A Disposable, At-home Anemia Test Kit

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OTT Breakfast Club, December 11th, 2012
Anemia

What? ↓ in number of RBCs or carrying capacity of RBCs

Why? 1) Impaired RBC production 2) ↑RBC destruction 3) Blood Loss

Who? o Impacts 1.6 billion people worldwide o All populations, regardless of ethnicity, age, sex o 5.3M doctor’s visits & 430K hospitalizations o Many different at risk populations: • Aged/eldery • Pregnant females • Cancer patients • Chronic immunodeficiencies • Chronic hematological diseases • Chronic Kidney Disease

Most suffer chronic anemia, requiring consistent testing
Current Tests

Gold Standard – Complete Blood Count (CBC)
+ Accurate
- Requires lab visit

At Home Options

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Cost</th>
<th>Disadvantage</th>
</tr>
</thead>
<tbody>
<tr>
<td>BioSAFE Anemia Meter</td>
<td>$25/test</td>
<td>Difficult to use, faulty readings</td>
</tr>
<tr>
<td>AnemiaScreen</td>
<td>$30/test</td>
<td>Only good for iron deficient anemia</td>
</tr>
<tr>
<td>STANBIO STAT-SITE M</td>
<td>$300+</td>
<td>Expensive, needs to be calibrated</td>
</tr>
<tr>
<td>HemoCue</td>
<td>$1200+</td>
<td>Expensive, complex</td>
</tr>
</tbody>
</table>

Current options do not meet needs
Technology

A proprietary single-use test kit for measuring blood hemoglobin levels

- Simple
- Fast
- Accurate
- Patient Operated
- Self Contained
- Disposable


Potential benefits:

- Lancet
- Testing strip & vessel
- Reference Guide

Reference Guide:

<table>
<thead>
<tr>
<th>Hemoglobin</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 8g/dL</td>
<td>Anemic</td>
</tr>
<tr>
<td>8-10g/dL</td>
<td>Borderline Anemic</td>
</tr>
<tr>
<td>&gt; 10g/dL</td>
<td>Healthy</td>
</tr>
</tbody>
</table>

Potentially addresses needs of chronic anemia sufferers
Testing

**Testing Steps**

1) Prick finger with lancet
2) Apply drop of blood to testing strip
3) Place strip in solution tube & close
4) Shake tube for 15 seconds
5) Wait 1 minute for color change
6) Compare to reference guide

**Test could be used repeatedly to monitor status**
## Validation & Specifications

<table>
<thead>
<tr>
<th></th>
<th>Ideal</th>
<th>Actual</th>
<th>Emory Anemia Kit</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Stability</strong></td>
<td>15° - 35°C</td>
<td>Up to 55°C</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Resolution</strong></td>
<td>&lt; 1g/dL</td>
<td>~1g/dL</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Specificity</strong></td>
<td>&gt; 90%</td>
<td>95%</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Selectivity</strong></td>
<td>&gt; 80%</td>
<td>~ 80%</td>
<td>Yes</td>
</tr>
</tbody>
</table>

**Meets or exceeds specs necessary to be viable**
Development & IP

• Current
  – 1\textsuperscript{st} generation prototype & validated
  – IP Status – US provisional patent filed 8/9/2012

• Future
  – Additional studies
    • Comparison to hematology analyzer
    • Expanded validation testing – differing pathologies
    • Additional stability testing – temp, humidity, light, etc.
  – 2\textsuperscript{nd} generation prototype & user testing
  – Looking for an entrepreneur
Thank you