NanoBreath: Affordable detection of Helicobacter pylori in the developing world
What?

- *Helicobacter pylori* is one of the most common bacterial infections.
- Spiral-shaped bacterium that infects well over 30% of world’s population.
- About 40% of people in the UK have the bacteria in their stomach.
- Higher infection rates correlate with: crowded living conditions, poor sanitation/personal hygiene/water supply (~80% in developing world).
- Most infections occur in childhood.
It invades the mucosal lining of the stomach and is the cause of up to 95% of duodenal and up to 75% gastric ulcers and has also been associated with gastric cancer and lymphoma.

About 15% of people with \textit{H. pylori} infection get ulcers either in the stomach or in the duodenum.

Ulcers tend to cause indigestion, they can bleed or even burst (perforate) which happens if the ulcer burrows deep enough to make a hole.

World Health Organisation has declared the bacteria to be a Class 1 carcinogen (1 to 3% of those infected will develop distal gastric adenocarcinoma).

http://www.nhs.uk/ipgmedia/national/core%20charity/assets/helicobacterpylori.pdf
How big an issue?

Estimated size of the patient populations presenting in our principal territories

<table>
<thead>
<tr>
<th>Country/Region</th>
<th>Population</th>
<th><em>H. pylori</em> Prevalence</th>
<th>Infected population</th>
<th>Number of patients (1% annual presentation with symptoms)</th>
</tr>
</thead>
<tbody>
<tr>
<td>India</td>
<td>1,211 million</td>
<td>80%</td>
<td>967 million</td>
<td>9.7 million</td>
</tr>
<tr>
<td>China</td>
<td>1,344 million</td>
<td>80%</td>
<td>1,075 million</td>
<td>10.8 million</td>
</tr>
<tr>
<td>Brazil</td>
<td>201 million</td>
<td>80% estimate</td>
<td>161 million</td>
<td>1.6 million</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>22.1 million</strong></td>
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</table>
Solution: An affordable Urea Breath Test (UBT)

1. A baseline patient breath sample is collected and the $\delta^{13}$C (‰) of their CO$_2$ determined

2. The patient then swallows a $\delta^{13}$C labelled urea pill

3. If present then $H.\ pylori$ will metabolise the urea resulting in a positive shift in $\delta^{13}$C (‰) of the CO$_2$

4. Patient’s breath is re-collected ~ 20 minutes after the labelled urea pill is taken

5. A delta-over-baseline (DOB) shift in the $\delta^{13}$C of > 10 ‰, between the two patient samples, is considered a positive sample

Source: Oridion Medical 1987 Ltd Clinical Study(NDA 21-314)
Link to Space?

Gas Analysis Package on Beagle2

NanoBreath Prototype

NanoBreath Final Product Philosophy
The Road to Market

1. **Regulatory Compliance Support**
   - Access to Regulatory Body appropriate for the target region
   - Medical Classification
   - CE Marking
   - Technical File Support

2. **Design for Manufacture**
   - Electronic PCBs and harnessing
   - Enclosure and internal architecture
   - Packaging

3. **Manufacture, Assembly and Integration of Production Product**

4. **Design for Test**
   - Test solution for production product - minimising time, cost and skill set yet accurate and reproducible acceptance testing

5. **Accessory Management**

6. **Warehousing / Logistics / Shipping & Distribution**

7. **Post Product Support**
   - Servicing
   - Warranties
   - Repair/maintenance
   - Rental Support

Invisible Service Badged as OMM

ANO

OMM

Distributors

Customers