**Business Proposal: Urea Breath Test (UBT) Solutions for H. pylori Detection**

**1. Executive Summary**

This proposal outlines a strategic plan to launch a diagnostic medical enterprise focused on distributing, customizing, and eventually manufacturing Urea Breath Test (UBT) kits and analyzers for *Helicobacter pylori* detection. The business will source high-quality ¹³C and ¹⁴C UBT kits from top Chinese manufacturers and deliver affordable, regulatory-compliant diagnostic tools to clinics, hospitals, and laboratories in the local and regional markets. Through tailored branding (OEM/ODM), flexible product design, and excellent supplier relationships, the company aims to become a leading provider of H. pylori diagnostic solutions.

**2. Problem Statement**

*Helicobacter pylori* infection is a major contributor to gastritis, ulcers, and stomach cancer worldwide. Many regions lack reliable, accessible, and patient-friendly testing methods. Existing diagnostics are often invasive (e.g., endoscopy), expensive, or logistically complex. There is an urgent need for scalable, non-invasive solutions that deliver quick and accurate results.

**3. Proposed Solution**

Our business will offer complete UBT solutions that include:

* **UBT Kits** (¹³C and ¹⁴C options)
* **Breath analyzers** (handheld and desktop)
* **Citric acid formulations** for enhanced test accuracy
* **OEM branding** and customized packaging
* **Training, after-sales support, and technical consultation**

We will partner with companies like:

* Shenzhen Bioeasy Biotechnology Co.
* Anhui Deep Blue Medical Technology Co.
* Beijing Wanjie Medical Equipment Co.

**4. Market Opportunity**

* **Target customers**: Public and private hospitals, diagnostic labs, family health centers, gastroenterologists.
* **Initial region**: Iraq and Kurdistan Region; scalable to neighboring countries (Turkey, Jordan, Iran, UAE).
* **Market growth**: The global H. pylori diagnostics market is projected to reach **$720 million by 2027**.
* **Competitive advantage**: Customization, affordability, and faster delivery from Asian suppliers.

**5. Business Model**

* **Initial Phase**: Import and distribute existing UBT products.
* **Mid-term**: Offer OEM-branded kits with custom design.
* **Long-term**: Manufacture locally or regionally, reducing costs and improving supply control.

**Revenue Streams**:

* Direct sales to hospitals and labs
* B2B partnerships with medical distributors
* Exclusive contracts with health organizations
* Technical service and training packages

**6. Product Specifications**

| **Component** | **Options/Details** |
| --- | --- |
| Urea Isotope | ¹³C (non-radioactive) or ¹⁴C (low-dose radioactive) |
| Kit Contents | Urea capsule, citric acid packet, breath bags/tubes |
| Analyzer Options | IRMS-compatible or scintillation detectors |
| Add-ons | App-connected handheld readers, customized packaging |
| Certifications | CE, FDA, ISO 13485 (depending on supplier) |

**7. Technical Partners (Suppliers)**

| **Supplier** | **Country** | **Capabilities** |
| --- | --- | --- |
| Shenzhen Bioeasy | China | OEM/ODM, app-based analyzers |
| Anhui Deep Blue Medical | China | ISO certified, ¹³C/¹⁴C kits |
| Beijing Wanjie Medical | China | High-end desktop analyzers |
| Cambridge Isotope Labs | USA/China | High-purity ¹³C and ¹⁴C urea sourcing |

**8. Financial Plan**

**Estimated Startup Costs (First 6 Months):**

| **Expense Category** | **Estimated Cost (USD)** |
| --- | --- |
| Initial inventory (kits) | $10,000 – $15,000 |
| Analyzer equipment | $5,000 – $8,000 |
| Shipping & logistics | $2,000 – $3,000 |
| Regulatory approvals | $1,500 – $2,000 |
| Marketing & branding | $2,000 |
| Legal & setup fees | $1,000 |
| **Total** | **$21,500 – $31,000** |

**Product Cost Estimates (per 100 units)**:

* ¹³C UBT kit: $25–$35
* ¹⁴C UBT kit: $10–$20
* Handheld analyzer: $800–$1,200
* Desktop analyzer: $2,500–$5,000

**Potential Revenue**:

* Each ¹³C UBT test retail price: $60–$90
* Estimated gross margin: 40–55%

**9. Timeline**

| **Phase** | **Duration** | **Milestone** |
| --- | --- | --- |
| Market research | Month 1 | Identify local demand and suppliers |
| Import licensing | Month 1–2 | Obtain Ministry of Health approval |
| Supplier contracts | Month 2–3 | Sign MoUs with 2–3 Chinese firms |
| Pilot distribution | Month 3–5 | Supply to 5–10 clinics/hospitals |
| Scale-up | Month 6–12 | Expand to 3+ regions, OEM launch |

**10. Risk Analysis**

| **Risk** | **Mitigation Strategy** |
| --- | --- |
| Regulatory delays | Work with local regulatory consultants |
| Supply chain disruptions | Secure multiple suppliers |
| Market resistance to new tech | Offer demo trials and technical workshops |
| Price competition | Focus on customization, value-added services |

**11. Conclusion and Next Steps**

This proposal outlines a feasible and scalable business in the growing field of non-invasive H. pylori diagnostics. With strong technical backing from Chinese manufacturers, a clear market gap, and a strategic financial model, this venture is positioned for success.

**Next Steps**:

* Finalize business registration and medical licenses.
* Select preferred suppliers and request product samples.
* Launch pilot distribution in selected hospitals and labs.
* Initiate branding and marketing campaigns.