

Portable Tick-Borne Pathogen Test

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Executive Summary

Detickt aims to address the unmet need of rapid tick-borne disease testing by providing a user-friendly method for detecting potential exposures to tick-borne diseases. Our flagship product is a portable, at-home enzyme-linked immunosorbent assay (ELISA) test kit that can detect the presence of Lyme Disease and Rocky Mountain Spotted Fever within a tick. The proposed test kit will include primary technologies, which include a lateral flow immunoassay and a new innovative method for processing tick samples. This product aims to reduce instances of delayed treatment and help prevent the long-lasting negative health impacts that arise from undiagnosed tick-borne diseases. The goal of this proposal report is to assess the feasibility and sustainability of our company and to provide a go-to market strategy for the Detickt test kit product.

Instead of entering into an existing market, Detickt aims to be an industry trailblazer and create a new market for rapid disease exposure testing. The customer segments within this new market were identified as based on a customer's potential risk for coming into contact with a tick. The primary target audience focuses on outdoor enthusiasts while the secondary target audience focuses on pet owners. Creating a new market is also a benefit when analyzing the market competition, as there are few direct competitors to contend with. The only direct competitor for our company is the Cutter test, which requires the tick samples to be mailed into a laboratory for testing. Our products bring a competitive advantage by providing a method for at-home testing with a shorter turnaround time for generating test results.

Necessary resources include a small, yet thorough, team with several overlapping roles as the company establishes its market, facilities for day-to-day operations, facilities for research, development, manufacturing, and distribution, funding via external sources, and intellectual property for the novel technology. When it comes to R&D and manufacturing, labor will be outsourced to capable organizations. Funding will be pursued through government-based grants, as well as through private investor groups. Acquisition of these funds will open the door for acquiring other resources. Potential partnerships to pursue include CDMOs/CROs for manufacturing, online and in-person retail stores to distribute test kits, and strategic collaborations with nonprofit/governmental organizations and similar companies to increase exposure and diversify revenue streams.

Our five year plan targets raising \$1.5 Million Dollars by year 2 to fund the product development of Detickt, with plans to outsource manufacturing by year 3 and launch by year 4. We aim to generate between \$3.75 and \$5 Million dollars in revenue by the end of year 5. Our cost structure, based on estimates for design, manufacturing, personnel, intellectual property, and competitor structure, projects upfront costs of about \$1 Million dollars to produce 250,000 tests kits. We anticipate raising the necessary funds through investments and grants to sustain operations until revenue starts in years 4 or 5. Revenue streams for Detickt include direct sales, volume dependent purchases, and licensing.

Detickt is a product that is highly feasible and relatively simple to manufacture, has low market competition, a significant amount of customer interest, and the ability to branch into different markets for product variation. There are technical challenges with the method to process the tick, as well as concerns about gaining the necessary funds, customer awareness, and lack of sustainability due to limited use of the product. We plan on counteracting these with plans to work closely with researchers on tick processing, diversify our funding opportunities as well as marketing, and create programs to educate people on tick-borne diseases and how Detickt can help them.



Background

Ticks are present across the globe, and with ticks, comes a variety of tick-borne diseases that can potentially be devastating to the host's health if transmitted. Unlike most insect bites in the United States, tick bites pose a greater threat to vertebrate hosts due to the nature of the bite and the pathogens the tick may carry. Tick bites tend to go unnoticed by their target host and the danger lies in the potential for these ticks to be carrying an infectious pathogen, typically in the form of bacteria. There are a large number of ticks that can act as a vector, as well as a variety of pathogens that could potentially be transmitted and cause diseases. Two potentially devastating and more common tick-borne diseases are Lyme Disease and Rocky Mountain Spotted Fever, which are caused by the bacteria *Borrelia burgdorferi* and *Rickettsia rickettsii* respectively (1). Both of these pathogens can cause diseases in both humans and animals and pose a major danger to the host's health if the disease is left untreated

These diseases are transmitted when a tick remains attached to an individual for a certain amount of time, as they transmit the infectious bacteria while feeding on the blood of their host. Tick bites are not always noticeable at first, so it can be easy for them to achieve several hours of attachment without being noticed. Many of the early symptoms of these tick-borne diseases are non-specific, and in some cases, infected individuals do not show any major symptoms at all. This can bring forth confusion in early diagnosis and uncertainty regarding whether or not to seek immediate medical attention when bitten by a tick. A portable testing kit, similar to an at-home COVID-19 test, for the most prominent tick-borne diseases could be essential for those prone to tick bites to receive prompt treatment and avoid major health risks.

Product Description

Detickt's proposed initial product is a self-testing, at-home enzyme linked immunosorbent assay (ELISA) test kit that can detect multiple tick-borne diseases within a tick simultaneously. The two tick-borne diseases this test aims at detecting are Lyme Disease and Rocky Mountain Spotted Fever. Unlike most traditional self-testing kits, the test specimen does not involve a human or host sample. Instead, the Detickt test kit detects the pathogens that are located within a tick, so the test specimen is the tick itself. Testing the tick as the test specimen can determine if a tick has the presence of either target pathogen, which are *Borrelia burgdorferi* and *Rickettsia rickettsii*. Detecting the presence of the target pathogen within a tick that has bitten a host can determine if a potential exposure to Lyme Disease and Rocky Mountain Spotted Fever has occurred. Since the tick itself is the test specimen, the success of the test kit depends on the presence of the tick on the host. With this in mind, the test kit is designed to be truly portable and so the user can perform the test immediately when the tick is found, regardless of their location.

The Detickt test kit will include two primary innovative technologies aimed at improving the detection and performance of at-home test kits. The first primary technology included in the test kit is the ELISA test assay. The format of the ELISA test will be a lateral flow immunoassay, very similar to the simple COVID-19/Flu self-testing assays. The lateral flow immunoassay test cartridge (Figure 1) will contain a single test-membrane that will detect the presence of both *Borrelia burgdorferi* and *Rickettsia rickettsii* target antigens on separated test lines for each pathogen. The second primary technology included in the test kit is a new, innovative method for



processing tick samples. Ticks can be difficult for specimens to process, so the test kit will include an innovative processing method to maximize the pathogen extraction from within the tick. The initial concept for the innovative tick processing method will include a combination of test reagents and a mechanism for effectively crushing and grinding the specimen. The specific details and practically for the test kit's tick processing method will require research to truly be both innovative and effective. The contents of the Detickt test kit for Lyme Disease and Rocky Mountain Spotted Fever includes:

- Information packet and test instructions
- Lateral flow immunoassay test cartridge
- Supplies for the innovative specimen processing method
 - Specimen collection tube, test reagents, utensils for the crushing/grinding mechanism
- Tool used to aid the user with tick removal

A brief overview of the process for the Detickt test kit begins with the user removing any ticks found and placing the ticks into the specimen collection tube. The user then performs the specimen processing method through a combination of adding test reagents and performing a crushing and grinding mechanism to ensure a maximum release of the target pathogens. Finally, the user would transfer the test reagent to the lateral flow immunoassay test cartridge before reading the results.

Company Values

Mission Statement

Our mission is to give outdoor adventures of all shapes and sizes peace-of-mind when it comes to tick bites by providing an accessible, portable, reliable, and user-friendly method for detecting potential exposures to tick-borne diseases.

Value Proposition

The major challenges patients face when dealing with tick-borne disease stem from the inconsistencies and timeframes for the diagnostic signs and symptoms. Many of the signs and symptoms for tick-borne diseases, especially lyme disease and rocky mountain spotted fever, don't show until weeks after the initial tick bite and in some cases, aren't expressed at all. However, these diseases can cause major long-term health complications if left untreated. The value proposition of Detickt aims to reduce instances of delayed treatment and help prevent long-lasting negative impacts to health which are associated with undiagnosed tick-borne diseases. Detickt would tackle this problem through the design, accessibility, usability of the test kit, while focusing on high sensitivity over specificity. Airing on the side of being "too sensitive" and allowing false positives in exchange to limited or no false negatives, would truly give the user peace of mind that if a tick tested negative, that tick truly did not have a pathogen presence and no exposure to either disease occurred.



Goals & Objectives

- Research and develop an innovative method for processing tick specimens to optimize the extraction of target pathogens
- Develop and commercialize a portable, highly sensitive, self-testing ELISA test kit for the detection of lyme disease and rocky mountain spotted fever within ticks
- Build awareness for the test kit product and establish the company as a trusted leader and partner in the self-testing diagnostics industry
- Achieve the targeted fund raising goal of \$1.5 million by Year 2
- Begin the manufacturing of the test kits by the end of Year 2 and beginning of Year 3
- Achieve anticipated revenue between \$3.75 Million and \$5 Million Dollars by Year 5

Market Analysis

The nature of the test sample for the Detickt test kit being the tick itself, does not limit the product's use to a single type of host. The test kit can be used to detect ticks that are found on any type of host organism, whether that be a human or an animal. This provides flexibility with identifying the customers segments and market potential for the company and its product.

Customer Segments

The customer segment for Detickt was identified as a segmented customer segment and would be based on the potential risk of a customer coming into contact with a tick. The primary target audience would be those who are at the highest risk of coming into contact with a tick, as they would find the most value out of the Detickt test kit. The primary target audience was identified as outdoor enthusiasts, which would consist of hikers, campers, hunters, or anyone else that spends an extended amount of time outdoors in nature. The secondary target audience was identified as pet owners, as they would be the second highest demographic at risk of coming into contact with a tick. Pet owners as a target audience would not be limited to the use of the product on just the owners themselves, but would also extend the use to their pets as well. Extending the secondary target audience to include the use of the product on pets allows for the potential entry into multiple markets.

Market Size & Growth Potential

Providing the primary and secondary target audiences with two different potential uses for the product allows for Detickt to enter into two different markets. Usually, it would not be advised for a startup company to attempt to enter into multiple markets. However, since the test sample for the test kit is ticks and not host samples, a majority of the test kit components would remain the same regardless of whether the product was used on ticks removed from humans or pets. The two potential markets for Detickt would be categorized as "Human Health" and "Animal Health". Detickt as a company does specifically enter into an existing market for either category. So in order to determine an estimated market size and growth potential, both market categories were analyzed to identify the Total Available Market (TAM), Served Available Market (SAM), and the Target Market.



Analyzing the human health market for Detickt, the TAM was identified as the Self-Testing Diagnostics market which had a global estimated value of \$11.4 billion in the year of 2024. The Self-Testing Diagnostics market is estimated to have a compound annual growth rate (CAGR) of 8.4% from 2024 - 2030, and is projected to have a value of \$18.3 billion in 2030 (2). The SAM within the TAM was identified as the U.S. Camping and Hiking market which had an estimated value of \$8.6 billion in the year of 2024. The U.S. Camping and Hiking market is estimated to have a CAGR of 4.2% from 2024 - 2030 and is projected to have a value of \$11.5 billion in 2030 (3). The Target Market provides the best estimate of the potential market size for Detickt with human health, as it represents the estimated number of potential customers. The Target Market for Detickt was identified as people who come into contact with ticks. A recent study estimated that roughly 31 million people came into contact with a tick within the U.S. in 2024 (4). This identified our target market size to be roughly 31 million potential customers with the human health market category.

Analyzing the animal health market for Detickt, the TAM was identified as the Veterinary Diagnostics market which had a global estimated value of \$10.71 billion in the year of 2024. The Veterinary Diagnostics market is estimated to have a CAGR of 10.0% from 2024 - 2030, and is projected to have a value of \$19.0 billion in 2030 (5). The SAM within the TAM was identified as the Veterinary Rapid Test market which had an estimated value of \$820 million in the year of 2024. The Veterinary Rapid Test market is estimated to have a CAGR of 12.3% from 2024 - 2030 and is projected to have a value of \$1.9 billion in 2030 (6). The Target Market for Detickt was identified as U.S households with pets, specifically households with dogs or cats. The American Veterinary Medical Association estimated that there were roughly 100 million households within the US with a dog or cat in 2024 (7). This identified our target market size to be roughly 100 million potential customers with the animal health market category.

Market Competition

The market competition for Detickt is essentially the same for both the human health and animal health market categories. The market competition for Detickt can be categorized as either direct or indirect competitors, depending on the sample type for the competitors test. The direct competitors are companies that also have a tick-borne pathogen test that are designed at detecting the presence of pathogens within ticks as the sample. There is currently only one direct market competitor for Detickt which is the Cutter Lyme Disease Diagnostic Test. This company's test is different from the Detickt test kit as the Cutter test requires the customer to collect the tick and mail the tick sample to their laboratory for molecular diagnostic testing. The indirect market competitors are companies that detect the presence of pathogens (or exposure to) within the patient samples. These types of tests also typically require the customer to mail the sample to a laboratory and tend to be expensive. Examples of indirect competitors include AcuDart Lyme Disease Screening Test and CVS Health At Home Lyme Disease Test Kit for human health, and Canine Lyme for animal health. Other indirect competitors would include tick preventatives as well as a potential Lyme Disease vaccine currently being developed by Pfizer.

Product-Market Fit

The current landscape of the specific and niche tick-borne disease testing market showed an absence in test kits that are portable in nature which can be performed at the user's home. Detickt



aims to fill this market gap by providing customers a portable method for testing tick specimens for the presence of diseases that generates immediate test results. A previous company called CarePlus Tick Test, brought a very similar product to market that only focused on detecting the presence of Lyme Disease in ticks. CarePlus only sold their tick test product within the European market, but do currently hold a patent for their Lyme Disease specific lateral flow immunoassay in both Europe and the U.S. However, the CarePlus Tick Test has been discontinued and is no longer on the market. The company is now focusing on other pest prevention products. Our team attempted to contact CarePlus in an effort to uncover why they discounted their tick test. The team's attempted methods of contact included:

- Multiple U.S. based CarePlus employees were connected through LinkedIn.
- Contact attempt through company's "Contact Us' website option.
- Multiple contact attempts for employees from CarePlus's parent company, Travel Health Group.
- Contact attempt through the author and innovator listed on the CarePlus Tick Test patent.

Unfortunately, our team was unable to contact and meet with someone from the CarePlus company. However, further literature research identified news articles and studies that provided potential insights into uncovering the reason for the CarePlus Tick Test's discontinuation. Two articles included studies that focused on evaluating the Careplus Tick-Test ability for detecting lyme disease and came to a similar conclusion. Both articles determined that there was a major issue with the CarePlus Tick Test's sensitivity (8,9). The Careplus test kit showed a lot of false negative results during their evaluation, which may be the underlying reason that the test kit was not successful on the market.

Market Barriers & Strategies to Overcome Barriers

Product Awareness: A major market barrier for Detickt is building awareness for the company and for the test kit product. The test kit requires the tick specimens be present at the time of testing and data from our VOC outreach indicated that most people remove a tick immediately when found. This would require the customer to have a kit ready at the time of testing. The overall success of Detickt and its product heavily depends on customers being aware of the product's existence. To overcome this barrier of product awareness, Detickt plans to establish strategic partnerships, allocate funds towards marketing, and foster strong customer relationships to help build awareness for the company.

Patent Protection: To protect the intellectual property of the test kit's two primary innovative technologies and to create a new potential revenue stream, Detick will need to consider the market barrier of patent protection. As previously stated. CarePlus currently holds a US patent for a lateral flow immunoassay aimed at detecting the presence of Lyme Disease within ticks. In order to avoid patent infringement, Detickt will ensure that the technology does not overlap with any of the specifically listed aspects of CarePlus's patented technology. Protecting the intellectual property of the innovative method for processing tick samples through patenting will also provide the opportunity to expand Detickt's revenue stream to licensing as well.

Product Reliability: The functionality and reliability of the test kit product will also be a major factor contributing to the success of Detickt. Research into CarePlus's previously marketed Lyme



Disease Tick Test uncovered that the test's poor sensitivity may have resulted in the product's departure from the market. To ensure that the test kit is both functional and reliable, Detickt will focus on ensuring the test has high sensitivity through an early phase of research and development. It will be crucial that Detickt hires a scientist with expertise in entomology and tick-borne diseases early on for the development of the test kit.

Competitive Advantage

- Increased Test Sensitivity: High test sensitivity will be a focus of the Detickt test kit to avoid the same mistakes as the CarePlus Tick Test. Ensuring high test sensitivity provides the user confidence and peace of mind that a negative test result is truly negative.
- **Decreased Turn-around Time**: The lateral flow immunoassay technology allows for at-home testing of tick samples and generates results immediately. This significantly reduces the turn-around time as compared to the direct competitors' mail-in tests.
- Ease of Use: Most consumers will be familiar with the testing process of lateral flow immunoassays from prior experience with at-home COVID-19 test kits. The Detickt test kit will provide a test kit for tick-borne diseases that is equivalent to the ease-of-use of COVID-19 tests.
- **Decreased cost**: The Detickt test kit will be priced at a lower cost than the indirect competitors that provide patient sample mail-in testing.

Marketing Plan

Customer Channels

The optimal channels for reaching out to the customer base of outdoor enthusiasts and pet owners consists of direct sales, web marketing and social media, and via word of mouth. For direct, off-the-shelf, sales, our goal is to sell our product in outdoor recreation stores, pharmacies, and pet stores. These locations will enable our desired customer-base to find our products in a somewhat obvious location. For those who are unfamiliar with the product, such central locations will make it easy for them to stumble upon. Online distributors like Chewy and Amazon will create another central and easily accessible location for customers to familiarize themselves with and purchase the testing kit.

By marketing via our website and social media, we can facilitate a stream of information to better convey the benefits of our product to our desired customers. Through posts on social media and specific pages within our website, we will spread educational content regarding tick-borne diseases, tick populations, associated risks, as the lack of awareness is one of the biggest hurdles in our marketing process. As this hurdle is being overcome, the desired outcome is for word-of-mouth to spread from existing customers to new potential customers. On one hand, this could come to fruition through online reviews and feedback. Another portion would be derived from outdoor communities sharing the product amongst one another. Testimonials regarding a positive experience from use of the product will be a key factor in obtaining new customers. Any negative feedback or testimonials will also prove beneficial, as they can provide us with areas for improvement.



<u>Customer Relationships</u>

It is essential for the relationship developed between Detickt and the customers to be one characterized by a high level of confidence in the test kit's ability to perform as advertised. Our customers should be able to obtain their proper results without having any difficulty in utilizing the equipment on their own. These aspects are what will create a strong, positive impact in our customers lives and convert them into repeat customers. In addition to being repeat customers, we hope that they will testify to the benefit of the product to their peers. The cost of a lost relationship is fairly high, so there will be opportunities for open communication between the customers and the Detickt team in the event where positive or negative feedback needs to be communicated and acted upon.

Marketing Mix

Product/Service

Detickt is a portable test kit for tick-borne diseases, specifically Lyme Disease and Rocky Mountain Spotted Fever, using an ELISA lateral flow assay to rapidly detect the above pathogens without the user having to send a sample to a lab and wait for results. The tick would be extracted from the user and crushed to create the sample, which would be run through the lateral flow assay to determine whether the pathogen(s) are present. Our VOC survey revealed that customers would prefer lightweight, yet durable packaging so the kit can be easily carried in a bag or backpack.

Price

According to VOC outreach, the most preferred pricing formats were a singular test kit for \$20 and two test kits in one package for \$30, with only a 2% difference in preference between the two. Our initial production estimate is around \$1 Million dollars to produce 250,000 kits, including operational costs. If we sell kits individually between \$15 to \$20 each we project about \$3.75 to \$5 Million dollar profit in the first year of launch. Given the lack of direct competition in the market for tick-borne disease diagnostic kits for ticks themselves, we believe a pricing between \$15 to \$20 per kit is both reasonable and accessible for customers, especially considering the convenience and peace of mind it could offer.

Promotion

For Promotion, we plan to leverage a multi-channel strategy to build awareness and drive customer adoption of Detickt. Our approach mostly includes online marketing such as targeted digital advertisements to reach both outdoor enthusiasts and companion animal markets. We also plan to develop educational content to highlight the importance of tick testing and empower customers with knowledge about tick borne diseases as well as how to correctly use the test kit. This content will be shared through Detickt's website, partner platforms such as Bass Pro Shops and PetSmart, and educational webinars or videos.

Place

Detickt would be distributed mainly in retail stores directly, focusing on outdoor and pet-related shops to reach our target markets. It is also planned to be sold in pharmacies, online retailers such as Amazon, and potentially distributed at outdoor spots such as U.S. national parks.



Operational & Financial Information

Key Resources

In order to move the operation of fulfilling the value proposition forward, there will be several key resources necessary to acquire. This includes personnel, facilities, adequate finances, and secure intellectual property. When it comes to personnel, there will initially be a low count of staff members in an attempt to reduce up-front costs. This limited staff would have mixed roles of customer relations and marketing across the board, would have a scientist with a background in entomology and immunology, and the role of an accountant/financial manager. Many of these roles would be shared amongst the staff members, but the scientist will need to be hired from outside of the founding team. By keeping the team small, we will be able to save costs via limited salaries.

When it comes to the location of our labor, the intent is to primarily work where it is free to do so. This could be in the comfort of one's own home, or more likely within a public co-working space accessible within RTP. The physical research and development lab work and manufacturing will be outsourced to contract research organizations and companies specializing in mass production of testing kits, respectively.

Having intellectual property rights for our technology will give us a competitive advantage within the market. However, the timing and development of it needs to be strategically coordinated. To effectively accomplish this, a patent attorney will be hired with the task of generating necessary documentation for the acquisition of provisional and utility patents when appropriate.

In order to pay for these resources, it will be critical to acquire funding through grants, loans, and investments. One grant pursued could be a Small Business Innovation Research grant or Small Business Technology Transfer grant, as we'd be bringing forth innovative technology that could stimulate the economy and further innovation. Another potential grant could be pursued through the Biomedical Advanced Research and Development Authority's Lab At-Home program (10). This program funds the development of at-home testing kits, but is currently paused by the government. It would be worth working towards in the event that it is unpaused in the future. Aside from grant money, we could also seek help via the North Carolina Biotechnology Center, from angel investors, or from venture capitalists.

Key Partners

There are many opportunities for the team to collaborate with different companies and organizations to help make Detickt a reality. These can be split into four categories: manufacturing, distribution, strategic partnerships, and funding. Different options are also possible for both the outdoor enthusiast market as well as the companion animal market.

1. Manufacturing: Detickt can be produced with the help of CDMOs/CROs. Fortis Life Sciences, Firalis Molecular Precision, and Abingdon Health can produce whole kits; Sinobiological and Operon specialize in producing the antibodies or antigens needed for the kit. Additionally, ThermoFisher Scientific offers kit assembly and packaging services as well as a private label that would allow Detickt to be sold under their name.



- 2. **Distribution:** Detickt would primarily be marketed through direct sales. Many retail companies allow different products to be sold through them. Dick's Sporting Goods, REI, ORVIS, and Bass Pro Shops have applications to sell a product at their store or in their catalog. Detickt would also be sold in pharmacies (CVS, Walgreens, etc.) and online via Amazon. For companion animals specifically, the team would also lean towards partnering with stores like Petsmart, Petco, and online retailers like Chewy.
- 3. Strategic Partnerships: These partnerships serve to increase the awareness and exposure of Detickt to the team's markets, as well as providing additional education about tick-borne illnesses. The National Parks Service's Commercial Use Authorization would allow Detickt to be provided or sold at national parks in the United States. Similarly, the team can partner with regional chapters of Scouting America to distribute the test to their troop, and through program partnerships, the team could educate scouts on tick diseases and tick safety. CDC is a potential partner in two ways a public-private partnership or a contract. Public-private partnerships would provide access to potential customer groups, as well as professional groups for more exposure; a contract would authorize the team to produce the kit, and the CDC would pay for them to distribute it.

 For the animal companion market, the American Veterinary Medical Association (AVMA) offers broad partnerships as well as advertising opportunities in their journals (JAVMA). There are also some companies that produce similar tick-borne disease diagnostic tests in animals specifically canines to potentially collaborate with. Idexx and Antech Diagnostics have point-of-care PCR panels for tick-borne diseases.
- **4. Funding:** Aside from grants, funding for Detickt can be secured through venture capital firms and angel investors.
 - a. Angel investors: RTP Capital works primarily in the North Carolina region and offers seed & early-stage funding. The Triangle Angel Fund offers early-stage funding, and tends to fund new ideas rather than improvements to existing ideas.
 - b. Venture capital: Hatteras Venture Partners offers early-stage funding and has a focus on medical devices and diagnostics; KdT offers seed, early-stage, and late-stage funding in a wide range of sectors in the life sciences. Coddle Creek Ventures offers early-stage funding for products that are past the proof-of-concept phase, making them only a viable option if Detickt is manufactured successfully.

In addition to these organizations, North Carolina State University can help provide funding through the Wolfpack Investor Network (WIN) and Office of Research Commercialization (ORC). The WIN offers seed and Series A funding for NC State-affiliated entrepreneurs through their vast network of connections to venture capital and angel investors. The ORC has services related to launching startups, patent/IP protection, and some funding, making them a very important resource to have as well.

Revenue Streams

The team identified three primary revenue streams based on fixed menu pricing to support and sustain Detickt as a viable business:

- 1. **Direct sales (List Pricing):** Revenue generated through the direct sale of the portable tick-borne disease testing kit to customers, either through distributors or over the counter purchases. Accessibility and distribution strategies depend on the primary market focus.
 - a. Outdoor enthusiast market: Distribution channels may include: Bass Pro Shops, Dicks Sporting Goods, Cabelas, REI, major pharmacies, and Amazon.



- b. Companion animal market: Distribution channels may include: PetSmart, Chewy, Amazon, Walmart, veterinary clinics and or hospitals, and Tractor supply Co.
- 2. Volume dependent purchases: Kits may be sold in bulk at discounted rates to large organizations or through strategic partnerships, with pricing dependent on purchase volume.
 - a. Outdoor enthusiast market: Potential partners could include the CDC, National Parks, and Scouting America.
 - b. Companion animal market: Potential partners could include veterinary hospital chains, Indexx, Antech, and Zoteis Petcare.
- **3.** Licensing: Licensing the proprietary technology and intellectual property behind Detickt allows for clients to integrate the lateral flow assay into their existing services or products. Developing and patenting a new innovative method for processing tick samples also provides the opportunity to license this new processing method to laboratories who process vector-borne diseases. This revenue stream is flexible and applicable across differing markets.

Future Considerations for Revenue Opportunities

Additional revenue streams under the consideration of the group include future adaptations of the lateral flow immunoassay for tick-borne diseases other than Rocky Mountain Spotted Fever and Lymes Disease, region-specific test kits, and expansions into other markets.

Cost Structure

In determining the cost of Detickt's tick-borne testing kit we had to take several factors into consideration, including designing and manufacturing costs, cost of personnel, intellectual property costs, acquisition of funds, and the cost structure of our competitors. The team initially believed that building a facility and having an internal team as well as outsourcing of manufacturing for Detickt was how we would shape our cost structure. Ultimately, through feedback from mentors, industry experts, and our directors, we decided that our cost structure would be based on completely outsourcing the designing and manufacturing aspects of our product development. This saves us the cost in facilities, but also opens up the need to pay for designing new antibodies, development of the assay, and the manufacturing of the test kit itself.

For this section, numbers were taken through general research cost values for manufacturing to create approximate ranges to complete the initial production phase of Detickt. The team concluded that manufacturing 250,000 kits for launch by year 4 of our 5 year timeline will cost anywhere in between \$500,000 to \$750,000. This includes pricing per kit based on market research as well as costs associated with manufacturing other lateral flow ELISA assays (11,12).

Other costs estimated include:

- Personnel: Projected annual costs for salaries and benefits are estimated at approximately \$300,000, beginning in year 2 or 3.
- Facilities: The team plans to utilize publicly available co-working spaces within the Research Triangle Park area such as Frontier RTP coworking which offers free access and free memberships.



- Intellectual property: Two patents are planned: one to cover the sample processing component of the tick, and one to cover the lateral flow assay technology used. The total estimated intellectual property costs is \$33,000.
 - Provisional Patent applications- estimated to be about \$600.
 - Utility patent applications- estimated to be about \$2,000.
 - Patent Attorney fees- estimated to be approximately \$30,000

As a team, we believe that the total upfront costs to produce 250,000 test kits is approximately \$1 million. With this in consideration, we anticipate the need to raise \$1.5 million through a combination of investments and grants to sustain business operations until revenue generation begins in year 4.

Permit & Licencing Considerations

The intent of this test kit is not to be a medical device, which prevents it from having to go through the strict procedures and fit within the regulatory constraints put forth by the FDA. It may be beneficial to have a consultation with a legal expert, but it is known that business licensing will need to be acquired. There are no current plans to license the testing kit, but if interest is shown then this could be a possibility further down the timeline. If a novel tick processing tool or kit of its own is developed in the process of developing the tick-borne disease testing kit, then there would be potential to license this product out to entomologists or others with an interest in adapting this technology to their own product lines. The licensing of this product would enable other researchers to obtain samples with minimal loss in the processing.

Key Activities

Our business development is structured across a five year timeline with phases from 2025 to 2029, each focused on strategic milestones designed to guide the growth and successful market entry of Detickt.

- 1. Pre-Launch and Ideation phase (2025)
 This phase includes the establishment of business operations and early stage product development. Branding and packing strategies will be initiated as we have received feedback through our initial voice of customer surveys. During this phase, steps should be taken to secure intellectual property of both the lateral flow immunoassay as well as the sample processing component involved to crush the tick itself. During this time, we will actively pursue initial funding and grant opportunities to support our early stage growth.
- 2. Product Development phase (2026)
 In the product development phase, we will focus on outsourcing the creation of the first prototype for Detickt and conducting quality assurance testing using Careplus tick test as a benchmark. Validation studies can also be conducted using negative and or positive disease carrying ticks. Simultaneously, platform creation and business networking will begin in order to support future marketing efforts, and pre-seed funding will be pursued to finance development of the business.
- 3. Final Product Development and Market Preparation phase (2027)



The final product development and market preparation phase centers on finalizing testing and preparing for the distribution of products within the distributors mentioned in the revenue streams portion of the report. We will also begin building online awareness for Detickt as well as providing educational marketing content in order to increase visibility before the product launch. During this phase, series A funding should be secured in order to support Detickts full market entry.

- 4. Go-to-Market phase (2028)
 - As we launch Detickt, our primary focus will shift towards executing our go-to-market strategy, acquiring customers, and providing effective support services. Continued awareness campaigns and content development is key in this stage to help drive engagement and build a trustable brand. This phase also marks the beginning of revenue generation and strategic funding efforts to support ongoing growth.
- 5. Scaling and Expansion phase (2029) With the product established and in both markets, we will shift towards post-market surveillance of Detickt to maintain quality and ensure a strong customer experience. Infrastructure growth is also a possibility at this stage depending on revenue generation. Market expansion efforts can also be considered dependent on revenue generation and market domination. During this phase, we aim to pursue series B funding and build strategic partnerships to further expand Detickts reach and impact.

This five year timeline approach allows us to manage growth while minimizing financial risk and ensuring consistent progress for Detickt. By aligning development milestones with funding goals, we believe we can position Detickt for long term success.

Production Method & Control

As mentioned in the cost structure, we plan to manufacture Detickt through outsourced contract manufacturing, including the outsourcing of quality and validity testing to ensure consistent test performance. We plan to begin batch production totaling 250,000 test kits by year 4 for market launch, with the potential to scale to mass production dependent on market demand. We believe that our outsourcing manufacturing partner of choice will operate in facilities that meet GMP standards, follow GDP, and adhere to established SOP documents. Throughout the production process, quality control measures such as visual inspections and routine performance checks, should be conducted and thoroughly documented to ensure consistency, compliance, and traceability.

Business Strengths, Challenges, and Recommendations

Overall, the greatest strength our business has is a unique and easy-to-make product. Detickt has very little market competition, being the only tick-borne disease test kit currently on the market that does not require samples to be sent to the lab. It is also predicated on simple scientific technologies, namely the ELISA lateral flow assay which has established use in similar rapid tests, making it easier to manufacture and test. While the kit in its current state only tests for Lyme Disease and Rocky Mountain Spotted Fever, there are other tick-borne diseases in different regions of the U.S. that could also be tested for. The ability to not only potentially produce regional variants of Detickt, but also to market different versions of the kit towards animals and humans, makes for a sustainable business. The two VOC surveys also showed a high level of



interest from potential customers - many expressed that they would use Detickt if it were successfully made, especially in the human health market. There was interest in the animal health market as well, but not as strong due to smaller sample sizes.

The development and production of Detickt test kits does pose some challenges to consider. The biggest technical challenge is finding the best way to process ticks in order to release enough target protein for the lateral flow assay to have high sensitivity, while also being safe and easy for the user. The innovative tick processing method that has been mentioned would combine manual and chemical methods and would hypothetically check the above boxes, but more research is needed to refine the exact process. As it is with any start-up business, securing the amount of funding needed to successfully manufacture and market Detickt is a major hurdle, especially in today's fluctuating economy. Customer awareness plays a major role in the success of a product like Detickt as well. Customers that may have a need for the kit cannot buy it if they are never reached and do not know that the product exists. Finally, there are some questions about the sustainability of selling Detickt from a customer standpoint. If the kits' use is limited, or if customers buy the kit and don't use it, the customer base could shrink if they feel it is not a necessary purchase.

Going forward, we are taking several steps to overcome the challenges that Detickt may face. The team is prioritizing working with personnel that can refine the innovative tick processing method, namely researchers in entomology and biotechnology. Marketing Detickt is also a major focus, and combining traditional advertising methods with more modern methods (i.e. social media) will be very important going forward. In addition to that, establishing strategic partnerships early on will help spread the awareness of the company and product through routes outside of direct marketing. Establishing strong customer relationships through education on tick-borne diseases alongside Detickt can aid in both marketing the product and increasing customer awareness; a potential application of partnering with Scouts of America is educational programs and/or live demos of the kit to regional scout troops, for example. Lastly, being cost-sensitive in general with business operations is a philosophy the team will put into practice while navigating the rocky path of getting Detickt into the user's hands.



Appendices

Figures

Figure 1. Diagram of the components for a simple lateral flow immunoassay (13).

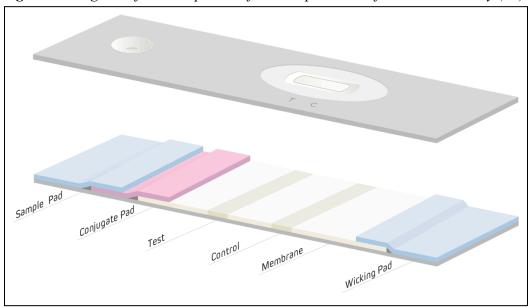


Figure 2. Cost structure and Payment Flow

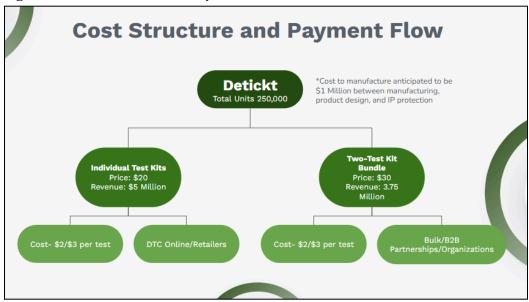
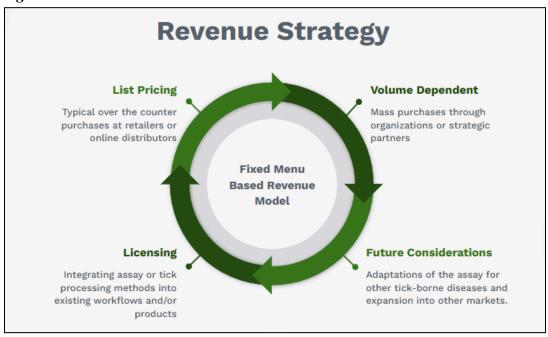




Figure 3. Revenue Model



KOL Interviews

Table 1. Contact List for KOL Interviews

Name	Organization	Position	Method of Contact
Joe Larsen	Kensington Street Consulting	Owner	Zoom Interview
Leslie Lewis	Start-up Similar to Detickt	Co-founder	Zoom Interview
Harish Marisiddaiah	CaroMont Regional Medical Center	Infectious Disease Specialized Physician	Phone Interview
Sophie (Carrell) Noel, Ph.D.	Former NC State Professor	Chemical and biomolecular engineer, ELISAs	Zoom Interview
Clyde Sorenson	NC State	Entomology Professor	Zoom Interview
Amanda Elam	Galaxy Diagnostics	CEO	Zoom Interview
Joshua Bernick	Virginia Department of Health	Vector-borne Epidemiologist	LinkedIn Interview
Ed Breitschwerdt	NCSU Veterinary School	Professor, Vector-borne pathogen expert	Zoom Interview
Joe Webb	Vitality Robotics	Founder	Zoom Interview
Barbara Qurollo	NCSU Veterinary School	Assoc Research Professor	Zoom Interview



VOC Customer Data

 Table 2. List for Distribution of VOC Qualtrics survey

VOC Contact Name	VOC Role	Method of Contact
Clayton Ruck & Hiking club	Outdoor enthusiasts	Facebook
Charlotte Hiking camping and backpacking group	Outdoor enthusiasts	Facebook
Lyme disease, Tick-borne Disease, Relapsing fever group	Tick-borne	Linkedin
Ticks and Tick-borne Disease	Tick-borne	Linkedin
Raleigh NC- Mountain Biking and Hiking trails	Outdoor enthusiasts	Facebook
WNC Mountain Biking	Outdoor enthusiasts	Facebook
Raleigh Trail Runners	Outdoor enthusiasts	Facebook
North Carolina Hiking and Waterfalls	Outdoor enthusiasts	Facebook
Charlotte Hiking, camping, and backpacking	Outdoor enthusiasts	Facebook
Purpose Driven Hikers	Outdoor enthusiasts	Facebook
Denver town talk	Outdoor enthusiasts	Facebook
Lincolnton town talk	Outdoor enthusiasts	Facebook
Rock climbing class NCSU	Outdoor enthusiasts	Email
Whitewater Center	Outdoor enthusiasts	Email
Outdoor Reddit Group	Outdoor enthusiasts	Reddit
Shops in Cashiers	Outdoor enthusiasts	Flyer
Shops in Highlands NC	Outdoor enthusiasts	Flyer
Cashiers Facebook group	Outdoor enthusiasts	Facebook
Mikayla Noguira	Pets tiktok	Email
Darcy Mcqueeny	Pets tiktok	Email
Yolanda Daviz	Pets tiktok	Email
Skylar Ray Rose	Pets tiktok	Email
Pet health advice	Pet health	Facebook
Personal Linkedin	Pet owners	Linkedin
MMB Group me	Pet owners	Groupme



MMBunch Group me	Pet owners	Groupme
Pet Online Marketing Group	Pet owners	Linkedin
MMBAN	Pet owners	Linkedin
Denver town talk	Pet owners	Facebook
Lincolnton town talk	Pet owners	Facebook
Cashiers town talk	Pet owners	Facebook
Clayton town talk	Pet owners	Facebook
Pets community	Pet owners	Reddit
Surrounding petsmarts	Pet store	Flyer
NC State Flea Market booths (3)	Petstore	Flyer
Apartment pet park	Pet owners	Flyer
Pets community 2	Pet owners	Reddit
Triangle Biotech Tuesday	Pet Owners	Flyer

Table 3: Detickt Outdoor Survey Results. Displays a summary of the questions asked and the highest percentage answers from a total of 204 participants.

Detickt Outdoor Survey Topic	Highest Percentage Answers (Out of 204 Total Responses)
Age range	26%- 55+ Years old
Gender Identity	71%- Female
Types of Outdoor Activities (select all that apply)	Range of activities, some fill in the blank answers. From list provided 82% chose Hiking.
Engagement of Outdoor Activities	44%- Extremely Often (Multiple times a week)
Frequency of tick bites within the past year	64%- 0 Times
Removal of Tick	64%- Immediately remove the tick when found
Concern of Tick Borne Disease	34%- Moderately Concerned
Likeness of using Detickt Test kit	47%- Extremely Likely
Practicality of Test kit size	42%- Small package with 1 test 48%- Medium package with 2 tests
Preference of Test kit material	55%- No preference Other answers provided- Durable, Lightweight, Environmentally Friendly.



Table 4: Detickt Pet Survey Results. Displays a summary of the questions asked and the highest percentage answers from a total of 51 participants.

Detickt Pet Survey Topic	Highest Percentage Answers (Out of 51 Total Responses)
Age range	35%- 26-35 Years old
Type of Pet owned	73%-Dog
Use or Not of Tick Prevention Methods for Pets	68%- Yes, Regularly
Interest in Using Health Related Products for Pets	39%- Somewhat Interested 47%- Very Interested
Types of Outdoor Activities	Range of Activities 71%- Walking or Jogging 85%- Playing in the Backyard
Frequency of Outdoor Activities	43%- Extremely Often (Multiple Times a week)
Frequency of Ticks on Pets in Past Year	56%- 0 Times
Removal of Tick	63%- Immediately remove tick when found
Concern of Tick-Borne Disease	38%- Slightly Concerned
Likeness of Using Detickt Test Kit	45%- Somewhat Likely
Ideal Packaging Material	57%- No preference Other- Lightweight, Durable
Practicality of Test Kit Format	45%- Small package with 1 test for \$20 43%- Medium package with 2 tests for \$32
Preference for Purchasing Detickt	57%- Online (Amazon, Chewy, etc)

Business Model Canvases

Figure 4. Version 1 - Detickt Business Model Canvas





Figure 5. Version 2 - Detickt Business Model Canvas

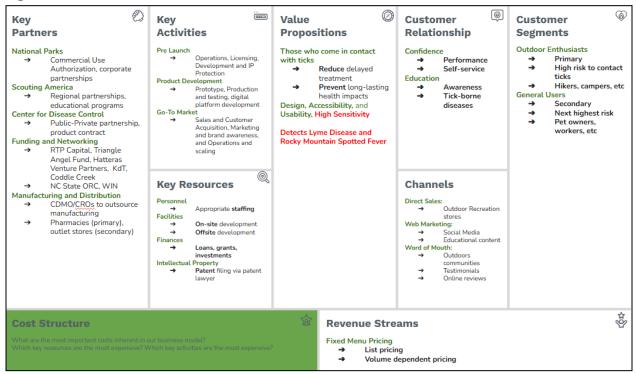
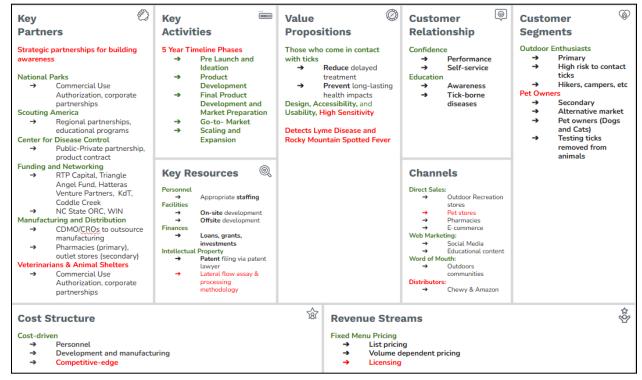


Figure 6. Final Version - Detickt Business Model Canvas





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