Product Market Fit

Group 5

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Dr. Arthur Brown

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Schulich School of Medicine and Dentistry

Western University

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Author Contributions

Student Name	Student Number	Contributions
Meghan Andreola	251210600	Equal Contribution
Zachary Lupson	251153349	Equal Contribution
Arani Harimohan	251234657	Equal Contribution
Olayori Olasode	251215427	Equal Contribution

1. The Problem

Shiga toxin–producing *E. coli* O157:H7 is a potentially dangerous foodborne pathogen as it can cause severe disease, including hemolytic uremic syndrome (HUS) that can lead to kidney failure and long-term complications (Centers for Disease Control and Prevention [CDC], 2024). Public health agencies estimate that about 5–10% of people infected with *E. coli* O157:H7 develop HUS, with the highest risk in young children and older adults (Public Health Canada, 2013). Outbreaks continue to occur across foods and regions, including large widespread events linked to hamburgers in the early 1990s, leading to hundreds of laboratory-confirmed cases and multiple deaths (CDC MMWR, 1993). Later outbreaks were tied to leafy greens, such as the 2006 spinach outbreak that sickened more than 200 people in the United States (Grant et al., 2008). For food processors, the practical problem is timing as conventional testing is often based on culturing and can require sending samples to external laboratories, with definitive results taking anywhere from days to weeks, which means the product may already be packaged or distributed before contamination is found (Mackay, 2018). This sample processing delay is where the market need can be found, as any unnecessary delay increases risk to avoidable exposures and will eventually cause much larger and more expensive recalls when the tests do finally arrive.

2. The Possible Solution

Dr. Michael Rieder's rapid *E. coli* O157 test is designed to move screening into the processing plant, enabling rapid decision-making before any products are shipped. Instead of waiting on lab culture turnaround, the unique assay targets a protein biomarker that is unique to *E. coli* O157 and uses a flow-through, pregnancy-test-style format with a visible readout (one line for negative and two lines for positive) so it can be easily understood (Mackay, 2018). Western's summary of the emerging technology reports that results are received in under 24 hours, allowing a facility to sample at the end of the day and have results back before the next morning's distribution window (Mackay, 2018). In a setting where traditional culture methods can take up to two weeks, including shipping and confirmation, this time compression is the core value behind the rapid test as it decreases the number of products at risk, reduces the scope of any potential recalls, and lowers the overall chance that any contaminated products reach consumers.

3. a. Summarize the Market

The market for a rapid *E. coli* O157 detection test falls within the food safety and foodborne pathogen detection market, which serves industries responsible for producing, processing, testing, and regulating food products. This market is driven by the need to prevent foodborne illness outbreaks, comply with food safety regulations, and protect public health. Key participants in this market include food producers and processors, food safety testing laboratories, government and regulatory agencies, and large food retailers with internal quality control practices. Demand for rapid pathogen detection tools has increased due to the significant economic and reputational costs associated with food recalls, as well as the continued occurrence of *E. coli* O157 outbreaks. Within this market, rapid testing technologies are especially valued for their ability to deliver timely results, allowing contamination to be identified earlier in the food production and distribution process.

3. b. What is the problem and who has the problem?

What is the problem?

The main problem is that *E. coli* O157 contamination cannot be detected early enough in the food production and distribution process to prevent contaminated products from entering or

remaining in the supply chain. Current conventional detection methods rely on bacterial culture and typically require samples to be sent to external laboratories, with results taking anywhere from 3 to 21 days to obtain (Schulich School of Medicine & Dentistry, 2015). During this time, potentially contaminated food products are often already shipped to grocery stores and restaurants before contamination is identified and may have already caused illness (Schulich School of Medicine & Dentistry, 2015). As a result of these delays, up to several weeks of food products may need to be recalled, protecting against potential cross-contamination, resulting in substantial economic losses (Schulich School of Medicine & Dentistry, 2015). This delay between contamination and intervention represents a critical gap in food safety monitoring and was the core issue that motivated the development of the rapid *E.coli* O157 detection test.

Who has the problem?

This problem is primarily experienced by food producers and processors, who face significant operational disruptions and an increased risk of recall due to delays in pathogen detection. Food safety testing laboratories are also affected due to time-consuming testing procedures and high testing volumes, which can slow reporting and limit testing capacity. Additionally, regulatory agencies are impacted because delayed detection limits their ability to respond quickly to emerging contamination events and outbreaks. Food retailers, including grocery stores and restaurants, experience downstream impacts such as product recalls, supply chain disruptions, and reputational damage. Consumers are indirectly affected through increased exposure to foodborne illness and reduced confidence in food safety.

3. c. How many customers are there (total, annually, or both, depending on the model)?

How many customers are there?

When evaluating the market for new *E. coli* O157:H7 rapid testing, the customers extend beyond food manufacturers alone. While food producers and processors represent the primary customers, several additional stakeholders benefit from and invest in these testing technologies. Food regulators such as the Canadian Food Inspection Agency (CFIA), government and public health bodies like Health Canada, municipalities, and ultimately consumers all rely on effective *E. coli* detection to ensure food safety. These groups collectively represent a large and recurring customer base, as routine pathogen testing is mandatory across high-volume food production systems. Significant financial resources are already allocated toward *E. coli* testing to prevent outbreaks, recalls, and downstream public health costs, demonstrating both demand and sustained investment in improved testing solutions.

3. d. Why are the current solutions inadequate for these customers?

Despite this established market, the current *E. coli* O157:H7 detection methods are inadequate for the operational needs of modern food production. Existing techniques are primarily laboratory-based and largely dependent on Polymerase Chain Reaction (PCR). One commonly used approach is the Manual Sampling Device (MSD), a swabbing technique used in conjunction with PCR (Hygiena, 2021). In this method, samples are collected, incubated for 8–24 hours to allow pathogen growth, and then tested using PCR for confirmation.

Similarly, Automated Immunomagnetic Separation (IMS) devices work in tandem with PCR by selectively separating and concentrating target bacteria before PCR-based quantitative detection (Park et al., 2020). While IMS improves specificity, it does not eliminate the need for incubation and laboratory processing. Non-PCR techniques such as bacterial culture methods

also remain widely used, requiring swabbing of samples onto Luria–Bertani (LB) agar and incubation for 18–24 hours before detection (Cai et al., 2025).

Due to these required incubation periods and PCR processing times, testing results are not immediately available. This delay extends the time needed before products can be packaged, shipped, and released to market. In large-scale food production environments, these delays increase holding and storage costs and slow product distribution. As a result, current solutions do not align with the speed and efficiency demands of the food industry.

The development of a rapid *E. coli* O157:H7 test addresses these limitations by significantly reducing time to result, allowing food producers to verify safety earlier in the production process. This acceleration supports faster packaging and distribution while maintaining food safety standards, making rapid testing technologies more suitable for the scale and pace of modern food systems.

3. e. What is the cost of the problem?

Timely detection of foodborne pathogens is critical for ensuring food safety and protecting public health. However, traditional *E.coli* testing methods typically require 24-48 hours or longer to return results, creating significant delays between sample collection and actionable decision-making. During this period, contaminated food or water may continue to move through the supply chain, increasing the risk that unsafe products reach consumers. In the food industry, delayed detection can result in large-scale recalls that carry substantial financial consequences, including product loss, transportation and disposal costs, legal liability, and long-term damage to brand reputation (Marel, 2025). Estimates suggest that a single food recall can cost companies approximately $10 million per event, even before accounting for indirect costs such as lost consumer trust and reputational harm (Food Manufacturing, 2019).

Beyond economic impacts, foodborne *E.coli* outbreaks also impose significant public health burdens, contributing to hospitalizations and increased strain on healthcare systems. In the United States, foodborne pathogens are responsible for an estimated 9.9 million illnesses and 53, 300 hospitalizations annually (Centers for Disease Control and Prevention [CDC], 2023). Overall, the core issue is that delayed detection limits timely intervention, leading to preventable harm for both consumers and industry.

Customer Segments and Initial Target Market

Given the significant cost associated with delayed *E. coli* detection, several customer segments stand to benefit from a rapid testing solution. These include food producers and processing facilities, water treatment and monitoring facilities, public health laboratories and regulatory agencies, as well as environmental and food safety laboratories. While each of these groups faces risk related to microbial contamination, food producers and processing facilities represent the most appropriate initial target market (Canadian Food Inspection Agency [CFIA], n.d.).

Food processors conduct frequent microbial testing and operate under strict food safety regulations, making timely detection essential for both compliance and risk mitigation. The rapid *E.coli* O157 test developed by Dr. Michael Rieder was specifically designed for use directly within processing plants, allowing results to be obtained on-site rather than relying on external laboratory testing (Robarts Research Institute, 2018). This capability aligns closely with the operational needs of food producers, who face immediate financial and reputational consequences when contamination is identified too late. By enabling faster decision-making and

easier integration into existing quality assurance workflows, the technology offers a clear return on investment through recall prevention and risk reduction, positioning food processors as the strongest candidates for early adoption (CFIA, n.d.).

4. The Value Proposition

The value proposition of the rapid *E. coli* O157 detection test is its ability to provide on-site results within hours rather than days, allowing food processors to identify contamination earlier and make faster decisions about holding or releasing products. Customers want to adopt this technology because of delayed detection using traditional laboratory-based testing, which can lead to contaminated products entering the food supply, resulting in costly recalls, reputational damage, and public health risks. By shortening testing time and enabling in-plant screening, the technology reduces recall risk, improves food safety outcomes, and offers a clear return on investment. For food processors operating under strict regulatory requirements and high financial stakes, faster detection provides both operational efficiency and greater confidence in their food safety practices, making adoption of the technology highly attractive.

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