufficient data on efficacy.

The Pylobactell tablet is for oral administration.

Adults: The tablet is to be dissolved in water and taken 10 minutes after the start of the breath test procedure.

The patient should fast for at least 4 hours before the test so that the test is taken on an empty stomach. If the patient has eaten a heavy meal then it will be necessary to fast for six hours prior to the test.

It is important to follow the instructions for use described in Section 6.6 adequately, otherwise the validity of the test result will be questionable.

4.3 Contraindications

The test must not be used in patients with documented or suspected gastric infection that might interfere with the urea breath test.
Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

A positive urea breath test alone does not clinically confirm that eradication therapy is indicated. Alternative diagnosis with invasive endoscopic methods might be indicated in

order to examine the presence of any other complicating conditions, eg. gastric ulcer, autoimmune gastritis and malignancies.

In individual cases of atrophic gastritis, the breath test result may have a false positive outcome and other tests may be required to confirm the presence of *H.pylori*.

If a repeat test is required, it should not be carried out until the following day.
For patients who do not tolerate the recommended test meal, an alternative test meal should be given. Care should be taken in patients where fasting may have medical implications.

There are insufficient data on the diagnostic reliability of the Pylobactell test to recommend its use in patients with partial gastrectomy and in patients younger than 18 years.

4.5 Interaction with other medicinal products and other forms of interaction

The validity of the test result may be affected if the patient is currently being treated with antibiotics or a proton-pump inhibitor or has completed a course of treatment with these drugs. The results may be affected in general by all treatments interfering with *H.pylori* status or urease activity.

Suppression of *H. pylori* might give false negative results. Therefore, the test must not be used until four weeks without systemic antibacterial therapy and two weeks after last dose of acid antisecretory agents. This is especially important after eradication therapy.

4.6 Fertility, pregnancy and lactation

The endogenous production of urea amounts to 25 - 35 g/day. It is therefore unlikely that the dose of 100 mg urea should cause any adverse effect on pregnancy and lactation.

The Pylobactell test is not expected to be harmful during pregnancy or to the health of the foetus / newborn child. Pylobactell can be used during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

None known.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V.

4.9 Overdose

Overdose is unlikely to occur in the intended clinical circumstances. No case of overdose has been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other diagnostic agents

ATC code: V04C X.

In the case of infection with *H.pylori*, orally ingested ^{13}C-urea is metabolised by the enzyme urease which is present in *H.pylori*.

$H_2N(^{13}CO)NH_2 + H_2O \rightarrow 2NH_3 + {}^{13}CO_2$

The carbon dioxide which is liberated diffuses into the blood vessels and is transported as bicarbonate to the lungs where it is then liberated as $^{13}CO_2$ in exhaled air. Infection with *H.pylori* will significantly change the $^{13}C/^{12}C$ - carbon isotope ratio.

The proportion of $^{13}CO_2$ in the breath samples may be determined by isotope-ratio-mass spectrometry (IRMS) or by another suitably-validated method carried out by any qualified laboratory, and stated as an absolute difference (excess) in the value between the pre-urea and post-urea breath samples (see Section 6.6).

The cut off point for discriminating between *H.pylori* negative and positive patients is set to an excess value of 3.5, i.e. <3.5 is negative and ≥3.5 is positive.

In comparison with biopsy based techniques for diagnosing *H.pylori* infection, using data from two therapeutic trials, Pylobactell achieved during different conditions (prestudy and follow-up visits) sensitivity estimates above 95 % with lower one-sided 95 % confidence limit ranging from 93 % to 98 %. The specificity estimates were all above 90 % with corresponding lower confidence limits ranging from 85 % to 90 %.

5.2 Pharmacokinetic properties

Urea is rapidly absorbed from the gastro-intestinal tract and distributed into extracellular and intracellular fluids including lymph, bile, cerebrospinal fluid and blood. It is reported to cross the placenta and penetrate the eye. It is excreted unchanged in the urine.

5.3 Preclinical safety data

There are no concerns in relation to the clinical use of the product.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Povidone (E1201)
Microcrystalline Cellulose (E460i)
Colloidal Anhydrous Silica
Sodium Benzoate (E211)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years. The dissolved tablet must be taken immediately.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

The Pylobactell ^{13}C-urea breath test kit contains a sachet containing the Pylobactell tablet, six glass tubes with caps and bar code labels, three additional bar code labels, a 30 ml mixing and administration glass vial with cap, two straws, a package leaflet and an Analysis Request Form. A security label for re-sealing the kit is also provided.

The Pylobactell breath test procedure includes the administering of a suitable test meal. This is not supplied within the box.
The Pylobactell tablet container is a heat-sealed PET/aluminium foil/LDPE laminated sachet.

6.6 Special precautions for disposal and other handling

The patient should fast for at least 4 hours before the test so that the test is taken on an empty stomach. If the patient has eaten a heavy meal then it will be necessary to fast for six hours prior to the test.

It is recommended that the breath test is performed while the patient is in a seated position.

Sampling instructions

t = 0 minutes Note the time the patient drinks the test meal.

t = 5 minutes Collect pre-urea breath samples. Three tubes of breath are to be taken by breathing normally through a straw held at the base of a small tube (white top). The patient must expire as the straw is slowly and completely withdrawn from the tube, which is then immediately capped. These breath samples are used to measure the natural level of ^{13}C in the carbon dioxide of the breath.

t = 10 minutes The Pylobactell tablet is placed in the 30 ml mixing vial and water added to the marked line. The bottle is capped and shaken well to dissolve the tablet. The entire contents must be swallowed immediately by the patient, the bottle is refilled with water to the line and the entire contents are again swallowed by the patient.

t = 40 minutes Collect post-urea (red top) breath samples. Three tubes of breath are to be taken, which are used to measure the presence of excess levels of ^{13}C, which will be present if the patient is *H.pylori* positive.

On completion of the test retain one pre-urea sample (white top) and one post-urea sample (red top). Return two pre-urea and two post-urea samples to the box. Safely discard the 30 ml mixing vial. Complete the Analysis Request Form; attach one of three spare bar code labels to the area marked "AFFIX BAR CODE LABEL HERE". This bar code is the doctor's reference number used at the analysing laboratory as a patient identifier; the two spare bar code labels are for the doctor's use on the patient notes/files etc.

After placing the four sample tubes and paperwork into the box, use the security label provided to seal the lid of the box, and send to a qualified laboratory for analysis.

The optimal test meal recommended is 200 ml pure undiluted orange juice.

Analysis of breath samples and testing specification

The accuracy and precision of the test depends heavily on the quality of the analysis and therefore only laboratories having appropriate certification are considered qualified to analyse the breath samples.

Satisfactory specificity and sensitivity have been demonstrated in clinical studies where breath was analysed using isotope ratio mass spectrometry (IRMS).

Breath samples collected during a test must remain in the original containers before analysis by IRMS.

IRMS instruments may be of continuous flow or dual inlet configuration.

A multi-position autosampler and bar code reader should be used to allow samples to be tracked throughout the analysis.

IRMS source parameters and tuning must be optimised daily.

Instruments must be linear over a wide range of CO_2 concentrations, typically 1.0 - 6.0%. This should be checked routinely.

Internal analytical precision must be less than $\pm$ 0.3 ‰ $\delta^{13}C$ for 20 replicate analyses of the same reference gas sample and remain within 3SD's of the mean for breath analyses.

Transfer of the breath sample through the analytical system must be accomplished without isotope fractionation.

The IRMS must possess a triple collector to allow the simultaneous detection of the ions at mass/charge ratio 44, 45 and 46 fluctuations in the oxygen isotope content.

There must be provision for correction of instrumental drift during an analysis.

Reference gases must be standardised against an appropriate international standard to allow inter-laboratory comparison of results.

Alternatively, any other suitably-validated method may be used, carried out by any objectively qualified laboratory.

Explanation of results:-

$\delta\ ^{13}C$:- Difference in parts per thousand (‰) with respect to an accepted international standard.
Excess $\delta^{13}C$:- Difference between pre- and post-urea sample measurements.

H. pylori status: -< 3.5 excess $\delta^{13}C$ = Negative
$\geq$ 3.5 excess $\delta^{13}C$ = Positive

7. MARKETING AUTHORISATION HOLDER

Richen Europe S.R.L
VIA San Cristoforo
78-20090
Trezzano Sul Naviglio (Ml)
Italy

Tel: +39 327 972 2938
Email: richencortexeurope@pec.it

8. MARKETING AUTHORISATION NUMBER

EU/1/98/064/001

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 07 May 1998
Date of latest renewal: 07 May 2008

10. DATE OF REVISION OF THE TEXT

Detailed information on this medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu.

ANNEX II

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. OTHER CONDITIONS AND REQUIRMENTS OF THE MARKETING AUTHORISATION

D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

Idifarma Desarrollo Farmaceutico S.L.
Polígono Mocholí
C/ Noáin, No.1
31110 Noáin
Navarra,
Spain

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Medicinal product subject to medical prescription

C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

- **Periodic Safety Update Reports**

The requirements for submission of periodic safety update reports for this medicinal product are set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and any subsequent updates published on the European medicines web-portal.

D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

Not applicable

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON/CARDBOARD BOX

1. NAME OF THE MEDICINAL PRODUCT

Pylobactell, 100 mg, soluble tablet
^{13}C-urea

2. STATEMENT OF ACTIVE SUBSTANCE(S)

One tablet contains: 100 mg ^{13}C-urea

3. LIST OF EXCIPIENTS

Povidone (E1201), Microcrystalline Cellulose (E460i), Colloidal Anhydrous Silica, Sodium Benzoate (E211).

4. PHARMACEUTICAL FORM AND CONTENTS

The kit contains:

A sachet containing one Pylobactell 100 mg soluble tablet.
Six glass tubes, with caps and bar code labels.
30 ml mixing and administration glass vial with cap.
Two straws.
Package Leaflet.
Analysis Request Form.
Security Label and three additional bar code labels.

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Diagnostic test kit
FOR ORAL ADMINISTRATION
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

8. EXPIRY DATE

EXP: {MM/YYYY}

9. SPECIAL STORAGE CONDITIONS

Do not store above 25°C

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Richen Europe S.R.L
VIA San Cristoforo
78-20090
Trezzano Sul Naviglio (Ml)
Italy

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/98/064/001

13. BATCH NUMBER

BN

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

16. INFORMATION IN BRAILLE

Pylobactell

17. UNIQUE IDENTIFIER – 2D BARCODE

Not applicable

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

Not applicable

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

SACHET LABEL

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Pylobactell, 100 mg, soluble tablet
^{13}C-urea
Oral

2. METHOD OF ADMINISTRATION

To be dissolved in water and taken orally. Read the package leaflet before use.

3. EXPIRY DATE

EXP {MM/YYYY}

4. BATCH NUMBER

Batch

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

One tablet

6. OTHER

Richen Europe S.R.L
VIA San Cristoforo
78-20090
Trezzano Sul Naviglio (Ml)
Italy

EU/1/98/064/001

ADDITIONAL KIT ITEM: MIXING AND ADMINISTRATION VIAL

LABEL

Fill to line with water
Dissolve tablet from sachet
Shake well to dissolve
When dissolved, drink entire contents
Refill with water to line, shake bottle and drink
Discard this bottle after use
Do not return with kit

ADDITIONAL KIT ITEM: SECURITY LABEL

LABEL

Seal lid of box before returning samples for analysis

B. PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

Pylobactell 100mg soluble tablet
^{13}C-Urea

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. WHAT PYLOBACTELL IS AND WHAT IT IS USED FOR

Pylobactell is a breath test for determining the presence of the bacterium, *Helicobacter pylori* (*H. pylori*) in the gut (stomach and adjacent bowel) which may be the reason for your stomach (gastric) condition.

Your doctor has recommended that you have a ^{13}C-Urea breath test, for one of the following reasons:
- Your doctor wants to confirm whether you are suffering from *H. pylori* infection to help diagnose your condition.
- You have already been diagnosed with *H. pylori* and have been taking medication aimed to clear up the infection. Your doctor now wants to find out if the treatment has worked.

This medicine is for diagnostic use only.

How does the test work?
All foods contain a substance called carbon 13 (^{13}C), in varying amounts. This ^{13}C can be detected in the carbon dioxide that you breathe out of your lungs. The actual amount of ^{13}C in the breath will depend on the type of food that you have eaten.

You will be asked to drink a "test meal". This will help keep the test ^{13}C-urea solution in your stomach.

Following the meal, 3 samples of your breath will be taken. These samples will be analysed to measure the normal amount of ^{13}C in the carbon dioxide in your breath.

You will then drink the Pylobactell ^{13}C-urea solution. If *H. pylori* is present and active in your stomach, these bacteria will break down the ^{13}C-urea and this is detected in the carbon dioxide in your breath.
A further 3 samples of your breath will then be taken 30 minutes later.

The amount of ^{13}C in these samples will be compared to your normal level. If there is a significant increase in the amount of ^{13}C, this will let your doctor know that active *H. pylori* is present.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE PYLOBACTELL

DO NOT use Pylobactell if you:
- are allergic to ^{13}C-urea or to any of the other ingredients of this medicine (listed in Section 6).
- suffer from any medical condition that you think may affect, or be affected by, the test.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before using Pylobactell if:
- part of your stomach has been removed (partial gastrectomy) as the reliability of the test has not been proven in these patients
- you have or suspect you have a gastric infection
- you have long term stomach problems (atrophic gastritis) as the breath test may give the wrong result and other tests may be required to confirm the presence of *H. pylori*.
- fasting (not taking food) may have medical implications for you
- you are under 18 years.

Other medicines and Pylobactell
Please tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Do not take the test if:

- **You have taken antibiotics or medication to treat Helicobacter pylori within the last 28 days**

- **You have taken proton pump inhibitors in the last 14 days**

- **You have taken H2 antagonists or antacids on the same day of the test.**

Do not stop taking medication without the advice of your doctor.

Taking Pylobactell with food and drink
You should fast for at least 4 hours before the test so that the test is taken on an empty stomach. If you have eaten a heavy meal it will be necessary to fast for six hours before the test.
You can drink water during the fasting period.
If fasting is a problem e.g. for diabetic patients, please tell your doctor, pharmacist or nurse.

Pregnancy and breast-feeding
Pylobactell can be used during pregnancy and breast-feeding.

Driving and using machines
This test should not affect your ability to drive or use machines.

3. HOW TO USE PYLOBACTELL

Always use this medicine exactly as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

The test will take about 45 minutes. A supply of drinking water will be needed.
It is recommended that the breath test is performed while you are in a seated position.
You must not smoke before or during the test.

The test procedure involves the following steps:
(A brief form of these instructions is included on the back of the Analysis Request Form)

1. **Fasting**:
   You should fast for 4 hours before taking the test (See Section 2 *Taking Pylobactell with food and drink*)

2. **Test Meal**:
Drink the recommended test meal. This is not included in this kit but may have been supplied separately. If no test meal has been supplied, the most suitable test meal is 200 ml of pure undiluted orange juice. If you cannot take the recommended test meal, an alternative test meal should be taken. Your doctor will advise you.

3. **Wait 5 minutes**

4. **Pre-test Breath Samples** (3 White Capped Tubes)

i. Remove the cap from the tube
ii. Breathe out through your mouth, using a straw, into the sample tube.
iii. Gradually remove the straw from the tube as you breathe out.
iv. Immediately replace the cap.
v. Repeat with remaining white capped tubes.

It is not necessary to blow hard into the tubes, just breathe normally and cap them quickly.
Try to avoid getting saliva in the tubes.

5. Preparing the **^{13}Carbon-urea solution**
Open the tablet sachet and empty the tablet into the mixer vial.
Add water to the mark on the vial and replace the cap.
Gently shake the vial to dissolve the tablet.
Drink the solution. Note the time upon drinking.
Fill the vial to the mark again with water and drink.

6. **Wait 30 minutes** from the time of drinking the Pylobactell ^{13}C-urea solution. Do not smoke, eat or drink during this time. This is important for the proper functioning of the test.

7. **Post-test Breath Samples** (3 Red Capped Tubes)
Using the red-capped, take samples of your breath as before (see step 4).

8. **Analysis Request Form**
Fill out the analysis request form with patient details on the left hand side of the form and the doctor's name and address on the right hand side.

9. **Test is now complete**
Put your breath samples and the completed Analysis Request Form back into the carton and send to the address supplied by your doctor. Your doctor will tell you when the results of your test will be available and who to contact for these results.

Dispose of the empty sachet, mixing vial and straws as normal waste, but keep this leaflet for reference.

If a repeat test is required, it should not be carried out until the following day.
If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. POSSIBLE SIDE EFFECTS

No side effects to Pylobactell have been reported. ^{13}C and urea are harmless naturally occurring substances which are found in your body.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting

system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE PYLOBACTELL

Keep out of the sight and reach of children.
Do not store the kit above 25°C.
The tablet must be taken when dissolved.
Do not use Pylobactell after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What the Pylobactell tablet contains

- The **active** substance is ^{13}C-urea. Each tablet contains 100 mg of ^{13}C-urea
- The **other** ingredients are povidone (E1201), microcrystalline cellulose (E460i), colloidal anhydrous silica and sodium benzoate (E211).

Each Pylobactell Breath Test kit contains:

- 1 Sachet containing 1 tablet.
- 6 glass tubes, 3 with white caps and 3 with red caps.
- 30 ml glass mixing tube with cap.
- 2 straws.
- Package Leaflet
- Analysis Request Form.
- Security Label and 3 additional bar code labels.

The contents of this kit are sufficient for a single test. If you need to repeat the test, a new kit will be required and it should not be carried out until the following day.

Marketing Authorisation Holder

Richen Europe S.R.L
VIA San Cristoforo
78-20090
Trezzano Sul Naviglio (Ml)
Italy

Tel: +39 327 972 2938
Email: richencortexeurope@pec.it

Manufacturer

Idifarma Desarrollo Farmaceutico S.L., Polígono Mocholí, C/ Noáin, No.1, 31110 Noáin, Navarra, , Spain.

For any information about this medicine, please contact the Marketing Authorisation Holder:

This leaflet was last revised in

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.

Analysis of breath samples and testing specification

The accuracy and precision of the test depends heavily on the quality of the analysis and therefore only laboratories having appropriate certification are considered qualified to analyse the breath samples.

Satisfactory specificity and sensitivity have been demonstrated in clinical studies where breath was analysed using isotope ratio mass spectrometry (IRMS).

Breath samples collected during a test must remain in the original containers before analysis by IRMS.

IRMS instruments may be of continuous flow or dual inlet configuration.

A multi-position autosampler and bar code reader should be used to allow samples to be tracked throughout the analysis.

IRMS source parameters and tuning must be optimised daily.

Instruments must be linear over a wide range of CO_2 concentrations, typically 1.0 - 6.0%. This should be checked routinely.

Internal analytical precision must be less than $\pm$ 0.3 ‰ $\delta^{13}C$ for 20 replicate analyses of the same reference gas sample and remain within 3SD's of the mean for breath analyses.

Transfer of the breath sample through the analytical system must be accomplished without isotope fractionation.

The IRMS must possess a triple collector to allow the simultaneous detection of the ions at mass/charge ratio 44, 45 and 46 to allow for fluctuations in the oxygen isotope content.

There must be provision for correction of instrumental drift during an analysis.

Reference gases must be standardised against an appropriate international standard to allow inter-laboratory comparison of results.

Alternatively, any other suitably-validated method may be used, carried out by any objectively qualified laboratory.

Explanation of results:-

$\delta\ ^{13}C$:-	Difference in parts per thousand (‰) with respect to an accepted international standard
Excess $\delta^{13}C$:-	Difference between pre- and post-urea sample measurements

H. pylori status: -

< 3.5 excess $\delta^{13}C$ = Negative

≥ 3.5 excess $\delta^{13}C$ = Positive

ANALYSIS REQUEST FORM:

Pylobactell [^{13}Carbon] -UREA BREATH TEST (^{13}C-UBT) for Helicobacter pylori

ANALYSIS REQUEST FORM - Please complete in block capitals
Please state clearly address for return of results:
Centre:
Patient Name:
Date of Birth:
Patient Reference:
Date of Test:
Referring Doctor:

AFFIX BAR-CODE LABEL HERE
PLEASE PLACE BAR-CODE LABEL ON PATIENT RECORDS, IF APPLICABLE

M.A. Number: EU/1/98/064/001
Marketing Authorisation Holder:

Richen Europe S.R.L
VIA San Cristoforo
78-20090
Trezzano Sul Naviglio (Ml)
Italy

MEDICATION RECORD Medical History - has the patient taken :	Type &Date	**Mins**	TEST CHECK LIST Test Check List	**Time**
(i) antibiotics in the last 28 days? If so, please indicate type and when last taken		t = 0	Note time patient drinks test meal	
(ii) proton pump inhibitors (PPIs) in the last 14 days? If so, please indicate type and when last taken.		t = 5	Collect Pre-Urea samples (White Caps - 3 times)	
(iii) eradication therapy in the last 28 days? If so, please indicate when treatment ended		t = 10	Patient to drink urea solution, then fill bottle to line again and drink.	
(iv) other medication (if applicable)		t = 40	Collect Post-Urea samples (Red Caps - 3 times).	
(v) patient fasted for hours Please note that (i) - (iii) will affect result of test.		Check	Bar-code label and all details entered on Analysis Request Form. 1 x Pre/Post sample reserved in store. 2 x Pre/Post samples + this form for return to a qualified laboratory.	

Laboratory use only
Date received:
Analytical file reference:

Comments:

Laboratory code:
Samples logged on by :