

BIOMARKER TEAM FINAL REPORT

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*Design in
Management*

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SECTION 1 - INTRODUCTION AND PROBLEM STATEMENT

Our team was approached to design for commercialization a product based on technology developed by Case Western Reserve University Professor C.C. Liu. This technology is able to detect the presence of select biomarkers, indicators of the presence of a specific disease or condition within the body. Dr. Liu's discoveries are held and processed through Case's Technology Transition Office (TTO), and those furthest along the path to commercialization with respect to pending patents include breast cancer and prostate cancer. The core issue is that, in spite of the product's sophistication and potential, there has been a lack of direction for moving forward in successfully marketing the technology and getting it out to consumers. The current state of the technology, while viable in the laboratory setting, is too raw and inadequate when looking through the lens of commercialization. Through discussion, analysis, and the design process we decided to narrow our focus to the biomarker for prostate cancer (AMACR). This choice resulted in the following problem statement:

Prostate cancer is the most common form of cancer in men over the age of 50. Early detection and treatment are vital to the survival of individuals who contract prostate cancer, yet current screening methods are only 60% accurate with many false positives. The biomarker technology developed by Dr. C.C. Liu provides an accurate, fast, and non-invasive method for detecting prostate cancer, but needs to be commercialized and developed as a consumer product.

SECTION 2 - HYPOTHESIS

In facing the complex, multifaceted issue of commercializing this biomarker technology, our team's ultimate goal is to choose a design path that will lead to a product that is robust in its ability to address both the emotional and technical needs of the user. Although we consider the full portfolio of Dr. Liu's discoveries, in order to succeed, our group ultimately decided to reduce the scope of the project to one biomarker. Our intention in doing this is to develop a flagship product that can serve as a benchmark for future biomarker technology endeavors. In focusing on the AMACR biomarker, our team developed a single-use disposable device that can leverage biomarker technology to screen for prostate cancer using only a single drop of blood. Our team developed this device to be safe and intuitive. We also developed a website to advise and comfort users in the event of a preliminary positive result. The resulting solution, as well as the components that it inheres, seek to fulfill our problem by providing a device that will deliver the intended user experience in a delicate but simple manner.

Our team saw an opportunity to develop a critical home health care product. We worked through several iterations of products that would serve our situation in various ways and in so doing, identified a number of priority factors for consideration. These include frequency of use, home use advantage, and emotional impact on the user.

SECTION 3 - DESIGN AND USER EXPERIENCE

In defining our problem and going through the associated steps to identify our central hypothesis, it was necessary to examine not only the physical representation of the technology, but the total

user experience as well. The design of the physical device is based on certain considerations taken from our hypotheses:

- 1) *Our design must be disposable* – Since the product will lance the finger and elicit a drop of blood, we must consider the risk in limiting biohazards. Our concept provides enhanced safety by also allowing the user to cover the test site.
- 2) *The concept should be familiar and non-imposing* – The product should not confer gimmicks that will turn away users.
- 3) *Easy-to-use* – The device must be intuitive and user-friendly.
- 4) *The product must be appropriately sized* – Should be large enough to incorporate the necessary components while remaining small enough to be easily held.
- 5) *Results should display words rather than symbols* – More so than words, symbols tend to elicit an emotional response. As we consider the condition of cancer, we seek to control at each step the emotional response of the user.

The result of our considerations will extrapolate the physical device from its current state, as a box and strip configuration (figs.1a and 1b), and culminate in a unified, single-use diagnostic device that incorporates all of the following:

- Electronics of the laboratory box
- Test strip
- Lancet required to draw a drop of blood

The engineered configuration is shown below in figure 2 & figure 3.



Fig. 1a

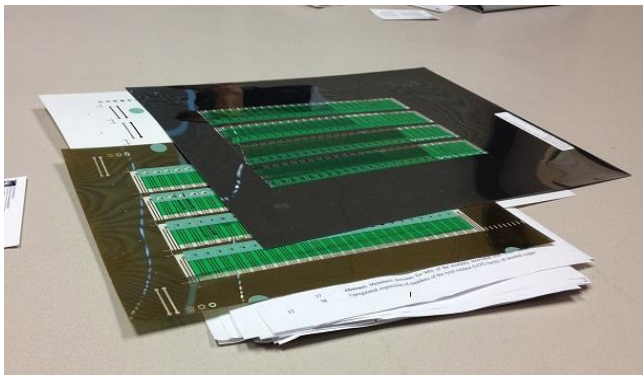


Fig. 1b

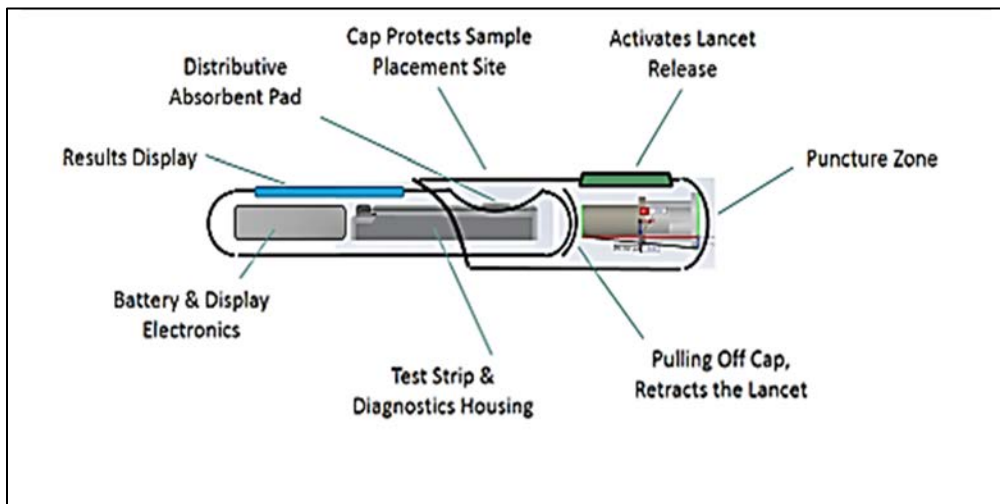


Fig. 2

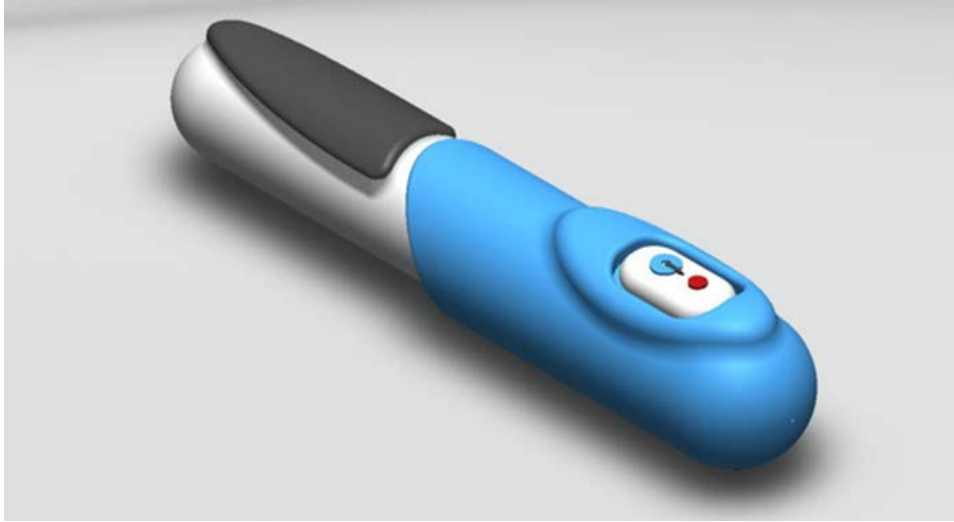


Fig. 3

The design is comprised of 2 pieces as depicted above in figure 3. The blue portion contains the cap containing the lancet, which pricks the finger, and the button for releasing the needle. The white and gray body contains the electronics, test strip, testing area, and results display.

The product is designed to be safe and intuitive. By removing the blue cap, the user primes the lancet and places a finger against the tip of the cap. The button is then pressed, pricking the finger. Once a sample of blood is drawn, the finger is then placed against the placement site, containing the test strip. The electronic components within the body will subsequently perform the necessary test, which takes 5 minutes, and initiate either a 'negative' or 'preliminary positive' result, which will be displayed on the screen.

The physical design is only part of that experience, and as we consider the condition of cancer, we recognize the importance of taking the entire user experience into account. Our design must not dismiss the emotional gravity tied to this condition, and this context was fundamental throughout our design process. Careful attention was offered to the user phases following the

preliminary indication of prostate cancer. We elect precisely to use the term ‘preliminary positive’ to indicate a positive result, as we do not hold the device to fully replace a physician’s guidance. This serves as well to mitigate distress and empower the user to treat the condition by recognizing that there is more to be done in verifying the diagnosis while also providing hope. To further assist in this, directions will indicate that upon receiving a preliminary positive result, the user should visit a proprietary website constructed to guide through the next steps. This website will contain simple instructions and frequently asked questions designed to provide the user with a network of physicians, assistance in scheduling an appointment, and will also provide additional information about prostate cancer.

Website Structure: User Action Categories



A sample excerpt from the “Follow Instructions” section of the website is shown below (fig. 4).

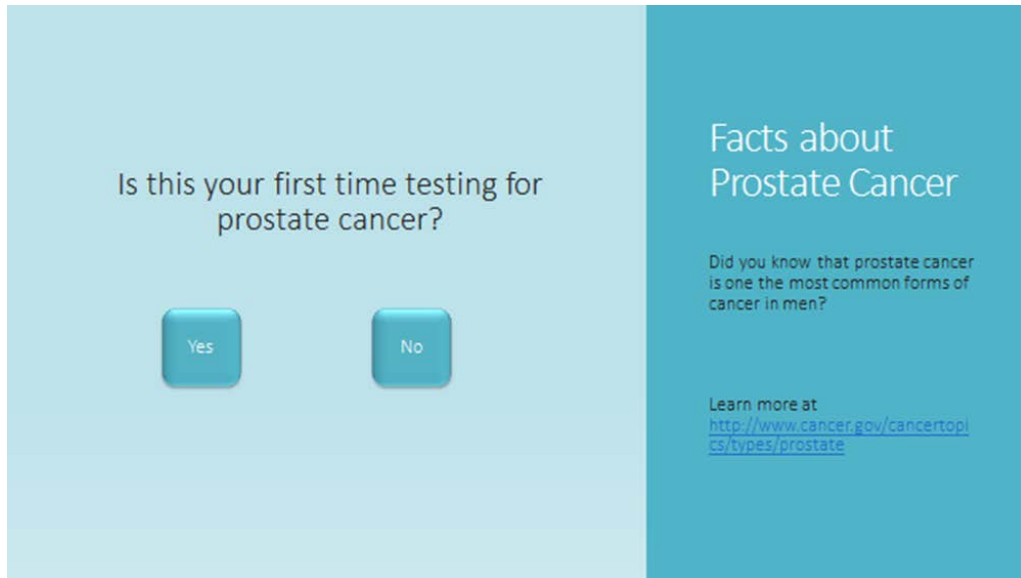


Fig. 4

MARKET

Although we consider both the discovery as well as the patenting of this scientific endeavor to be complex in their many pieces, the fundamental basis for detecting the biomarker is fairly easy to understand. The process works by using a small sample of biological fluid, in our case blood, and testing the electrical potential across a catalyst that will check for the presence of the biomarker. This removes any need for complicated circuitry or computation, lending itself towards commercialization as a small, simple device.

Our primary audience is men who are at risk of prostate cancer (essentially all men over 50 years old) electing to increase their chances of early detection. In the U.S. alone there are approximately 40 million men over the age of 50, which is the age widely considered within the medical field to be the recommend age at which men must begin testing for prostate cancer. The most widely used method of detection currently in place is known as PSA, which is both invasive and relatively inaccurate, and can be performed only in clinical settings. Our concept would be the first of its kind: a home use diagnostic that can detect prostate cancer.

To determine a potential price point for this design we must examine how much it will cost to miniaturize the electronics and then look for comparable items. The closest comparable devices currently on the market are digital pregnancy tests and home blood glucose monitoring systems. Using these devices to show the technical feasibility of miniaturizing medical technology for home use gives us a price point between \$15-\$50, which is well within reason for a low-frequency, high accuracy, novel test such as the one provided by our design.

FUTURE CONSTRAINTS

Our biomarker device faces two major obstacles in its path to market. The first is its obligatory FDA approval as a medical device. The second concern relates to the necessity for early stage prostate cancer detection. This device will follow a Class I Medical Device 510k path, meaning that there exist approved medical devices that use similar methods. This is the fastest path to approval, and in consideration of the device's simple lancet mechanism, we feel that there is precedent to use it. More significantly, however, is the concern surrounding the device in the face of clinical trials. As of now, there have not yet been enough clinical trials with the AMACR biomarker to determine whether this test can depict the severity of the condition. If it were verified that AMACR offers this advantage, our product would have incredible scope in the marketplace. Alternatively, if the outcome were the opposite, the result would significantly dampen market penetration and the overall success of the device.

PROCESS

The first step taken in our design process was meeting with our sponsors Dr. C.C. Liu and associate manager Michael Allen from Case's Technology Transfer Office (TTO). These individuals informed us of all key pieces surrounding the technology and its potential in a range of diagnostic applications. While there are current patents pending for a variety of biomarkers,

including breast cancer and concussions, we elected prostate cancer as the focus of our study due to its relatively advanced progress in terms of testing, the progression of its associated patent applications, and the prevalence of prostate cancer within the population. By choosing to work with a single biomarker, we were better able to focus our efforts on a complete user experience. Upon refining our focus, the next step was to determine a form and method for the diagnostic. Through research and discussion, we evaluated many variables in shaping the direction of the device. Focal considerations were made as follows:

1) *Blood as the fluid sample* – The technology lends itself towards use with various biological fluids including blood, saliva, and urine. Although saliva is less invasive and perhaps easier to use, and moreover in spite of the fact that this method is scientifically plausible according to Dr. Liu, it is not as strongly supported in the present state.

2) *A disposable device rather than a reusable device* – Arriving at this decision provided the most contention among our discussions since there were a number of promising iterations centered on a concept similar in practice to a blood glucose monitor: a reusable unit (monitor) paired with disposable components (i.e. test strips, lancets). Ultimately this was rejected in favor of a disposable device, due primarily to frequency expectations that limit use, but also to remove added clutter and the potential to lose the device or other pieces.

3) *A method for transmitting results* – In evaluating the use and performance of other at-home-diagnostic devices, including pregnancy tests, drug screens, and paternity tests, we discovered a wide range of symbols and language used for conveying results. It was recognized that the user's expectation of the test results and the associated personalized connotation through which the result is received varied widely by test and circumstance. It was noted as well that some tests apparently offered little or no attention to the user's emotional response.

Throughout all of our discussions, it was considered necessary to control the emotional impact to the user in the event that the test implies the presence of cancer. Research suggests that symbols tend to evoke a greater emotional response. For this reason, we chose to display results with words. We have termed positive results as ‘preliminary positive,’ a phrase suited towards our intent to control emotional impact.

4) *Adding a web page* – In designing a justifiable concept, we seek to honor an entire patient experience. To better assist patients, upon receipt of a positive result, they will be directed to a webpage designed to help locate a physician, make an appointment, provide additional information, and answer questions that the user may have.

5) *Selecting a form* – The technology and relevant purpose of this study required that we develop an appropriately sophisticated yet refined form. Our team developed several representative prototypes, and eventually refined the concept to the two-part, pen-like form that is here exhibited. Primary considerations revolved around the familiarity of the design and the aim to demonstrate reliance and avoid gimmicks. Figure 5 shows one example of an alternative design that was examined.



Fig. 5

This form, based on the shape of a blood cell, was ultimately rejected in favor of a more easily producible and packable shape as reflected in our final design.

SECTION 4 - CONCLUSION

Although our concept focused on the AMACR biomarker as discussed previously, a wave of biomarker technology has emerged in medical research. As these discoveries are patented and approved for use, the potential for our design to become a platform technology expands rapidly. It is viable that, by using the same basic technology, there exists a possibility to develop a home diagnostic center that could detect multiple diseases or conditions with only a single drop of blood.

We presently abide to the constraints associated with the approval of this technology, but see strength in a future that passes through the aftermath of these obstacles. In any event, our team considers this product to be promising for commercialization, and marketable as a device that is both positive in impact and wide in scope.