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Business Plan

2025

Rule Out Acute Rejection in Renal Transplant Patients

Presented By McMaster iGEM

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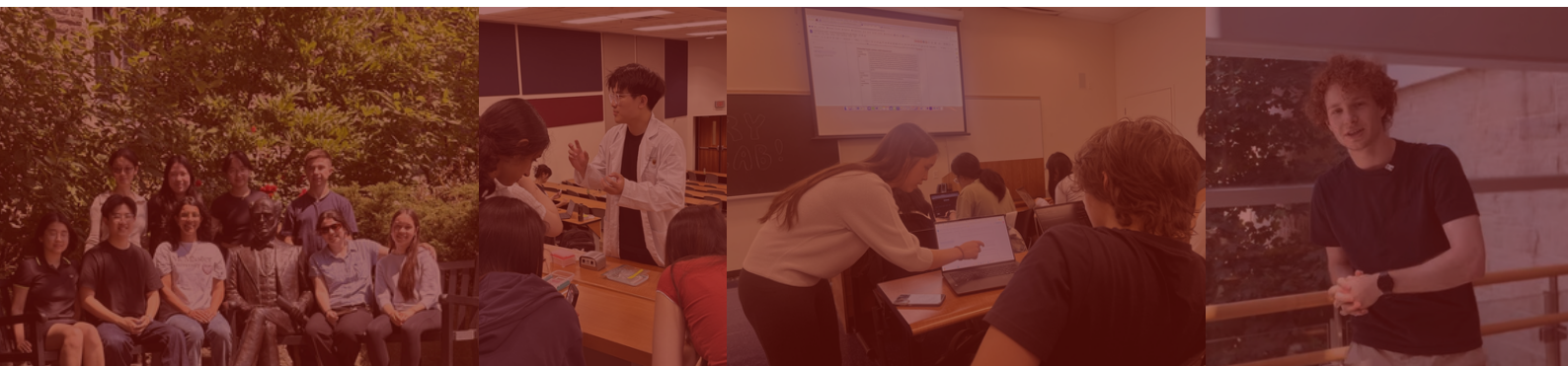


1. Product

1.1 Opportunities

Early detection of acute allograft rejection remains a major clinical challenge during the postoperative period. Although organ transplantation can be life-saving, long-term graft survival depends heavily on early identification and treatment. Subclinical allograft rejection remains a major concern for many transplant recipients, as its immune activation against alloantigens on the transplanted tissue ultimately leads to the loss of the graft (Liau et al., 2020). In 2023, 3,369 Canadians underwent solid organ transplantations (Canadian Institute for Health Information, 2023), a small fraction of the 172,397 procedures performed globally (Eflein, 2025). Yet, 15% of transplant recipients commonly experience acute rejection within the first three months, a period when symptoms are often subtle or entirely absent. Without proper immunosuppression, the risk of rejection eventually approaches 100%, leading to the irreversible loss of the transplant (National Kidney Federation, 2019).

Current diagnostic tools fall short in accuracy and routine surveillance. Long considered the “gold standard”, biopsies are invasive and prone to risk. A study found minor complications occurred in 20% of biopsy cases, while major complications —such as transfusions, hospitalizations, or surgical interventions—occurred in nearly 2% of cases (Han & Lubetzky, 2023). Beyond procedural risk, biopsies also suffer from diagnostic limitations. Their invasive nature makes frequent use impractical in clinical settings. Furthermore, histological interpretations are often subjective and inconsistent, raising concerns about reliability. Noninvasive methods like measuring serum creatinine and eGFR lack specificity and sensitivity for detecting early graft injury or subclinical rejection —injuries that occur without apparent clinical symptoms (Lee et al., 2023). Their values are heavily influenced by non-graft-related factors such as a patient’s age, muscle mass, and nutritional status. Moreover, these biomarkers often remain within normal ranges for 24–36 hours after acute kidney injury, delaying detection until substantial damage has already occurred. Recent developments in donor-derived cell-free DNA (dd-cfDNA) tests have introduced alternative non-invasive options for rejection monitoring (Oellerich et al., 2022). These tests are reimbursed by Medicare at approximately $2,841 USD per test for patients who meet eligibility criteria (U.S. Securities and Exchange Commission, 2022). These solutions are not practical for clinical testing and do not allow for frequent monitoring, which is critical during the first post-transplant year when patients are most vulnerable to complications.

Current testing procedures require post-transplant patients to have labs done on a monthly basis (BC Transplant, 2021, p.32). Patients living in remote areas must allocate half a day or even a whole day for travelling and attending hospital visits. Patients and physicians alike recognize the need for point-of-care (POC) solutions. With over 100,000 kidney transplant recipients in the U.S. alone (Wang & Hart, 2021), routine monthly testing could translate into 1.2 million tests annually. There is a pressing need for accessible, rapid, and affordable diagnostics that allow patients to test from home and deliver results to hospitals. That is why the iGEM McMaster team is developing ***REACT*** (Renal Ease-of-Use Assessment for Clinical Transplants): an accessible POC synthetically engineered to rule out early acute rejection in transplant patients.

1.2 Proposed Solution

REACT is a novel POC screening test for acute graft rejection. By combining Rolling Circle Amplification (RCA), an isothermal nucleic acid amplification technique, single-stranded DNA aptamers, and G4 DNAzymes, our system will quickly detect low concentrations of specific biomarkers that indicate graft rejection. In the context of kidney rejection, we've targeted urinary CXCL9 and NGAL as our biomarkers.

The system contains aptaprimer sequences containing an *aptamer region* targeting NGAL, CXCL9, or creatinine and a *primer region* forming an RCA initiation complex when bound to its complementary circle template in solution. The circulate template, another nucleic acid sequence, contains a primer-binding region and encodes a G4 DNAzyme which produces a colorimetric change. The test results are then captured by smartphone camera on the SnapREACT app.

Our prototype is intended to function as a preliminary screening test that would "rule out rejection"; a negative result would rule out rejection, while a positive result would lead to further, more specific tests being conducted. In general, the purpose of "rule-out" tests is to eliminate certain conditions from consideration when a patient presents with symptoms. As such, ensuring against false-negative results, especially when the condition being ruled out is dangerous, is essential (Worster et al., 2002). REACT achieves this to a high degree, displaying a very high sensitivity, with CXCL9 protein levels demonstrating an overall NPV of 92% (Hricik et al., 2013). In addition to its extreme sensitivity, our device demonstrates a low specificity, which can lead to false positives. However, given that further tests would be conducted in the wake of a positive result, and REACT's ease of use, a false positive result would in no way compromise patient well-being, and actually helps further reduce the risk of a false-negative result. By ruling out rejection quickly, easily, and cheaply, our product would streamline the monitoring of postoperative kidney graft function, improving patient quality of life and health outcomes.

As a commercially available POC test, users would have access to reliable rejection testing without the typical time investment required for a trip to the hospital, all while circumventing the risks associated with more invasive screening procedures. As a result, our product would promote health outcomes by both limiting risks related to the diagnosis of rejection and by increasing accessibility, particularly for those in rural communities with less access to healthcare. Furthermore, our product boasts a lower price compared to other means of testing, only costing end users an estimated $140.08 per test kit containing 10 units in Canada, and $169.30 in the USA. At that price, it would be far more practical for clinical testing than current methods, and enable frequent monitoring of patients.

1.3 UN Sustainable Development Goals

As we work to address the shortcomings of post-operative renal monitoring devices, sustainability is at the core of REACT. This technology has the potential to aid the 27% of transplant patients who suffer from subclinical rejection (ABMR and TCMR) worldwide (Loupy et al., 2015). McMaster iGEM is committed to REACT's sustainable development by addressing all relevant UN Sustainable Development Goals (SDGs), ensuring we improve human lives while protecting the environment.

SDG Goal 3: Good Health and Well-Being

In answer to the UN call for improved health and well-being, we targeted subclinical rejection, a major, yet overlooked cause of preventable transplant failure. On average, 15% of transplant recipients experience acute rejection, and without treatment, it eventually leads to irreversible loss of the graft. Current methods lack accuracy and accessibility. Our REACT platform addresses this gap by remotely detecting three kidney health biomarkers through colourimetric test results, enabling reliable results that lead to earlier intervention.

Guided by Dr. Blydt-Hansen, our team identified the urgent need for rapid, low-cost POC tools to enable more frequent monitoring and earlier intervention in transplant care. We re-envisioned our platform for low-resource and remote settings. In response, we began to explore more user-friendly paper-designed designs, focusing on clinical utility over laboratory optimization. Dr. Blydt-Hansen's patient-centred perspective has driven our strategy to ensure equitable, sustainable transplant care for all.

SDG Goal 10: Reduced Inequalities

Many transplant patients, particularly underrepresented populations, experience worse outcomes in graft health, often due to systemic disparities. In rural areas with limited post-operative renal care resources, individuals have no choice but to travel long distances to visit the nearest transplant centre. In response to the UN's call to action to reduce inequalities, REACT's procurement strategy will account for geographical context, ensuring test kits are accessible in both rural and urban settings. To the patient, POC testing saves transport cost, time lost from work, and the stress of having to return for test results later (Kuupiel et al., 2017). POC testing also expedites treatment and increases equitable access to testing, significantly reducing the number of transplant recipients who are unaware of their renal health status (Kuupiel et al., 2017).

SDG Goal 12: Responsible Consumption and Production

By using bio-derived materials and natural fibres like cellulose, we reduce the plastic pollution and chemical waste associated with the traditional disposal of POC tests. The WHO estimated that PCR testing for COVID-19 generated 15,000 tons of plastic waste globally and 731,000 L of chemical waste (Street et al., 2022). To ensure responsible production and consumption, we will manage REACT's afterlife through the use of biodegradable materials and streamlined sustainable disposal procedures.

2. Stakeholder Analysis

2.1 Stakeholders

To ensure the success of REACT, we will establish contacts with various key parties. Understanding the needs and influence of stakeholders, from transplant patients to industry experts, is essential for aligning our solution with market and regulatory requirements. Establishing contacts with different key parties that fill the gaps in the resources and expertise we are lacking is crucial in refining our strategy.

Transplant Patients

Transplant patients have high interest but relatively low power in influencing product implementation or policy. However, their lived experiences and struggles make their voices critical for shaping a solution that targets their needs. Incorporating their feedback early in development will ensure our product provides real-world value.

Many transplant patients, particularly underrepresented populations, experience worse outcomes in graft health, often due to systemic disparities. For instance, African American recipients face a higher risk of acute rejection (11.8%) than white patients (Ilori et al., 2015). Social determinants such as public insurance, neighbourhood poverty, and low SES have also been associated with increased graft failure (Hartje-Dunn et al., 2024). Additionally, pediatric and adolescent transplant recipients are more prone to acute rejection, with a study showing 21.7% rejection rate in adolescents and a 12.6% in younger children during the first year post-transplant (Arassi et al., 2024). Our team aims to target and survey these demographics in order to better understand their needs.

Furthermore, patients often live under significant emotional distress. Surveys show that fear of allograft rejection is a top concern, affecting mental health and quality of life (Forsberg et al., 2023). By offering a non-invasive, side-effect-free solution with early and rapid detection, our platform directly addresses both the physical and psychological burdens transplant patients face, particularly in resource-strapped or rural areas.

Healthcare Providers

Nephrologists, nurses, and their transplant coordinators are integral to implementing new post-transplant treatments as supporters of high-quality graft care. Their buy-in is critical to our product's integration into existing clinical workflows. Their expertise also ensures we remain compliant with the top practices and safety protocols. We will also consult healthcare providers throughout the implementation of REACT, integrating their feedback to ensure its successful use in clinical monitoring.

Investors

These stakeholders provide vital support for scaling, funding, and navigating regulations, as well as ensuring IP protection and commercialization pathways. By engaging with these stakeholders, we can tap into their funding, facilities, and expertise, facilitating market entry while positioning our solution for long-term adoption and commercial viability.

- Canadian Donation and Transplantation Research Program (CDTRP): supports research and innovation that address barriers in donation and transplantation, aiming to advance long-term health outcomes and quality of life for Canadian transplant patients (CDTRP, n.d.). Establishing a relationship with them presents opportunities of potential funding and research collaboration to further validate and develop the technology within the field of transplantation.
- The Hospital for Sick Children (SickKids), Toronto: Ontario's leading center for pediatric transplantation and applied genomics. A partnership could result in access to facilities, resources, and potential collaboration opportunities for clinical trials and validation studies in pediatric care.
- BIOTECanada: An industry association with 250+ members across diagnostics, pharmaceutical, and government bodies. Offers network access and support to form partnerships or find investors that McMaster iGEM could leverage for scaling and market entry of REACT.
- CAMEDA (Canadian Medtech Alliance) program: enables life science entrepreneurs to leverage up to $100,000 in matching funds to collaborate directly with a contract development and manufacturing organization (CDMO) to help build manufacturing capacity in Canada (CAMEDA, n.d.). With CAMEDA, iGem McMaster can gain access to mentorship and advisory services from experts to make informed decisions and establish medical device manufacturing processes. This partnership will support later stages of commercialization, where financing is needed to advance regulatory approvals, conduct clinical trials, and undertake initial batch manufacturing (CAMEDA, n.d.).

Transplant Centres

Transplant centres hold high influence and moderate-to-high interest, especially those engaged in novel treatments or overwhelmed by patient demand.

Partnering with them allows us to gather feedback and assess real-world performance. Centres like St. Joseph's Healthcare Hamilton, home to the Renal Transplant Clinic, or Ajmera Transplant Centre at UHN, which performs 700+ transplants per year (UHN Foundation, n.d.), offer one-of-a-kind opportunities for scaling. This is to ensure our therapies address real-world pains, such as limited treatment efficacy and complex administration, while meeting needs for safety, accessibility, and ease of use. By integrating these insights into our therapy design, we create patient-centric solutions that offer improved outcomes and a better overall experience for patients and clinicians. Additionally, we plan to partner with hospitals to set up clinical trials and gather critical data on the requirements and deployment of REACT, ensuring our POC test is practical, effective, and aligned with healthcare standards.

These centres face challenges with transplant workforce shortages, long waitlists, and delayed evaluations. For example, mean waiting times for admission for renal biopsy averaged over 13 days before implementing streamlined practices (Tsai et al., 2024), demonstrating the impact of novel solutions. By integrating our solution into the diagnostic workflow, we can help reduce burden, significantly shorten diagnosis time, and alleviate clinician burnout.

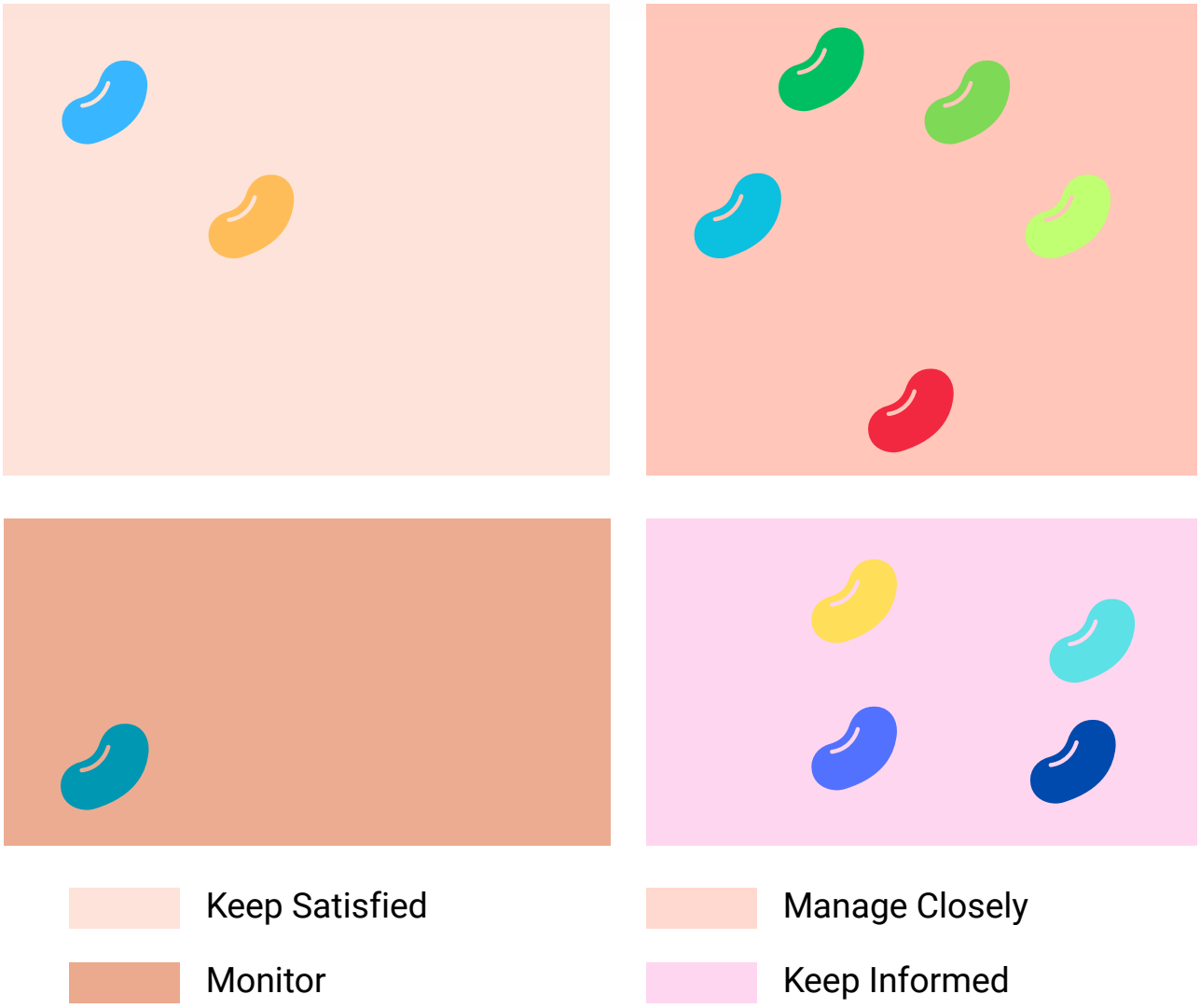
Government

The Canadian Institutes of Health Research (CIHR) plays a pivotal role in advancing health innovation across the country. As Canada's leading federal agency for health research funding, CIHR invests approximately $1 billion each year to support health research (CIHR, n.d.). CIHR is a critical government partner that can fuel the clinical validation of our project through competitive grants and infrastructure support. Their funding mechanisms can help us navigate regulatory pathways, conduct pilot trials, and generate the scientific evidence needed to gain clinical and industry trust.

Engaging CIHR early in our development process not only provides financial backing but also increases the credibility and visibility of REACT in both academic and healthcare settings. Their backing could open doors to further public-private collaborations and ensure alignment with national health priorities—especially in improving transplant outcomes and patient quality of life.

2.2 Stakeholder Mapping

In the stakeholder map below, we have visualized the interest of each stakeholder, mapping it against the impact they could have on our project.



Keep Satisfied

Manage Closely

Monitor

Keep Informed

- Regulators
- Corporate Partners
- Transplant Recipients
- Nephrologists
- Transplant Centre Workers
- Investors
- Research Consultants
- Business Consultants
- REACT Employees
- Advocacy Groups
- Government
- Competitors

3. Market Analysis

3.1 Competitive Analysis

Allosure: Allosure is a highly specific test for rejection that detects donor-derived cell-free DNA (dd-cfDNA). Its usefulness stems from its non-invasive nature compared to biopsies, and its ability to detect rejection before clinical signs are present. It's been implemented as a surveillance test by clinicians, but it still presents significant limitations (CareDX, 2025). Its expensive detection system, layered analytics, centralized lab workflow and limited competition all contribute to its price of $2700+ (CareDX, 2020), which is far too expensive to allow for more frequent testing to be practical. Additionally, while it avoids the danger and discomfort an invasive biopsy presents, consumers must still invest the time needed to receive a blood draw and wait for at least a week for results, which can be too inconvenient for many consumers to do frequently.

PlexAPR: PlexAPR is another highly specific test used to rapidly detect for rejection via presentation of donor antigen B-cells. Only requiring a blood draw, it also presents a much less invasive alternative than biopsies, and is able to deliver same day results due to the rapid-flow cytometry-based assays (Plexision, 2025). Despite these benefits, PlexAPR's demand for lab testing renders it inaccessible compared to REACT.

ExoTru: ExoTru is another test that scans for rejection by identifying immune activation within the kidney transplant, via detection of exosomal RNA signatures (Azzi, 2025). As a urine test, it is non-invasive, but ExoTru itself still requires in-lab testing, making it far less accessible than REACT.

TruGraf: TruGraf is another competing alternative that is currently designed to rule out silent rejection, or rejection without typical symptoms or signs. TruGraf requires consumers to visit a lab or clinic for a blood draw, the results of which take at least 3 days to confirm, and will cost insurance providers $2840.75 (Eurofins, 2025). In the context of preliminary screening, these three factors all make TruGraf notably less accessible than REACT.

	Allosure	PlexAPR	ExoTru	TruGraf	Our product
Cost per test to consumer	$2700+	Unavailable Estimation:	Unavailable Estimation:	$2800+	$14.08 in Canada
Speed of Detection	2-3 days	Within 6 hours of	“Same day”	3-5 days	2 hours
Accessibility	Visit lab for testing	Visit lab for testing	Visit lab for testing	Visit lab for testing	Point-of-care
Invasiveness	Blood draw	Blood draw	Urine Test	Blood draw	Urine test
NPV	91%	90.3%*	93.30%	91%	92%
PPV	62%	63.2%*	86.20%	65%	67.60%

*Assumed 30% prevalence

3.2 Competitive Advantage

Currently, standard post-transplant testing occurs monthly for one year after surgery. After this point, the frequency of testing varies. However, since damage to the kidney can occur quickly after the onset of rejection, ideally, testing would be more frequent (as confirmed by Dr. Blydt-Hansen). Addressing barriers that prevent more frequent monitoring is critical to any post-operative monitoring product. Compared to its competitors, REACT addresses these issues far more effectively, and so, can be used to monitor kidney rejection at a much more frequent interval. As an over-the-counter product that any transplant patient can easily use, the time commitment that the alternatives demand for lab tests is eliminated, especially for patients who have to drive for hours to reach a hospital. From a financial perspective, the product’s drastically lower cost per test compared to its competitors would make more frequent testing feasible for typical consumers. REACT also provides consumers with results in roughly 2 hours, enabling them to be made aware of the presence of rejection quicker than if they had used alternatives. By greatly reducing the cost and time associated with testing, REACT could realistically be used by consumers far more often than alternative methods for post-transplant surveillance.

3.3 SWOT Analysis

Strengths	Weaknesses
• Expanding Customer Base: While testing is most frequent in the first year after transplant, patients with functioning transplants continue to test for rejection indefinitely, resulting in a growing customer base every year (OPTN, 2025a). • Cost Effectiveness: By avoiding costs associated with clinical testing of rejection, the product will be significantly cheaper than current methods of rejection screening. • Accessibility: REACT's results will be far easier and faster to obtain than those of existing tests.	• Small Starting Market: As the target market (kidney transplant patients) comprises a relatively small number of potential users compared to many other fields of medicine, capturing a large portion of the market is essential to success. • Limited Research: Our device includes relatively novel technology, including components not widely used in therapeutics or diagnostics. • Regulatory Challenges: Extensive research will be required to ensure safety and efficacy standards are met.
Opportunities	**Threats**
• Urgent need: As POC systems to monitor rejection would be extremely useful, but aren't available in practice, our product would be highly in demand if successful. Evidently, there is an unmet need for tools to detect subclinical rejection, which contributes to the early diagnosis of acute rejection and maintenance of long-term graft survival. • Modularity: The product's RCA system can be repurposed to detect other conditions, broadening its overall potential as a platform technology.	• Growing Competition: Post-transplant care is a significant field with clear gaps, so more and more companies are focused on developing products to address it. • Economic Uncertainty: Investors may be hesitant to provide the resources necessary for research and development due to current events shifting the market. • Policy Shift: As a novel product that would change how patients are monitored post-transplant, clinicians and regulators must be willing to adapt to new norms in order for it to be successfully integrated into the healthcare space.

3.4 PESTLE Analysis

Factor	Disadvantages	Advantages
Political	As a Canadian company with plans to operate in the United States, we will face increased costs of production due to the ongoing tariff negotiations, which would raise the sale price for consumers. Currently, the universal 10% tariff on Canadian imports to the USA would apply to REACT (Zolfl, 2025). Boycotting of a Canadian product by American end-users is another potential threat, but given that our product would be a necessity for its target market, and that there are currently no identical competitors, this threat is unlikely to materialize.	While the United State's's current policy is an exception, medical goods have typically been exempt from trade restrictions and tariffs. Prior to the resurgence of tariffs in 2025, the USMCA reaffirmed 0% tariffs on medical devices across North America (Global Affairs Canada, 2024), and in 2017, the CETA eliminated tariffs on most medical technologies between the European Union and Canada (Global Affairs Canada, 2018). In the long term, REACT will then likely avoid complications due to trade policy. As a POC test for acute rejection, REACT would affect a consistent and stable number of consumers, and would thus avoid the threat that supply chain breakdowns and protectionism can pose for medical products whose demand can be elastic.
Economic	Since REACT would also be considered a necessity to its target market, demand for it (or one of its competitors) would remain largely unchanged if economic factors encouraged more frugal buying habits. When consumers do want to cut spending, REACT projects to be several times cheaper per test compared to alternatives, which would only make it more attractive relative to them.	The rigorous testing that potential medical devices must undergo contributes to their typically long go-to-market timelines. When coupled with the high investment needed to develop these products, investors may prefer other investments, especially in times of economic turbulence.

Social	Distrust toward POC tests is prevalent among healthcare professionals. Many have concerns of over-reliance, which may lead to erroneous decision-making based on false results and under-utilization of more accurate but complicated measures. A study that surveyed healthcare workers in Uganda highlighted a disengagement between developers of POC tests and end-users in low-income countries (Rasti et al., 2017). Most diagnostics are produced in high-income settings and poorly implemented in settings with weak health care infrastructures (Rasti et al., 2017). Many devices fail to address knowledge gaps, test for relevant pathogens in their area of distribution, and remain affordable for all communities. These factors together provide guidance to make our product more applicable.	The majority of the transplant landscape, particularly patients, would likely be supportive of our product. Transplant recipients often live under significant emotional distress with fear of graft rejection as a top concern (Forsberg et al., 2023). The user-friendliness of POCTs reduces workload at health facilities, improves treatment targeting and creates the potential for improvements in public health of low-income settings (Koshner et al., 2024). Even for those who are more skeptical, transparency about our product can reduce both the spread of mistrust and misinformation.
Technology	For REACT to be deemed effective as a rule-out test, specific criteria must be satisfied, and difficulties in doing so can result in varying costs and benefits. Further technological innovations by competitors could lead to greatly increased competition; REACT's usefulness is based on its logistical and economic superiority over current alternatives, but the emergence of competing POC tests for organ rejection would swiftly eliminate these advantages.	The REACT system demonstrates high modularity via the implementation of the system with different aptamers and biomarkers. This modularity enables potential applications beyond the scope of solid organ rejection, allowing for high scalability. Advancements in technology can hasten these advancements, with a prominent example being the implementation of AI in genetic modelling to improve efficiency.

		As a POC tool intended for frequent use, REACT would greatly benefit from technological advances in production and distribution, given its extensive scope of manufacturing and broader customer base.
Legal	The complexities of federal and state regulatory pathways in the U.S. present challenges to the implementation of POC tests. As per law, state CLIA (Clinical Laboratory Improvement Amendments) agencies are granted oversight over the use of laboratory-developed tests within their states (Oyefolu & Gronvall, 2025). Hence, a device approved at the federal level may not always be waived within the state. However, most of these conflicts regarding in-vitro diagnostics occur in the context of emergency use authorization, not at-home authorization (Oyefolu & Gronvall, 2025). Nevertheless, such regulatory barriers will pose a challenge in the international adoption of REACT.	Health Canada has taken steps to modernize medical device regulation. Under the Medical Devices Action Plan, independent researchers can now submit applications for investigational testing of devices, when previously only manufacturers were permitted (Health Canada, 2021a). Additionally, Health Canada will adopt an agile licensing model to regulate medical devices throughout their life cycles more effectively. They also proposed relying on foreign regulatory pathways to address gaps in treatment options (Health Canada, 2021b). These recent changes align research access with international best practices and expand innovation pathways.

Environmental	Experimental design and testing in the lab can generate excess single-use waste, contributing to plastic pollution. Additionally, disposal of biologically hazardous waste requires energy-intensive autoclaving and often relies on landfills, leading to greater environmental and resource costs. While necessary for ensuring safety and sterility, these impacts remain a significant drawback in synthetic biology research.	Our Wet Lab's waste tracking and reduction regimen serves as a launching pad to alleviate the proliferation of single-use waste. Beyond lab work, REACT's bio-derived and cellulose components ensure our environmental impact is minimized. By lowering reliance on petroleum-based plastics, our platform reduces the strain on the release of microplastics into the environment. Its lighter, compostable design can also lessen the carbon footprint associated with transportation and disposal.

3.5 TAM, SAM, SOM

TAM (Total Addressable Market)

The total addressable market accounts for every available and potential user globally, multiplied by the cost per unit and frequency of use. In the context of our product, potential users would encompass all recipients of solid organ transplants. In 2023, an estimated 172,409 transplants were performed, based on data from 93 countries that comprise 75% of the global population (GODT, 2024). Currently, the vast majority of transplant patients receive lab tests either every 2-3 months or more frequently, with monthly tests being the standard (Rostaing et al., 2023). REACT's affordability and convenience allow for it to be used weekly in the 1st year post-transplant, and at a sale price of $14.08 per unit, the TAM would be approximately $126.23 million.

TAM = # of solid transplants x frequency of use per year x sale price
TAM = 172409 x 52 x $14.08
TAM = $126,230,973.40

SAM (Service Addressable Market)

The service addressable market includes the portion of the TAM that can reasonably be attained. For the SAM, we've focused exclusively on the detection of kidney rejection, as kidney transplants are by far the most common, accounting for roughly 64% of solid organ transplants globally, or 111,135 operations (GODT, 2024). Focusing on kidney rejection allows us to account for specific factors to include in the product, raising its overall effectiveness. Additionally, about 4% of overall transplants tracked should be discounted from the total because they were performed in countries that either have trade sanctions imposed upon them (Global Affairs Canada, 2024) or aren't signatories of the Patent Cooperation Treaty (WIPO, 2025). This would leave the number of potential users at about 106690, and the SAM at approximately $78.11 million.

SAM = # of kidney transplants (0.96) x frequency of use per year x sale price
SAM = 111135(0.96) x 52 x $14.08
SAM = $78,113,857.54

SOM (Service Obtainable Market)

The service obtainable market includes the portion of the SAM which can reasonably be obtained after 5 years. During this timespan, we believe restricting the product to Canada and the United States is most important, as expanding outward would require overcoming international barriers to trade, physical and financial barriers to manufacturing and distribution, as well as validation of the product under regulatory bodies other than Health Canada and the FDA. Additionally, while our estimates for pricing have been generated based on Canadian standards, typical high markups from wholesalers (Seeley, 2022) and retailers (Fein, 2023) result in REACT's higher price to consumers in the U.S. In 2023, there was an estimated number of 1929 kidney transplants in Canada (CIHI, 2024), and 27,759 in the U.S. (OPTN, 2025b), for a total of 29,688. The resulting SOM would be about $27.55 million.

SOM = (# of kidney transplants in Canada x frequency of use per year x sale price) + (# of kidney transplants in the USA x frequency of use per year x sale price)
SOM = (1929 x 52 x $14.08)+(29688 x 52 x $16.93)
SOM = $1,412,336.64 + $26,136,127.68)
SOM = $27,548,464.32

4. Regulatory & IP Strategy

4.1 Regulations

Before introducing our product to the market, it must get approved by different authorities. REACT will simultaneously undergo the Canadian and United States regulatory processes for class III IVDDs and class II IVDs, respectively. A team of physicians, statisticians, chemists, pharmacologists, and scientists will conduct an independent and unbiased review before judging whether our diagnostic is approved for sale.

To obtain FDA clearance, we will submit a traditional premarket notification (510k), demonstrating substantial equivalence to an existing, legal and marketable device (FDA, 2018). Our submission will adhere to FDA guidance on establishing performance characteristics for molecular IVDs, including studies on analytical sensitivity (LoD), inclusivity, cross-reactivity, and reproducibility. To prove equivalence, we will ensure our device does not raise different questions of safety and effectiveness compared to the predicate. Where necessary, we will consult the FDA through a Pre-Submission (Q-Sub) to confirm our study design, choice of comparator, and suitability of our predicate device.

As a Class II device, REACT will be subject to both general controls and special controls as defined under the Federal Food, Drug, and Cosmetic Act. General controls include requirements for device registration and listing, labelling compliance, manufacturing under Quality System Regulations (21 CFR Part 820), and post-market reporting through the FDA's Medical Device Reporting (MDR) system. Special controls, which are unique to Class II devices, may include specific performance standards, post-market surveillance, guidance documents, and special labelling requirements that directly address the risks associated with molecular diagnostics. Compliance with these controls ensures that our device meets the FDA's expectations for safety, effectiveness, and risk mitigation throughout its lifecycle.

Labelling is a critical component of the 510(k) process and must meet requirements outlined in 21 CFR 809.10, including intended use, specimen type, procedural steps, warnings, limitations, interpretation of results, and performance characteristics. Labelling materials will undergo user comprehension testing, especially if REACT is intended for decentralized or low-resource environments.

In parallel, we will ensure compliance with Quality System Regulations (QSR, 21 CFR Part 820), covering manufacturing process controls, validation procedures, and documentation. Our device will be developed and manufactured under Good Manufacturing Practices (GMP), and we will maintain a robust Design History File (DHF) and Device Master Record (DMR). These documents will support traceability and post-market surveillance efforts, including complaint handling and adverse event reporting through MedWatch.

As our device is classified as a non-laboratory test, we will be running flex studies to evaluate the most common or likely sources of error based on the use locations and test procedure. In general, they should be conducted to the point of failure to determine the maximum deviation that will still generate accurate results. Each study will be performed using a pre-defined study protocol that includes the following: the objective of the study, detailed test procedure, and the materials used.

The 510(k) submission will be prepared using the FDA's eSTAR template. Overall, our regulatory approach is designed to meet the FDA's rigorous standards for safety, effectiveness, and reliability, while ensuring a clear and streamlined path to clinical impact for RCA-based detection of acute allograft rejection.

Domestically, in Canada, our device is classified as a Class III IVDD. To be legally sold and distributed, we must first meet the requirements of the federal government, many of which align with the FDA. We will request a pre-submission meeting with Health Canada to confirm the type of safety assessments required in future documents requesting approval, such as an analysis of our REACT's POC properties and risk management strategies.

As part of our regulatory strategy, we will align our submission with international standards established by the International Medical Device Regulators Forum (IMDRF), as adopted by Health Canada. This alignment ensures our application follows a globally recognized structure, streamlining both review and future international expansion. To begin, we will complete and submit all necessary administrative documents, including the Medical Device License Application Form (F202) and the fee submission form, both of which must be signed and reviewed by Health Canada. We will also complete the Quality Management System (QMS) certificate, certified under ISO 13485. This system overlaps with the QSR required by the FDA. Health Canada requires a clear and comprehensive statement of the intended use of the device, along with a thorough hazard and risk analysis in compliance with ISO 14971. Finally, we will ensure our device meets the labelling requirements listed in Sections 21 - 23, which address the mandatory details to be included on the label and the requirements to be sold to the general public.

Below are some required pre-clinical studies for an IVDD submission to Health Canada. Guidance was derived from the HIV Rapid Diagnostic Test Home Use Guidelines and Class III IVDD Application Procedures.

Non-Clinical Inclusions (Analytical Performance)

Health Canada requires applicants to submit the following evidence:

Components (evidence)	**Objective**
Specimen type validity	Data proving that the sample type(s) are accurate, reliable, and valid during tests.
Stability of IVDD	Data supporting shelf-life, in-use stability, and transport stability.
Repeatability and reproducibility	Intra- and inter-operator precision data; multiple instruments/lots/sites where applicable.
Measuring range	Linear and non-linear measuring systems. This measuring range should include the lower limit of quantification.
Analytical sensitivity (LoD) and specificity of IVDD	Smallest quantity of target analyte that can be reliably detected and assessment of cross-reactivity and interference from structurally similar proteins/substances.
Measuring range of IVDD	Establish dynamic range, including lower limit of quantification and upper threshold.
Trueness of measurement	Comparison with a reference method to demonstrate analytical accuracy.
High-Dose Hook / Prozone Effect	Demonstrate no false negatives at very high analyte concentrations.
Assay Cut-Off Determination	Justification of key assay parameters in different reaction conditions (e.g., time, temperature, volume, reading time).

Clinical Inclusions

Although our future pharmaceutical partner will manage the formal clinical trials, iGem McMaster is committed to ensuring that each stage will be equitable and inclusive. Understanding the importance of accurate representation during studies, we will gather samples of various relevant backgrounds, ensuring all individuals have fair access to participate. McMaster iGEM will recruit a demographically balanced participant pool, focusing on patients who are traditionally underrepresented in research and those negatively impacted by social determinants. By analyzing this clinical data, we aim to create a device that meets everyone's needs.

4.2 Patenting

In Canada, REACT is eligible for patent protection covering our novel method of quantitatively detecting urinary CXCL-9 and NGAL through the coupling of dendritic rolling circle amplification (RCA) and proprietary “apta-primer” sequence. Throughout our application, we will frame our invention as a solution to a “data acquisition problem” rather than a “data analysis problem”, as required by the Canadian Patent Office (Keuling, 2020). Although RCA has been used to detect acute allograft rejection, we will highlight that REACT offers optimized and innovative techniques for detecting and quantifying urinary biomarkers.

Our intellectual property strategy is designed to safeguard the competitive edge of REACT. As per McMaster’s Joint Intellectual Property Policy, any technology produced by McMaster iGEM is subject to shared ownership with the university. We will work closely with MILO and their team of patent attorneys to file a combination of patents, trademarks, and contractual agreements with partners, including our future pharmaceutical collaborator. First, we will perform a comprehensive patent search on various databases (e.g. USPTO, ic.gc.ca, EPO) to avoid infringing on any existing patent claims. Given that there are no IP infringements, we will file the Patent List within 12 months of the iGEM Jamboree and claim the IP for approximately 20 years of market exclusivity in Canada. The costs of the patenting fees, including the price of a patent agent, patent application, examination fees, and international maintenance fees, amount to $15,000 to $25,000 within ten years of the initial application (Government of Canada, 2025a). We will mitigate such costs through our partnership with MILO. MILO will also support us in obtaining a PCT patent, which is an international patent that will protect intellectual property rights in the 158 contracting states (WIPO). All partnerships will be governed by robust non-disclosure agreements (NDAs) to safeguard sensitive information, and regular intellectual property audits will be conducted to provide detailed protection.

5. Short-Term Strategy

5.1 Research & Development (R&D)

Early-Stage R&D: We will focus on the early stages of POC diagnostic development. This includes the initial phases of technical design, identification of key biomarkers, and prototype development. Further phases will expand into preclinical studies to assess the development of the in-vitro platform.

MVP: McMaster iGEM will also complete the development of a functional Minimum Viable Product (MVP) capable of demonstrating key diagnostic capabilities: specificity, time-to-result, and portability. Develop and meet performance KPIs while incorporating feedback from key stakeholders and identifying relevant Health Canada/FDA pathways.

IP Strategy: REACT will be developed within the McMaster University labs, where we have leveraged university sponsorships to support early-stage R&D. Under McMaster's Joint Intellectual Property Policy, the IP associated with our technology is subject to shared ownership with the university, with future revenues divided equally (50/50). To ensure commercial viability, we plan to file an IP through the McMaster Industry Liaison Office (MILO, n.d.). MILO provides extensive assistance and institutional funds for grant applications, research and development, patenting, marketing, industry partnerships, regulatory approval and commercialization strategies. Through our collaboration with MILO, we can access a network of manufacturers who can maintain the consistent and mass production of our product without sacrificing quality. Our partnership will also allow us to negotiate more favourable terms for the costs of production. Strong IP protection is vital for safeguarding innovations in biotechnology and ensuring their commercial viability (Giugni & Giugni, 2010). The costs of the patenting fees, including the price of a patent agent, patent application, examination fees, and international maintenance fees, are estimated to amount to $15,000 to $25,000 over the first ten years of the initial application (Government of Canada, 2025a). Our partnership with MILO will mitigate such costs while securing patents that cover the engineered POC technology. This structure is not uncommon in early-stage biotech, and we believe it will not impede future collaboration with pharmaceutical partners such as Roche.

Outside of IP protection, a partnership with MILO will provide the following resources:

- **Research funding**: seed funding (McMaster Seed Fund, n.d.), access to government and private sector grants, assistance with the application process
- **Research assistance**: affordable lab space and partnerships with research staff at McMaster, as well as access to Co-op students and databases
- **Research & ethics clearance**: assistance in obtaining ethics approval and research clearance
- **Joint intellectual property policy**: funding, guidance and access to legal counsel to help protect intellectual property by filing a provisional patent
- **Industry connections**: to industry partners (mainly pharmaceutical companies) who will be essential to the mass production, distribution and retail of the product (MILO, 2024)

5.2 Clinical Trials

Domestically, REACT would be considered a class III IVDD, which, under current regulations, requires 3 phases of clinical trials to validate before being commercialized. While the actual execution of these trials will be our partner's responsibility, the design of them will be roughly as follows.

Phase 1:
The first phase would take place over roughly 5 months with the participation of an individual hospital. A range of 20-30 Patients with suspected rejection who consent to participate will be given the REACT test to use, in addition to their standard treatment. The overall goal of this phase would be to determine the test's efficacy in a clinical setting.

Phase 2:
The second phase would take place over a similar time period, except with several hospitals, ensuring that those chosen are in communities of varying demographics so the results are fairly representative. The trial would include 100+ patients, and would be focused on establishing efficacy in a larger sample.

Phase 3:
The third phase would take place over a year, with a sample of several hundred patients from hospitals over Ontario participating. Patients who had consented and received transplants in the past year would be assigned REACT to use as intended if sold commercially. The goal of this trial would be to prove REACT's effectiveness rather than efficacy, and ensure the test's rate of false positives is low enough to be acceptable.

5.3 Seed Funding & Institutional Support

We will apply to the **Residency @ The Clinic** program and gain clinical mentorship, access to McMaster Innovation Park resources, and connect with MACcelerate advisors. Gaining feedback from such seasoned professionals will further our market discovery and pitch development. From our learned experience and formed connections at the Residency and MILO, we will apply and compete in grants and pitch competitions.

McMaster Seed Fund (MSF): An early, pre-seed investment fund tied to milestone delivery, requiring a filed IP and incorporation of a for-profit entity. Funding is capped at a max of $250,000 per application and managed by MILO (McMaster University, n.d.). Successful companies are awarded tranche investments, where funds are released based on achieving pre-negotiated deliverables.

Startup Survivor at The Forge: Over 4 months, all startups have business and technical deliverables to compete. The final challenge involves teams pitching to a venture capital firm that could invest further with them. All teams receive $5,000 in funding throughout the summer. The top five teams with the highest scores are invited to pitch for a collective amount of $30,000, with $15,000 non-dilutive prize money for the grand prize winner (The Forge, n.d.). We aim to compete for the highest award, while also receiving coaching and investor exposure from their weekly workshops.

Using **Pocketed**, a platform that simplifies the process of finding and applying for government funding, we will navigate complex grant programs and maximize funding opportunities.

The **Canadian Institutes of Health Research (CIHR)** is a critical federal government partner that can fuel the clinical validation of our project through competitive grants and infrastructure support. They invest approximately $1 billion each year to support health research (CIHR, n.d.). Their funding mechanisms can help us navigate regulatory pathways, conduct pilot trials, and generate the scientific evidence needed to gain clinical and industry trust.

The **Ontario's Life Sciences Innovation Fund (LSIF)** is a pre-seed or seed investment that eligible companies can receive up to $500,000 in early-stage risk capital to scale their made-in-Ontario health solution both at home and in global markets (OCI, n.d.). This will further grow the sector and strengthen its competitiveness in key areas such as cancer treatment, regenerative medicine, neuroscience and medical technologies.

The **SOPHIE (Southern Ontario Pharmaceutical and Health Innovation Ecosystem)** is a program funded through the Federal Economic Development Agency for Southern Ontario (FedDev Ontario, n.d.), in partnership with Innovation Factory and the Synapse Consortium. Provides up to $100,000 in non-dilutive grant funding to support commercialization projects with an academic or clinical partner (Southern Ontario Pharmaceutical and Health Innovation Ecosystem, n.d.).

The **Strategic Innovation Fund (SIF)** provides major investments in innovative projects that will help grow Canada's economy for the well-being of all Canadians. supporting large-scale business R&D, technology development, and commercialization in Canada. It provides both repayable and non-repayable contributions to help Canadian companies grow (Government of Canada, 2025b).

We will also pursue loan-based investments from banks, financial institutions, and entrepreneurship-focused organizations that ideally offer no-collateral loan options. In the initial stages of financing, our goal is to secure approximately $100 million through a combination of grants, loans, and other funding sources.

6. Long-Term Strategy

Prior to implementation, we will strategically partner with a large pharmaceutical company by leveraging pitch results and preclinical data. These companies have the necessary infrastructure and resources to conduct clinical trials and can handle the significant costs associated with bringing a POC diagnostic to market. Additionally, they manage the critical process of registering the product with regulatory bodies such as the FDA and Health Canada.

6.1 Scalability

Risk Assessment

When scaling an at-home POC device, it is essential to conduct a thorough risk assessment to scan potential sources of error, safety hazards, and misuse. Patients will be operating REACT devices outside of a controlled clinical environment. If POC tests are conducted incorrectly or used for unintended purposes, then ambiguous results may lead to more testing, which may increase patient costs and risks (Satheesh et al., 2025). It's imperative that we educate patients on REACT's proper use with clear and comprehensive labelling and well-structured instructions. By addressing these risks proactively, we can help ensure our scaling process supports accurate diagnoses and patient safety.

Partnership

Our team is looking to partner with Roche, which has had 53 new collaboration agreements in 2024 for diagnostics alone. Within their areas of interest for new partnerships, Roche has a strong interest in companies focused on decentralized testing and renal disease, both of which are major areas our product addresses.

- Roche does not impose a "one-size-fits-all" structure; each partnership is negotiated based on the specifics of the science, the partner, and the intended impact.
- Roche typically seeks to retain or obtain rights necessary to commercialize the partnered asset, while respecting the partner's contributions and IP. Roche's standard partnership model often involves an upfront payment to the partner, followed by milestone-based incentives and royalties.

- Our strategic objective is to transition clinical trial and manufacturing responsibilities to the pharmaceutical partner, allowing the startup to focus on innovation, early-stage development, and pipeline expansion while leveraging the pharma company's infrastructure, regulatory teams, and global clinical trial capacity.

McMaster iGEM, alongside our pharmaceutical partner, will work with manufacturers to build a user-centred design. We aim to manufacture our colorimetric, RCA-based point-of-care test design as devices that are logically easy to use, portable, and able to function reliably in varied environments. Through our prospective partnership with Roche, quality assurance, production consistency, compliance with ISO standards, and standardization of protocols and interoperability on the manufacturer's end are ensured. With these requirements met, iGem McMaster can focus on refining assay performance.

Production

The manufacturing plan will first focus on establishing means of production in Ontario to create a strong foothold in the region, due to the stakeholder connections in the region our team has already established and the location of Roche Canada's head office in Mississauga. After we've established means of manufacturing and distribution in Ontario, we plan to expand to the rest of Canada and the USA. The cost to manufacture a unit of REACT currently stands at $4.924, and is planned to be sold to wholesalers at $12.35 per test, resulting in a 60% gross margin; in line with other Medical Devices. In order to reduce REACT's logistical costs, REACT will initially be sold in test kits containing 10 individual tests, and will be stored and transported using Roche's existing logistical infrastructure.

Ethics

Scaling REACT is directly linked with the ethical responsibilities of delivering timely, accessible and equitable healthcare. With advances in diagnostics and the shift toward decentralized care, POCT is poised to transform how patients, providers, and healthcare systems interact—offering faster results, reduced lab burden, and improved outcomes. To ensure equitable access, we will prioritize patient-friendly design, clear usage instructions, and multilingual support materials, while adhering to streamlined regulatory pathways that maintain patient safety. Knowing our impact, we must be especially considerate of ethics and safety at every stage of development and implementation.

Once Roche has successfully launched the product, the commercialization phase begins. Typically, the product is then sold to pharmaceutical wholesalers.

6.2 Distribution

Distribution will be handled through established pharmaceutical wholesalers, who ensure reliable delivery to pharmacies, hospitals, and clinics. They are responsible for logistics, storage, and inventory management, helping the product reach a broad market quickly and efficiently.

After launch, the product is expected to enter the maturity phase, marked by peak sales and widespread clinical adoption. Over time, sales may decline due to patent expiry or new competing technologies. However, because our platform is modular and adaptable, it can potentially be repurposed for other indications. This creates opportunities for product lifecycle extension, allowing for new approvals and renewed revenue streams, leading to a potential market rebound.

6.3 Pricing

REACT will be sold to wholesalers for a price of $123.50/test kit, and after markups imposed by wholesaler and retailers, will be available to patients for an estimated unit price of $140.80 CAD/test kit in Canada, and $169.30 USD/test kit in the USA. The estimated production cost, based on market material and regent costs, is $4.924 per unit, or $49.24 per 10-test kit, with estimated wholesale and retail markups accounting for the price difference between markets. Each unit consists of 3 RCA reactions, one test to detect CXCL9, NGAL, and creatinine simultaneously. This translates to a healthy gross margin of 60%, which falls in the range of the Medical Devices industry's average (FullRatio, n.d.). It should be noted, our estimate is from online price listings. Our prospective partnership with Roche could aid in negotiations to reduce the cost. Therefore, this estimate is likely the maximum price per test in terms of material/reagent cost. Provided these pricing and production cost assumptions hold true, REACT would require sales of roughly 809,717 test kits to recoup the initial $100 million investment (break-even point). This target is achievable within three years of market entry under projected adoption rates in transplant centers and hospital nephrology units. By year six, sales are forecast to exceed $200 million annually, maintaining an operating margin near 50%, allowing investors to recover their capital quickly.

6.4 Advertisement

To promote our value proposition, we will emphasize our novel solution's quality assurance and regulatory compliance, reinforcing trust with both hospitals and patients. Our core sales focus is B2B, publishing our pre-clinical findings and creating pitch-decks to attract corporate clients, particularly our potential partner, Roche. Additionally, we will lead targeted advertising efforts, pursuing direct outreach to transplant centers, nephrologists, and patients. Our goal is to position our device as a trusted, streamlined component of post-operative care and allograft health monitoring. To establish visibility and encourage early adoption within the nephrology network, our multi-pronged strategy includes:

- Presenting at major nephrology and transplant conferences
- Building a strong digital presence on professional medical platforms
- Hosting targeted informational workshops for clinicians and transplant coordinators

For patient outreach, we will prioritize low-cost, high-impact targeted strategies such as word-of-mouth and targeted educational materials (brochures, online videos, Q&A resources) to reinforce REACT's role in their allograft health. A highly communicative feedback loop between our team and consumers will ensure our messaging remains accurate, persuasive, and responsive to evolving patient and provider needs.

6.5 Operations: Location & Production

Sustainable Considerations

A large share of POC waste is infectious and must be separately collected and treated, often via incineration, which contributes to GHG emissions (Ongaro et al., 2022). In many LMICs, facilities lack adequate incinerators or fuel, leading to open-pit burning that releases toxic pollutants like dioxins and furans (Ongaro et al., 2022). In these settings, waste is also disposed of in landfills or water supplies, risking exposure to hazardous reagents such as cyanide derivatives in PCR cartridges (Ongaro et al., 2022). During COVID-19, over 140 million test kits shipped via the UN portal alone could generate 731,000 L of chemical waste (Street et al., 2022). Regulators are increasingly requiring sustainable single-use products, with initiatives such as the US BioPreferred Programme, the EU Green Public Procurement framework, Horizon EU funding requirements, and EPA preferences for sustainable healthcare products (Ongaro et al., 2022). During our operations, it is a primary goal to consider these environmental impacts, not only for patient safety but for our planet.

Production

During production, we will prioritize biocompatible, biodegradable materials, such as bio-derived materials, instead of traditional plastics. Incorporating materials like polylactic acid, a thermoplastic produced from starch, largely reduces environmental impact and toxicity (Swetha et al., 2023). These biomaterials comply with compostability standards like ASTM D6400 & EN12432, ensuring both safety and functionality (Prüser, 2024). In addition, we'll explore paper-based microfluidic substrates (e.g., cellulose nanofibers), recognized for their low cost, suitability, and renewability/biodegradability in diagnostics. Paper microfluidic devices have been demonstrated to detect pathogens and biomarkers (Ongaro et al., 2022), utilizing labelled antibodies to capture and detect biomolecules through a visual, colorimetric readout. Fluid is transported via capillary action, without the requirement for fluid handling equipment, while enhancing biocompatibility and reducing hazard (Ongaro et al., 2022).

Safety & Quality Control

For safety considerations, we will ensure materials are non-toxic, inert in contact with samples, and degrade safely without leaving harmful residues. All kits will undergo functional QC (e.g., sensitivity and specificity checks) and biocompatibility testing for patient safety. We'll also incorporate shelf-life studies, ensuring the biodegradable components remain stable through their intended use.

Customer Service

Our customer support representatives will guide patients on safe disposal protocols, especially for biodegradable components, and provide real-time troubleshooting. Dedicated training materials will emphasize handling standards to avoid contamination or misuse.

Inventory Control

We'll manage storage to protect biodegradable materials from premature degradation (e.g., humidity control, temperature monitoring), guaranteeing consistent safety and performance on delivery.

Product Development

The product will constantly be going through design iterations and improvements to release newer, sustainable, and safer models over time.

Suppliers

We will source certified suppliers for biodegradable housing materials to ensure consistent quality and reduce transport-related contamination risks. Critical components such as reagents will be supplied by established partners under Good Manufacturing Practices (GMP) conditions, ensuring purity and patient safety.

Location

Production and assembly will occur in facilities compliant with ISO 13485 standards for medical device manufacturing and ISO 14644 cleanroom protocols. These environments will uphold contamination control, traceability, and sterility.

Growth Strategy

Our growth strategy hinges upon product diversity and market expansion. By harnessing the system's modularity, we can develop diagnostics targeting a variety of markets, allowing us to maximize potential for growth. By pairing the RCA system with disease-specific biomarkers, similar interventions can be developed for all forms of solid-organ transplants, and even other forms of disease. REACT's low cost to consumers and ease of use should remain largely unchanged if used to detect a different disease, leading to clear advantages over competitors in those fields too.

Currently, the obtainable market is limited to Canada and the United States, and so expanding into global markets is pivotal to achieve long-term growth. The first steps of expansion would involve breaking into the European market, where kidney transplants are most frequent after North America among WHO regions (GODT, 2024). Successfully doing so would require extensive trials and research to satisfy regulatory frameworks imposed by the European Medicines Agency, and partnerships with European institutions for distribution. After expanding to Europe, opportunities in Asian markets with the highest incidences of solid organ transplant, such as China and India (GODT, 2024), will be pursued.

Exit Strategy

Considering the regulatory barriers and risks involved in developing a novel medical device, a clear exit-strategy is essential to our long-term plan. A strategy that considers the specific challenges that will be faced in different phases of the product's development is essential as well.

In the earlier stages of development where the product has yet to be commercialized, an exit may be necessary if the company lacks the resources to continue development, or if the product fails to achieve the standards set out by regulatory guidelines during clinical trials. If a partnership with a major pharmaceutical company is achieved as planned, these risks should be heavily mitigated. If not however, then a buyout from a pharmaceutical investor, who would be able to fund further research and who would believe in the product's future profitability, would be ideal. For REACT, this strategy presents a potential recourse that reduces the operational risk of the project, and mitigates the financial risk to potential investors, making it a more attractive buy.

Once the earlier stages of testing have been completed, exit strategies diversify as the companies as paths to maximizing return on investment open up. The ideal exit strategy at this point still appears to be acquisition by a larger company, as it would provide us with resources to push from late-stage clinical trials to commercialization. Other options include a merger, or an IPO, both of which are less feasible due to the sizable market presence they typically require. As a startup initially addressing a niche problem, our operation if successful, would still be smaller scale.

7. Reimbursement

7.1 Public Path

Reimbursements are critical to the widespread and rapid adoption of new medical devices. In Canada, these decisions are decentralized and occur on a provincial and territorial level. The application process begins with the Medical Devices Directorate (MDD), the federal regulator responsible for medical devices for human use (Health Canada, 2021c). The MDD conducts the first step of authorizing the sale of a medical device by verifying that the device meets the safety, effectiveness and quality requirements of Health Canada and the FDA. Once market authorization is granted, Provincial & Regional Ministries of Health, like the Ministry of Laboratory Services and Diagnostics Branch, will rely on provincial Health Technology Assessment (HTA) bodies to evaluate the clinical and economic value of new medical technologies. The submission should include (Hogue et al., 2014):

- Test description
- Data on laboratory performance
- Data on economic impact
- Data on clinical utility and health outcomes (if available)

Hospitals and treating physicians also hold high influence over these budgets decisions, determining whether a device is adopted in practice. In most provinces, budgets are allocated to hospitals through geographically or operationally defined health regions or authorities (Davidson et al., 2015). If a POC test is recommended for use in a physician's office, the provincial medical association may request reimbursement from the Physicians Billing Health Services Branch. If approved and a budget is available, a fee code is created; if not, additional funding is requested from the Ministry of Health (Davidson et al., 2015). In certain cases, hospitals may consider broader health system costs or the overall value for money when making purchasing decisions. However, the presence of in-house HTA capabilities varies widely across institutions and regions.

To ensure successful implementation, our team will build an HTA-grade evidence dossier early in the process. Alongside our pharmaceutical partner, we will design clinical studies to show clinical utility and an economic model; these are central to provincial HTA reviews. Typically, a review is initiated following a request from a specialist physician.

Information requirements vary by hospital or region, but commonly include (Davidson et al., 2015):

1. Local need
2. Evidence of positive clinical benefit and provider consensus regarding the procedure
3. Supplier information
4. Feasibility of implementation
5. Budget impact on the hospital and price

Our strategy will prioritize contact with leading academic and research hospitals, which are often more keen to adopt new medical technologies. Furthermore, the global consensus on attaining universal healthcare coverage (UHC) by 2030 (Yin et al., 2024) is likely to motivate governments and non-profits to invest in decentralized care, especially in resource-limited settings. We will work to gain support from resident physicians, facility administrators, and laboratory directors, with the goal of encouraging hospital outpatient clinics to adopt the point-of-care test under their hospital budget. Given REACT's rapid diagnosis abilities, simplicity, and cost-effectiveness, there may be a strong interest among healthcare workers to adopt the technology.

7.2 Private Path

In addition to pursuing public funding, we aim to mirror the reimbursement pathway of continuous glucose monitors, which in several provinces are covered under public programs for qualified Canadians while remaining eligible for private insurance claims (Ministry of Health). This dual-coverage model would reduce out-of-pocket costs for patients and provide an alternative for those not eligible under provincial criteria.

Private insurance accounts for 12% of total health system expenditure, while out-of-pocket costs account for roughly 15% (Davidson et al., 2015). Services not publicly covered include non-medically required practices, such as appliances issued for use after discharge from the hospital. In Canada, private health insurance is predominantly employer-sponsored. Private plans often set annual or lifetime reimbursement caps; they tend to have longer formularies, adopting more innovations, often faster than the public approval processes (Ontario Chamber of Commerce). For diagnostic companies, engagement with both public payers and major private insurers can therefore be an effective strategy to accelerate implementation.

8. Financial Plan

8.1 Costs

2024-2025

This is the Initial research phase, during which our team will conduct literature reviews and interviews, train new members in the necessary lab skills, and develop the initial market strategy, all within the context of the iGEM competition. In this phase, all members of the team will volunteer their time, and costs will be limited to the funding provided to the team by McMaster. By the end of 2025, we aim to have a provisional patent file submitted.

2026

In this second stage, our focus is on validating the product's efficacy. We aim to have both pre-clinical trials and the development of the product's technological platform completed, both of which will require a substantial amount of funding. To meet this need and to begin to compensate core members, we plan to hold rounds of pre-seed investment. While completing the pre-clinical studies, we also aim to begin the filing of a full enforceable patent and initiate the clinical trial design process in partnership with a major pharmaceutical company, whose resources and experience will streamline our implementation of clinical trials and manufacturing setup.

2027-2028

In this span of time, the primary focus will be to complete the first 2 stages of clinical trials, and nearly finish the 3rd, while finishing patent filing. In our prospective partnership, primary responsibility for the execution and funding of clinical trials would be passed on to the pharmaceutical company in question, exempting our core team from the responsibility of finding sponsors.

2028-2029

In this phase, our focus will be split between finishing the 3rd stage of clinical trials and preparing for market entry. By working in conjunction with our partners, we aim to have created effective manufacturing and distribution systems for the release to market.

We plan to allocate the funds as follows:

Category	Year 1 (Discovery & Development)	Year 2 (Verification & Regulatory Prep)	Year 3 (Launch Readiness)	Post-Year 5 (Market Entry)	Total
Research & Development	$20M Prototype refinement, usability studies, risk assessment	$15M Preclinical trials, design validation testing	$5M Pre-production testing, pilot runs	$0M Device finalized	$40M
Regulatory & Quality Systems	$4M QMS setup, early regulatory consultation	$6M Submission prep, ISO compliance systems	$3M Pre-approval audits, documentation finalization	$0M Regulatory finished	$13M
Advertisement & Market Entry	$3M Branding, market research	$4M Conference presence, early clinician engagement	$6M Hospital training materials, digital presence, adoption strategy	$10M Advertising campaigns, social media outreach, patient education, workshops, conference follow-ups	$23M

Operations	$6M Establish regulatory compliance infrastructure, initial quality assurance systems, legal and administrative setup, lab space, equipment, IT systems, cybersecurity	$5M Maintain and expand QA processes, compliance documentation, contract management	$4M Finalize administrative systems, risk management, ongoing QA oversight, logistics planning, service models	$0M Pre-market operations complete	$15M
Employee Compensation	$5M Core hires (R&D, regulatory, ops)	$2M Market access, business development, support teams	$2M Performance bonuses, retention programs	$0M Salaries ongoing in pre-market years	$9M
Total	$38M	$32M	$20M	$10M	**$100M**

8.2 Funding

The following are potential investors:

Party	Background	Explanation
Roche (Roche, 2025)	A large pharmaceutical company that frequently partners with smaller organizations, with expressed an interest in renal disease and decentralized testing	Delegate responsibility for (and costs associated with) clinical testing and manufacturing, allowing the team to focus on innovation.
McMaster Seed Fund (Mcmaster University, 2025)	An early, pre-seed investment fund tied to milestone delivery, requiring a filed IP and incorporation of a for-profit entity	Would give up to $250,000 for pre-seed investment, funding in vitro studies and platform development
Ontario Life Sciences Innovation Fund (OCL, 2025)	An early-stage co-investment fund that supports opportunities often hampered by the unique challenges of life sciences entrepreneurs	Would give up to $500,000 at the pre-seed and seed investment stages
MaRS IAF (MaRS IAF, 2025)	Provide investment, guidance and connections to support breakthrough Canadian technology companies	Up to $500,000 seed funding
LSSUF (Government of Ontario, 2025)	Funding support for life sciences tech. Through the Ont. Government	Up to $2,500,000 or 33% of project cost - for scale-up

9. Future Impacts

9.1 Positive, Long-Term Impacts

- Improved Patient Health Outcomes: With access to more frequent testing, patients will detect acute rejection quicker after its onset, reducing the overall harm they suffer as a result. In particular, earlier detection of acute rejection is essential to patients in remote communities, where patients may have to drive hours to a hospital to receive treatment.

- Improved Quality of Life: All transplant recipients, and especially those in remote communities, must commit a significant amount of time to post-operative testing, a sacrifice that a POC device like REACT renders unnecessary.

- Encourage further research: If REACT, a novel POC device, is successful, it could encourage further research and investment into POC devices and transplant testing, which could lead to further innovation that improves patient outcomes.

9.2 Negative, Long-Term Impacts

- Global Accessibility: Over time, REACT can spread to foreign markets beyond those outlined, but costs due to regulatory challenges, differences in clinical standards and medical inequality will render it difficult to profitably sell REACT in countries witha lower incidence of transplantation.

- Barriers to Treatment: While REACT improves accessibility of diagnostic testing for remote and under-resourced communities, barriers to immunosuppressive therapies to treat acute rejection persist, which impede patients from effectively acting on the information REACT provides them with. Therefore, in order to optimally improve transplant patient outcomes, investigating ways to break these barriers down is essential.

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Contact us for further inquiries.