Pylobactell®

^{13}C-urea breath testing for *Helicobacter pylori*.

Pylobactell® An introduction

Urea breath testing

What is the PYLOBACTELL ^{13}C-Urea Breath test and how does it work?

The ^{13}C-Urea Breath Test (^{13}C-UBT) is recognised by Healthcare Professionals [1], [2] as the easiest, safest and most reliable non-invasive test for identifying *Helicobacter pylori* status. It is essential to remember that ^{13}C is a stable isotope and therefore has no associated radioactivity. It should not be confused with the ^{14}C radioactive isotope.

The ^{13}C-UBT takes full advantage of the strong urease activity of *H pylori*. Effectively if urea is introduced into the gut, the *H. pylori* urease enzyme will hydrolyse the urea into ammonia and carbon dioxide. The carbon dioxide produced will be absorbed into the blood system, transported to the lungs and exhaled. If the urea is labelled with the non-radioactive isotope ^{13}C and introduced into the gut colonised by *H. pylori*, the CO_2 produced will be labelled with ^{13}C. If *H. pylori* is not present the urea will pass through the gut with no immediate change in the ^{13}C content of the exhaled CO_2.

Our exhaled breath naturally contains ^{13}C (1.1% of normal body Carbon is ^{13}C). It is therefore necessary to measure a patient's basal $^{13}CO_2$ content (Pre-Dose sample) before drinking the ^{13}C-Urea solution. Peak excretion of $^{13}CO_2$ in *H. pylori* positive subjects is thirty minutes after drinking the ^{13}C-Urea solution (Post–Dose sample).

The difference in ^{13}C content between the Post-Dose and the Pre-Dose samples is expressed as "excess ^{13}C". It is the excess value which is recorded on reports to distinguish between *H. pylori* negative or positive. Excess ^{13}C values greater than 3.5 per mil indicate an *H. pylori* positive status.

In the UK, the ^{13}C UBT was extensively tested in the late 1980's against recognised biopsy methods by the Central Middlesex group under Dr George Misiewicz. These comparisons have been well documented in two publications:

1. Logan RPH, Polson RJ, Misiewicz JJ, Johnson PG et al. A simplified single sample ^{13}C urea Breath test for detection of Helicobacter pylori; comparison with histology, culture and ELISA serology *Gut 1991, **32**, 1461-4*

2. Logan RPH, Dill S, Bauer FE et al. The European ^{13}C-Urea Breath Test for the detection of *Helicobacter pylori*. *Eur. J. Gastroenterology 1991, **3**, 915-21.*

Safety of the Test

The ^{13}C urea breath test is a development of the ^{14}C urea breath test. Where the radioactive nature of ^{14}C means the test is limited to facilities able to handle the compound, ^{13}C-urea tests can be performed by patients and clinical staff. Although the analysis requires instruments not normally found in primary or secondary care, analysis is routinely handled by external laboratories able to cater for the whole healthcare sector regardless of customer size or frequency of testing need.

The Pylobactell Test Kit

The ^{13}C-UBT is completely safe and is regularly used in paediatric studies and is safe for use by expectant mothers. ^{13}C is naturally occurring and represents 1.1% of all Carbon in our body. Therefore, in an average 70kg adult there are 192 grams of ^{13}C naturally present. The normal daily food intake of a 70kg adult will contain approximately 3 grams of ^{13}C.

During the Pylobactell ^{13}C-UBT the subject takes 100 mg ^{13}C-Urea which only represents a further 0.7% of ^{13}C on top of their normal daily intake of ^{13}C. The amount of Urea (100mg) which the subject takes during the breath test is only a small percentage of the average total body urea pool of 10g.

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Breath Testing Information Sheet: Medication

Torbet Laboratories Ltd recommend that certain medication which may influence the ^{13}C-UBT and could give a false negative result should be avoided prior to the test.

The classes of medication and abstention period are as follows:

Class Of Medication	Examples of Medication	Abstention period
H. pylori eradication therapy	HeliMet "triple therapy"	28 days before test
Oral Antibiotics	Amoxycillin	28 days before test
Bismuth compounds	DeNol, bismuth subcitrate	28 days before test
Proton Pump Inhibitors (PPI's)	Omeprazole, Lanzoprazole, Zoton	14 days before test
H2 Receptor Antagonists	Zantac, Cimetidine, Ranitidine	12 hours before the test
Antacid preparations	Gaviscon	12 hours before the test

There are a few natural remedies promoted for treating ulcers and/or by inference *H. pylori*. If the patient is taking any medication or natural remedies with the specific intention of treating an *H. pylori* infection this should be noted.

If you have any queries about particular medication, please contact us and we will advise as to compatibility with Pylobactell.

If you have any queries about the information on this sheet or any other issue about Pylobactell, p lease contact us.

Pylobactell Support Line 01953 607856

Torbet Laboratories Ltd
Unit 1 Chestnut Drive, Wymondham, Norfolk, NR18 9SB
Tel 01953 607856 Fax 01953 713649
email:pylobactell@breathlab.com

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Breath Testing Information Sheet: Test Meal

The test meal is part of the testing procedure. It delays gastric emptying, allowing increased retention time of the urea solution within the stomach.

Most patients are able to use the supplied test meal. However if this is unsuitable for the patient, an alternative can be used:

Suitable test meals for *Pylobactell* ^{13}C-UBT

Citrace sachet[1] (lemon flavoured ascorbic acid)	As supplied with Pylobactell test. Dissolve contents of sachet in 200ml of drinking water
Milk	200ml of full cream milk. Especially if the patient has difficulty with high acidity drinks
Orange Juice[2]	200ml of pure orange juice
Bread and butter	Two slices of brown bread, buttered. (Margarine and other vegetable spreads are not recommended)

Notes

1 Citrace contains a source of phenylalanine. May be harmful for people with phenylketonuria.

2 Orange squash and diluted orange juice are not suitable substitutes for the Citrace sachet or orange juice.

If none of the Test Meals listed above is suitable for the patient, please contact Torbet Laboratories.

If you have any queries about the information on this sheet or any other issue about Pylobactell, p lease contact us.

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Breath Testing Information Sheet: The Diabetic Patient

Since the Pylobactell breath test requires a fasting period, there may be some concerns about the suitability for use in diabetic patients.
Each patient for whom fasting may be an issue should be considered individually so this information sheet gives pertinent background information to help the clinician make a judgement.

Test timing and food intake

The test is performed after a 4 hour fast (6 hours after a large meal). The test starts with a test meal* (an ascorbic acid solution or pure fruit juice) The test then takes approx 40 minutes to complete.

* Test meal is covered by Pylobactell Information sheet No 2

Patient Constraints

The patient can

- Eat or drink immediately the test is completed
- Perform the test at home to fit their routine rather than conform to surgery hours/appointment
- Take water during the fasting period

Patient Medication (insulin use)

Unless medication is known to affect:

- Stomach emptying rate
- Acid production within the stomach
- Activity of *H. pylori* urease
- CO_2 elimination through the lungs
- Deliver carbonate with unusual levels of ^{13}C into gut or blood

We presume there is no effect on test performance, and we believe none of the above apply to insulin injections or oral insulin

If you have any queries about the information on this sheet or any other issue about Pylobactell, p lease contact us.

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Breath Testing Information Sheet: Composition

This sheet gives information on the composition of the Pylobactell tablet and Torbet Laboratories 'Test Meal'.

Pylobactell Tablet - ^{13}C -urea soluble tablet

Active ingredient

^{13}C Urea	100mg

Excipients 15 mg total

- Povidone
- Sodium benzoate
- Microcrystalline cellulose
- Colloidal anhydrous silica

To be dissolved in 30ml of water during the test procedure

Test Meal - *Citrace*

The test meal provided by Torbet Laboratories for use with Pylobactell is a lemon-flavoured sweetened ascorbic acid mixture. [1]

Citrace is supplied as a foiled sachet containing 1g of powder to be made up to 200ml with water. Each sachet contains:

Ascorbic acid (E300)
Lemon flavour
Aspartame (E591)*

*Aspartame is a source of phenylalanine. May be harmful to people with phenylketonuria.

Each test meal carries an expiry date crimped on the side of the sachet.

1) Alternative test meals are covered by Information Sheet No. 2

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Breath Testing Information Sheet: Analysis

This sheet gives information on the analysis of the samples from the Pylobactell breath test kit by Torbet Laboratories Ltd.

Analysis of Pylobactell samples by Torbet Laboratories is covered by our Quality System which is accredited by UKAS against an international standard.

UKAS

UKAS, the United Kingdom Accreditation Service, is the only body recognised by the government to assess the ability of laboratories against international standards. For Torbet Laboratories the standard is ISO 17025:2005.

Assessment

UKAS uses its own assessors to determine if a laboratory is able to meet the standard; once accepted the laboratory is subject to yearly assessments. All aspects of the work and the management of the laboratory are described in written procedures and considered by the assessors during evaluation and assessment.

Accreditation

Accreditation by UKAS demonstrates the competence, impartiality and performance capability of our laboratory so you can be "...sure that the laboratory has the people, facilities, technical expertise, management systems and track record to do the job right. Each time, every time."

ISO 9000

Some laboratories may have the ISO 9000 standard, however this only relates to management systems used, it does not specifically evaluate the **technical** competence. The managment system requirements of ISO 17025:2005 (the latest standard) meet the principles of ISO 9001:2000.

Accreditation mark

Test reports issued under our managment system carry our UKAS registration mark and number.

Don't risk it. UKAS brochure (2005)
Joint ISO-ILAC-IAF communique (18/06/2005), www.ukas.com

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Pylobactell® ^{13}C-urea 100 mg

Urea breath test for the detection of *Helicobacter pylori* infection

^{13}C urea breath testing protocol

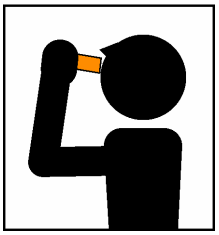
START

CONFIRM PATIENT FASTED AND OFF MEDICATION
PUT PATIENT DETAILS ON 'ANALYSIS REQUEST FORM'

SEE THE PYLOBACTELL INFORMATION SHEET 1 FOR MEDICATION DATA

10:00

PATIENT DRINKS TEST MEAL

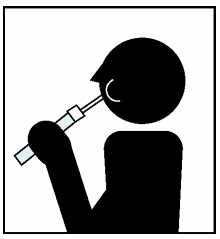


ALTERNATIVE TEST MEALS CAN BE USED
SEE INFORMATION SHEET 2

10:05

PATIENT GIVES PRE-UREA BREATH SAMPLES
3 X WHITE CAPS WHITE LABELS

PREPARE UREA SOLUTION



DON'T COVER BARCODES WITH PATIENT LABELS

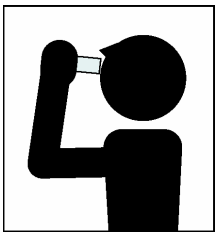
BLOW GENTLY

NO SALIVA

10:10

PATIENT DRINKS UREA SOLUTION

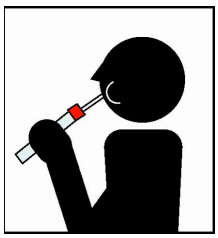
PATIENT WAITS 30 MIN
SEATED
NO FOOD OR DRINK
NO SMOKING



DRINK, REFILL WITH WATER AND DRINK AGAIN

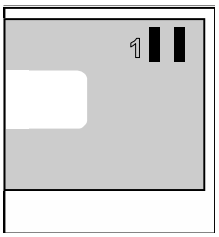
10:40

PATIENT GIVES POST-UREA BREATH SAMPLES
3 X RED CAPS RED LABELS



DONE

REPACK TUBES WITH ANALYSIS REQUEST FORM AND SEAL
SEND OFF IN FREEPOST ENVELOPE
DISCARD VIAL, STRAWS AND SACHET



KEEP PAIR OF TUBES IF REQUIRED

USE EXTRA BARCODE LABELS ON PATIENT RECORDS AS NECESSARY

Supplied as a service by Torbet Laboratories Limited, manufacturer of the Pylobactell ^{13}C Urea Breath Test kit and provider of Laboratory Services for the analysis of ^{13}C in breath samples.

For all Pylobactell Enquiries
Tel: 01953 607856
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Email: Pylobactell@breathlab.com

Torbet Laboratories Ltd
FREEPOST RSSX-TSLG-XSET
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Wymondham
NR18 9SB

IMPORTANT - BEFORE YOUR TEST

You will have been given instructions about preparation for the test. These are repeated here. If you have been given instructions that are different to these, then you should follow the advice of your doctor.

For the best result from your test it is important that:

You take the test on an empty stomach.

Please do not eat or drink (except water) for at least 4 hours before the test. If fasting is a problem, please ask the advice of your doctor.

You should not have taken certain medicines in the time before the test:

Antibiotics

(e.g. penicillin, metronidazole)

- 28 days before the test

Proton Pump Inhibitors

(e.g. lansoprazole, omeprazole)

- 14 days before the test

H2 antagonists, antacids

(e.g. ranitidine, cimetidine, Gaviscon)

- 12 hours before the test

Do not stop taking any medicine unless told to by your doctor.

You may be asked about medicines you are taking when you take the test. If you are unsure about the name or type of your medicine, bring it, the packet, or the patient information leaflet along with you.

GP/Clinic Stamp

Torbet Laboratories Ltd is the manufacturer of the Pylobactell urea breath test.

If you have a question about the Pylobactell breath test you should speak to your doctor or you can contact Torbet Laboratories Ltd at the address below.

Your test may be analysed at Torbet Laboratories Ltd or at another laboratory. If you have been tested but have not been told the results of your test, please contact your doctor. Torbet Laboratories Ltd cannot give you the result of your test or answer questions about your result - you must see your doctor.

This leaflet has been produced by the PYLOBACTELL license holder:

TORBET LABORATORIES LTD
Unit 1 Chestnut Drive,
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Phone: 01953 607856
Fax: 01953 713649

 PAL-ENG-SEP-2013

YOUR ^{13}C UREA BREATH TEST

Your Doctor has recommended that you have this simple test to investigate the presence of *Helicobacter pylori*, a bacterium that can be found in the stomach.

Name

Appointment

Please contact your test centre or GP if you will be unable to attend your appointment.

Please read the contents of this leaflet before your test

Pylobactell®

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 appropriate national reporting system (see details below)

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

Ireland
HPRA Pharmacovigilance
Earlsfort Terrace
IRL-Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517

Website: www.hpra.ie
e-mail: medsafety@hpra.ie

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.

<u>Sampling instructions</u>

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

7. MARKETING AUTHORISATION HOLDER

Torbet Laboratories Limited
Unit 1 Chestnut Drive
Wymondham
Norfolk
NR18 9SB
United Kingdom

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+44 (0)1953 713649
enquiries@torbetlaboratories.co.uk

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

03/2017

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

United Kingdom Accreditation Service

ACCREDITATION CERTIFICATE

UKAS
UNITED KINGDOM ACCREDITATION SERVICE

TESTING LABORATORY
No. 2556

Torbet Laboratories Limited

is accredited in accordance with the recognised International Standard ISO/IEC 17025:2005
General Requirements for the competence of testing and calibration laboratories.

This accreditation demonstrates technical competence for a defined scope as detailed in and at the locations specified in the schedule to this certificate, and the operation of a laboratory quality management system (refer joint ISO-ILAC-IAF Communiqué dated January 2009).

The schedule to this certificate is an essential accreditation document and from time to time may be revised and reissued by the United Kingdom Accreditation Service. The most recent issue of the schedule of accreditation, which bears the same accreditation number as this certificate, is available from the UKAS website www.ukas.com.

This accreditation is subject to continuing conformity with United Kingdom Accreditation Service requirements. The absence of a schedule on the UKAS website indicates that the accreditation is no longer in force.

Accreditation Manager, United Kingdom Accreditation Service

Initial Accreditation date
28 May 2004

This certificate issued on
21 August 2012

UKAS is appointed as the sole national accreditation body for the UK by The Accreditation Regulations 2009 (SI No 3155/2009) and operates under a Memorandum of Understanding (MoU) with the Department for Business, Innovation and Skills (BIS).

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

2556

Accredited to ISO/IEC 17025:2005

Torbet Laboratories Limited

Issue No: 008 **Issue date:** 22 November 2016

Units 1-2
Wymondham Business Park
Chestnut Drive
Wymondham
Norfolk
NR18 9SB

Contact: Mr Graeme Leggett
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Fax: +44 (0)1953 713649
E-Mail: GraemeLeggett@breathlab.com
Website:

Testing performed at the above address only

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BREATH SAMPLES	Chemical Tests Determination and comparison of the $^{13}C/^{12}C$ ratios in carbon dioxide from exhaled breath collected as part of a 100 mg ^{13}C Urea Breath Test (Pylobactell®)	Documented In-House Methods using Gas Chromatography and Stable Isotope Ratio Mass Spectrometry
	END	