BiteWatch

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Introduction

Many packaged food products have a "sell-by" date or a "refrigerate after opening" label, but these both serve as vague indicators of the product's longevity. In fact, roughly 1 in 6 Americans contract a foodborne illness every year, leading to 56,000 hospitalizations and 1,300 deaths.[1]

Our product simultaneously tests for the 3 most common foodborne illness-causing bacteria- salmonella, clostridium perfringens, and campylobacter with a lateral flow assay.[2] The strip consists of one plastic card holder with 3 different test strips each labeled with bacteria-specific antibodies that indicate the presence of said bacteria within the sample.

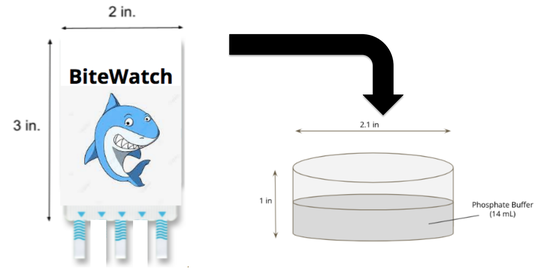

Figure 1—Visual prototype of our product, BiteWatch.
The plastic card holds 3 strips that are dipped into the buffer.

Market

The total food pathogen food pathogen market is expected to grow to over $5.5 billion by 2024.[3] This overall market can be broken down by pathogen, technology landscape, and region. Salmonella and E. coli make up $1.2 billion and $1.1 billion of the market, respectively.[3] The rapid food pathogen testing technology makes up $3.5 billion of the total market, and the North American is about $2 billion.[3]

Current competitors such as UltraKlean sell salmonella and *E. coli* 2-in-1 tests for $30 and individual antigen tests for $6.[4] There is also SMART-II Salmonella Detection Tests, but these are marketed for commercial purposes.

We expect to sell a set of 5 units for $12 in one box. Our revenue stream is anticipated at $72 million based on selling 6 million units a year by selling to 6% of the 100 million people who care about food pathogens.[5]

Scientific Principles

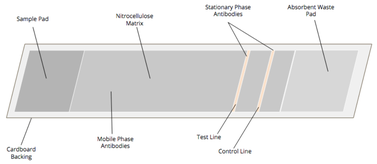

Figure 2—Lateral Flow Assay

Fick's 2nd Law

$$dx^2/dt = D_{AB}\nabla^2 x$$

$$dc^2/dt = D_{AB}\nabla^2 c$$

Binding Kinetics

$$Ag + Ab \leftrightarrow AgAb$$

$$K_A = \frac{[Ag-Ab]}{[Ag][Ab]}$$

Pathogen Antibodies	Concentration on Test Strip (mol/L)
Norovirus	$2.5 * 10^{-3}$
Salmonella	$5 * 10^{-7}$
Clostridium perfringens	$2.5 * 10^{-8}$
Campylobacter	$2.5 * 10^{-4}$
Staphylococcus Aureus	$5 * 10^{-4}$

Length	3.8 cm
Cross-sectional Area	0.03 cm^3
Estimated Diffusivity Coefficient	0.14 cm^2/s
Time to Result	~ 15 minutes

Table 1- Antibody and Test Strip Data

We use a lateral flow assay as the basis for each pathogen strip (Figure 2). Each strip consists of a sample pad, nitrocellulose matrix, an antibody test and control line, and an absorbent waste pad. The sample is absorbed and follows Fick's 2nd Law allowing us to predict elution time (Table 1). The antibodies having specific binding kinetics that allowed us to accurately assess the quantity of antibodies needed for proper pathogen indication (Table 1). These antibodies are gold-plated and serve as indicators of the pathogen.

Manufacturing Plan

Our manufacturing plan consists of two steps: preparing the gold-plated antibodies and the assembly of the device itself. To tag the antibodies, we plan on using an EDC/NHS covalent reaction (Figure 3). This step requires a mixer, centrifuges, and incubators for successful manufacture. Once the antibodies are generated, they get added to the nitrocellulose membrane of the strip.

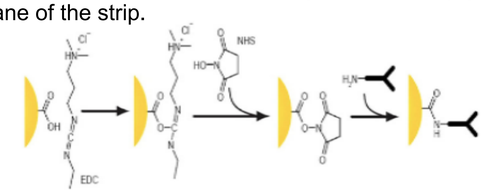

Figure 3—EDC/NHS Covalent Reaction for tagging antibodies with gold nanoparticles

The physical test strip will be assembled in individual components (sample, absorbent waste, conjugate pads), and fed into an automatic lamination system to create one individual strip. Three of these strips, testing for the three different pathogens, will then be combined in final assembly onto carboard packaging with individual phosphate vials. (Figure 4)

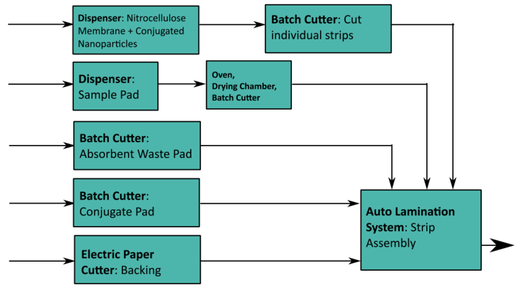

Figure 4 – Test Strip Assembly Process Flow

Financial Analysis

For developmental timeline estimations, we expect the legal and engineering pre-production tasks to take about a year and half with total costs of $12 million before production of any units. Cost per unit will be $7.74 with a price of $12.

Assuming an annual growth in operating and business costs of 5% and an annual growth in revenue of 20%, it is expected for the net present value to become positive within the next 8 years (Figure 4).

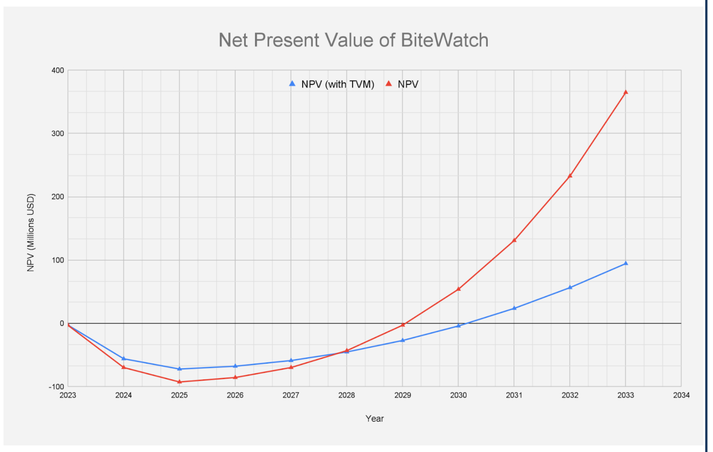

Figure 4—Net Present Value over 10 years

	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033
Development Costs	2.8	2.8	2.8								
Capital Costs		64	20								
Operating Costs			33	34.65	36.3825	38.201625	40.11170625	42.11729156	44.22315614	46.43431395	48.75602965
Business Costs			39	40.95	42.9975	45.147375	47.40474375	49.77498094	52.26372998	54.87691648	57.62076231
Revenue			72	86.4	103.68	124.416	149.2992	179.15904	214.990848	257.9890176	309.5868211
Gross Profit	-2.8	-66.8	-22.8	10.8	24.3	41.067	61.78275	87.2667675	118.5039619	156.6777872	203.2100292
Taxes	0	0	0	3.78	8.505	14.37345	21.6239625	30.54336863	41.47638666	54.83722551	71.12351021
Net Income	-2.8	-66.8	-22.8	7.02	15.795	26.69355	40.1587875	56.72339888	77.02757522	101.8405617	132.086519
Net Cash Flow	-2.8	-69.6	-92.4	-85.38	-69.585	-42.89145	-2.7326625	53.99073637	131.0183116	232.8588733	364.9453922
Discount Factor	1.12	1.2544	1.404928	1.57351936	1.762341683	1.973822685	2.210681407	2.475963176	2.773078757	3.105848208	3.478549993
Discounted Cash Flow	-2.5	-53.25255102	-16.22858965	4.46133691	8.962507186	13.52378316	18.16579601	22.90962944	27.77691582	32.78993525	37.97171787
NPV (with TVM)	-2.5	-55.75255102	-71.98114067	-67.51980376	-58.55729657	-45.03351341	-26.86771739	-3.958087955	23.81882787	56.60876312	94.580481
NPV	-2.8	-69.6	-92.4	-85.38	-69.585	-42.89145	-2.7326625	53.99073637	131.0183116	232.8588733	364.9453922

Figure 5 – Annual costs and revenue across the first 10 years of business

References

1. https://www.cdc.gov/foodsafety/foodborne-germs.html
2. https://www.who.int/health-topics/foodborne-diseases#tab=tab_1
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