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Sample6: Partnering to Make Food Safer

It was a beautiful spring day in May 2013, and Tim Curran, CEO of synthetic biology and data monitoring start-up Sample6, glanced out his office window at the glistening Boston seaport. Curran eagerly awaited the arrival of several food industry leaders: Roger Berkowitz, President and CEO of Legal Sea Foods; Will Daniels, SVP of Operations and Organic Integrity at Earthbound Farm; Tony Ricker, Chief Operating Officer of Pacific Cheese; Sharon Birkett, VP North American Quality and Food Protection at OSI Industries; and David Acheson, former Associate Commissioner of Foods at the U.S. Food and Drug Administration (FDA). This coalition of executives was gathering to discuss how industry players could best partner with technological innovators to improve food safety in the United States.

It was an exciting time for Curran and Sample6, which was eagerly approaching the commercial launch of its diagnostic platform to monitor pathogenic bacteria. Using a proprietary bacteriophage technology, Sample6 had developed a food safety assay that was capable of detecting harmful *Listeria spp.* bacteria in the environment in less than 4 hours, significantly faster than the current standard of 30-48 hours.¹ Additionally, Sample6 had developed a software system to help companies monitor, analyze, and remediate their pathogen test results through an easy-to-use and highly visual data analytics platform.

Curran hoped that, together, Sample6's assay and software would enable food suppliers to significantly improve their ability to detect, address, and ultimately prevent microbial contamination of food products. In his eyes, the Sample6 platform offered myriad benefits to food suppliers. It held the potential to significantly reduce costs, both the direct costs of the diagnostic itself and also inventory holding costs incurred while waiting for test results under the current standard. Moreover, through careful data monitoring and increased visibility into test results and trends, it could also help companies quickly and effectively address any positive findings, potentially preventing a highly damaging or even deadly product recall. Lastly, Curran believed that Sample6's product could transform food safety testing from "a necessary evil" to a differentiating, brand-enhancing feature that would allow food suppliers to command premium prices in an increasingly competitive industry.

Today's meeting with key players from the food industry, however, was a special opportunity for everyone at the table to address issues at the heart of food safety management, and at the core of the agribusiness industry more broadly. How might industry players partner with start-ups like Sample6 to effectively develop a better food-safety-monitoring standard? Given the diverse perspectives and

Professor Robert F. Higgins and Kirsten Kester (MBA 2013) prepared this case. It was reviewed and approved before publication by a company designate. Funding for the development of this case was provided by Harvard Business School, and not by the company. HBS cases are developed solely as the basis for class discussion. Cases are not intended to serve as endorsements, sources of primary data, or illustrations of effective or ineffective management.

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food categories represented at the meeting—from seafood to meat to fresh produce—how should Sample6 adapt its product offering to meet their different needs? Finally, what responsibility, if any, did Sample6 have to other authorities in the food industry such as the FDA or USDA?

Context: The U.S. Food Industry

With retail sales over \$1.2 trillion in 2011, the food industry in the United States represented a large and extremely broad market.² The food supply chain was composed of a vast network of primary producers (e.g., farmers and growers), processors, distributors, and retailers (e.g., supermarkets and restaurants) that ultimately sold to end consumers. While supermarkets and restaurants accounted for the majority of food sales—tallying \$524 billion and \$464 billion, respectively^a—other important food outlets included convenience stores, warehouse clubs (e.g., Costco), home delivery, hotels, schools, bars, vending machines, and military outlets.³

The food industry could be further subdivided into categories including dairy, meat and poultry, seafood, fresh fruits and vegetables, oils, grains, and other processed foods. Overall, the industry was quite mature; for example, the industry's projected value-added growth rate of 0.6% was below projected U.S. GDP growth of 1.8% through 2017.⁴ However, the industry nonetheless remained dynamic, with key segments experiencing rapid change.

Key Trends

Shifting consumer tastes Perhaps the strongest trend in the industry was the shift in consumer demand toward healthier products. Reflecting the larger trend toward health and wellness in the United States in response to rising obesity and chronic disease rates, consumers were increasingly demanding healthful, nutritious foods.⁵ Some examples included the increased demand for whole-grain products, coupled with the pressure to lower the levels of sodium and added sugar in many food products.⁶

Similarly, consumer tastes shifted toward natural and organic foods. U.S. sales of organic foods and beverages hit nearly \$39 billion in 2010—a 63% increase over sales five years earlier.⁷ Additionally, a 2011 survey indicated that 37% of consumers “seek out natural/organic foods and beverages,” with a particular emphasis on organic produce including fresh fruits and vegetables, dairy, and meat and poultry.⁸ This trend was driven in part by the desire to avoid ingesting pesticides, preservatives, and other artificial additives, as well as by the perception that organic foods offered enhanced nutritional value.

Another driver behind the organic food movement was an increasing interest in eco-friendly, sustainable, and locally sourced foods. This trend was rooted in “ethical consumerism” and consumers “increasingly . . . shopping with their conscience.”⁹ In fact, sales of foods and beverages making “ethical claims” (e.g., locally grown, Fair Trade, humane, eco-friendly) grew at a compound annual growth rate of 14.3% between 2005 and 2009, reaching over \$28 billion in retail sales.¹⁰

Additionally, consumers were demanding more convenient, ready-to-eat foods.¹¹ Driven by shifting demographics such as smaller and more dual-income families,¹² prepared food sales in the United States were expected to top \$32 billion in 2012—a 7.5% increase over the previous year.¹³ The majority of ready-to-eat retail purchases took place in supermarkets, including single-serving and “heat-and-eat” selections.¹⁴

^a Sales numbers included sales tax.

Finally, the Internet continued to play an ever-increasing role in consumers' food purchasing decisions, especially for individuals concerned with the organic movement. For example, in one survey, 38% of consumers agreed that "the Internet has changed the way they shop for products." For consumers who purchased organic or all-natural foods, this number increased to 44%.¹⁵

Globalization The food chain continued to globalize. In the United States, increased international food trade resulted in cheaper food imports such as fresh fruits and vegetables from Central and South America.¹⁶ In the past five years, the value of agricultural imports in the U.S. grew at a compound annual growth rate of 9%, and the U.S. imported food from over 150 different countries through 300 different ports.¹⁷ While imports accounted for 15% of the 2012 U.S. food supply (by volume), this proportion was much higher in particular categories such as fresh fruits and vegetables (60%) and seafood (85%).¹⁸ Globalization promised to help lower costs and bridge demand for U.S. food manufacturers and supermarkets, but also presented the challenge of managing an increasingly global supply chain.

Food safety and traceability Food safety also emerged as an important focus in the food industry, especially in response to an increasingly globalized supply chain and heightened consumer awareness in the digital age. Several food contamination scares attracted widespread media attention, including mad cow disease and a decade-long ban on British beef exports, the spread of avian flu in Asia, and the 2008 scandal in China over melamine contamination in infant formula. Additionally, the number of food recalls in the United States due to pathogen contamination (e.g., *E. coli*) increased between 2008 and 2012, with several becoming front-page news.¹⁹ By 2011, 73% of U.S. consumers indicated that they had grown more concerned about the safety of their food in the past five years.²⁰

In response to these safety concerns, food companies were increasingly adopting technologies to improve monitoring, visibility, and traceability in their global supply chain.²¹ For food traceability, common techniques included bar codes and scanners, durable labels and tags, radio-frequency identification (RFID), GPS tracking, and other software solutions. (Food pathogen testing is discussed at length later in the case.)

An emerging trend within food traceability was the application of genetic technologies. On the one hand, consumers expressed concern over the safety of genetically engineered crops and genetically modified organisms (GMOs). In parallel, there was a rising interest in DNA-tracing technologies to confirm the identity and integrity of food products, especially meats and seafood.

In a notable example, scandal erupted in January 2013 when hamburgers labeled as beef and sold in Irish and British supermarkets were found to contain significant amounts of both horse and pig DNA. In the ensuing weeks, a number of other European food products—including frozen beef lasagna and other ready-to-eat meals—were also found to be adulterated with horsemeat. In the wake of these shocking findings, police arrested several individuals for fraud, and the European Commission (EC) announced plans to perform random DNA tests on processed meats. In an effort to win back consumer confidence, the EC also vowed to reexamine its controls and regulatory policies. Nonetheless, the issue of DNA traceability in food had caught worldwide attention.

Food Safety in the United States

Food safety was a significant concern in the United States and worldwide. Broadly speaking, there were four major types of food contaminants:

1. Physical agents, such as glass or metal
2. Chemical agents, such as pesticides or veterinary drugs
3. Allergens
4. Microbiological agents and their toxins, such as Shiga toxin-producing *E. coli*

This last category—pathogens—was responsible for the devastating impact of food-borne illness. The U.S. Center for Disease Control (CDC) estimated that nearly 48 million Americans—approximately 1 in 6 people—were sickened, 128,000 hospitalized, and 3,000 died *annually* as the result of food-borne illness.²² Additionally, food-borne illness cost the U.S. over \$78 billion each year.²³ This heavy human and economic toll applied worldwide, especially in emerging markets with less stringent food-safety standards.

In the U.S., four types of bacteria were especially problematic and accounted for a disproportionate number of hospitalizations and deaths: *Salmonella* spp., *Listeria monocytogenes*, *Campylobacter* spp., and *E. coli*. Additionally, one virus (norovirus) and one parasite (*Toxoplasma gondii*) accounted for a significant number of food poisonings. A CDC study found that up to 46% of food-borne illnesses could be attributed to fresh produce (fruits, nuts, and vegetables) and 22% to meat and poultry.²⁴ Especially common sources included leafy vegetables, fruits, dairy products, and poultry.²⁵ (The most common pathogens causing food-borne illness are listed in **Exhibit 1**.)

The CDC carefully monitored trends in food-borne illness and in 2012 reported data that illustrated “a lack of recent progress in reducing food-borne infections and highlight[ed] the need for improved prevention.”²⁶ Specifically, the study showed a failure to significantly reduce the incidence of food poisonings caused by seven types of bacteria in 2012 compared to 2006–2008; in some cases, the incidence of infection actually increased (see **Exhibit 2** for the CDC food safety progress report).²⁷ In response, the CDC set goals to reduce rates of infection by 2020, citing a number of measures to achieve these targets, including increased surveillance, new time and temperature controls, improved outbreak response, and better oversight of food imports.²⁸

Current Regulations and Requirements

Two regulatory bodies were responsible for the oversight of food safety in the United States: the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA). The FDA regulated all food products except meat, poultry, and eggs, which the USDA regulated. Broadly speaking, these agencies regulated food safety by overseeing the registration of food facilities, the standards of food manufacturing processes, the analysis and control of potential food hazards, the quality of food imports, and the storage and preparation of food in retail and service settings. These agencies also played a role in monitoring product recalls in the event of a hazardous risk.

An important development in food safety regulation took place in January 2011 when President Obama signed the Food Safety Modernization Act (FSMA) into law. The main purpose of FSMA was to give the FDA increased power to prevent and react to food safety outbreaks. Additionally, FSMA enabled the FDA to hold imported foods to higher standards. Some of the key mandates of FSMA were in prevention, inspection, and recall.

Prevention FSMA introduced mandatory and scientifically verifiable controls to the food industry. Specifically, food facilities would be required to document and employ a preventative controls plan to evaluate food safety hazards. They had to take steps to reduce risks, monitor and record the efficacy of their controls, and detail corrective action in the face of any issues.²⁹ Additional

stipulations were outlined for fresh produce, including the establishment of “science-based, minimum standards for the safe production and harvesting of fruits and vegetables.”³⁰

Inspection To ensure compliance with the new regulations, FSMA mandated increased, risk-based inspections of food facilities. Food facilities deemed “high risk” would be inspected at least once every three years, and the FDA would have access to the written plans and records mandated under the prevention portion of the bill.³¹ The FDA would also increase its inspection and certification of food facilities abroad. Finally, the FDA would also create a laboratory accreditation program and require additional food testing by accredited labs.³²

Recalls FSMA importantly gave the FDA the power to mandate a food product recall in the event of a clear public-safety risk (previously, the FDA was limited to recommending and monitoring product recalls). Likewise, the FDA was granted authority to preemptively hold suspect food, pending verification of health risks. Lastly, FSMA also called for improved food traceability systems to more rapidly locate contaminated food in the event of a recall.

The Impact of Food Recalls

Food recalls were extremely damaging events to companies in terms of both economics and reputation. The number of food recalls in the U.S. rose between 2008 and 2012, including a peak of 669 pathogen-related recalls in 2009 (pre-FMSA).³³ These recalls had a clear economic impact, including lost sales, plant closures, investigation and clean-up costs, and legal liabilities, not to mention the direct cost of actually implementing the product recall itself. In one study, it was demonstrated that serious food recalls led to an average drop in shareholder value of 1.5%–3%, and that these losses persisted for longer than one month.³⁴

Furthermore, recalls also had a significant impact on consumer confidence, especially in an era of Internet news and mass media.³⁵ Reporters and consumers alike seemed to have an increased appetite for sensational food-recall stories. As Acheson observed, “Things like *Salmonella* . . . *E. Coli* . . . *Listeria*—[are] bugs that 10 years ago nobody had ever heard of except some scientists stuck at Harvard. Today, it’s frontline news on CNN. It’s frontline news on the *Washington Post*. When there’s a *Salmonella* outbreak, an *E. coli* outbreak, everybody knows about it.”³⁶

Several examples highlighted the different costs of a food recall. In 2008, the Canadian food processor Maple Leaf Foods recalled deli meats contaminated with *Listeria monocytogenes*. This unfortunate outbreak sickened 57 and killed 23,³⁷ and cost the company nearly \$30 million.³⁸ This incident illustrated how a recall could affect consumer thinking, as the crisis highlighted the dangers of deli meat to vulnerable populations, such as pregnant women and the elderly. In fact, it was recommended that pregnant women avoid eating deli meats entirely unless the meats were properly reheated.³⁹

Another example showed the devastating and focused impact a recall could have on a particular company. In 2008–2009, peanut products manufactured by Peanut Corporation of America were contaminated with *Salmonella*, resulting in over 700 illnesses and up to nine deaths.⁴⁰ The outbreak resulted in the recall of thousands of products and quickly drove the company out of business. Peanut Corporation of America filed for Chapter 7 bankruptcy in February 2009, and criminal charges against the company’s executives were filed.

A final example—the summer 2006 recall of fresh spinach—demonstrated how a food recall could dramatically affect an entire product category. In the summer of 2006, fresh spinach originating from a farm in California was contaminated with *E. coli*. This product was subsequently distributed and

repackaged across a number of sellers, brands, and retailers in multiple states, causing three confirmed deaths and an estimated 4,000 illnesses.⁴¹ Notably, the economic impact of this recall was felt not just by the companies directly involved, but by the entire category of fresh spinach and leafy greens. In fact, fresh spinach sales in the United States initially fell more than 70% and did not fully recover to their pre-recall levels until January 2008 – 18 months later.⁴²

Food Safety Diagnostic Industry

In 2011, the U.S. food-safety diagnostics industry hit an estimated \$3.3 billion in sales, \$2.9 billion of which was attributed to pathogen testing specifically.⁴³ This industry provided solutions to help food companies ensure the integrity of their products and comply with FDA and USDA regulations, including FSMA's mandate for a documented, preventative controls plan. Moreover, the food pathogen testing market was growing, driven by trends of increased regulation, food imports, and consumer awareness.⁴⁴ The U.S. market was projected to grow by 5.7% annually to \$3.9 billion by 2017.⁴⁵

Food safety testing was divided into two main categories: product testing and environmental testing. Traditionally, food safety testing programs focused on testing food products directly for pathogens. However, there was a new focus on environmental testing, in which food facilities and equipment were screened for contamination. This type of testing was usually described in terms of "zones," with Zone 1 including all direct food-contact surfaces (such as a food conveyor belt), Zone 2 including all adjacent surfaces (such as the leg or rail of a conveyor belt), and Zones 3 and 4 moving outward. Acheson explained the shift toward environmental testing:

Some of the largest outbreaks we've had in the last two to three years have been linked back to what food scientists call environmental contamination. That basically means that we've got the wrong bugs in the processing environment and that they are getting into food after it's been cooked or after it's been prepared. . . . The FDA has recognized that environmental control is really, really important. . . . We know from science that if you literally blitz testing in Zone 2, you are able to control risk. If it's not in Zone 2, it isn't going to get in Zone 1.

The food safety testing market was largely fragmented, with the top three suppliers capturing 21% of the market.⁴⁶ Some food companies performed food safety testing directly, while others outsourced the testing to third-party laboratories. (See **Exhibit 3** for a list of the top food-safety diagnostics companies by market share.) Many of the top food pathogen diagnostics suppliers were large companies whose primary focus was not food safety.

Three common testing technologies were used to detect pathogens: traditional microbiology, immunodiagnosics, and molecular diagnostics.⁴⁷ Traditional culture-based microbiology, which represented the highest-volume method, involved plating and growing bacteria on selective media ("cultural enrichment").⁴⁸ Alternatively, immunodiagnostic methodologies tested for specific toxins or antigens associated with pathogens. Finally, molecular diagnostics involved testing for pathogen DNA or RNA directly through methods such as polymerase chain reaction (PCR). Typically, pathogen testing through a third-party lab cost \$20–\$30 per test and took 30–48 or more hours.⁴⁹

Industry Approach to Food Safety

There were differing opinions regarding the thoroughness and efficacy of the industry's approach to food safety testing programs. Some asserted that the "level of testing still lags behind the problem" and that "current levels of testing and monitoring are not resolving fundamental problems with food

contamination.”⁵⁰ Others argued that the level of testing and commitment to food safety was adequate, but that better and more affordable technology was needed to fully address the problems. Acheson noted, “Food companies have recognized that we cannot do business as usual. We need to invest in food safety. . . . Scientists understand how one goes about this. Cost-effective solutions that are quick and sensitive and competitively priced are a huge need today.”⁵¹

Similarly, other members of the food industry noted, “With the exception of a few bad seeds, the industry is doing a good job with testing.”⁵² Christine Hurckes, Corporate Food Safety and Sanitation Manager for OSI Group, noted the industry’s shared commitment to food safety: “We consider food safety a non-competitive advantage. We realize that a hot dog outbreak somewhere hurts the whole industry. There is a lot of sharing in the [meat] industry of new best practices, and we pass them on to other industries as well such as dairy and produce.”⁵³

Software

In the wake of FSMA, regulators and companies alike recognized that it was not enough to merely perform food safety testing; the results had to be analyzed and interpreted in a meaningful way. Indeed, Michael McCain, President and CEO of Maple Leaf Foods, testified that its deadly 2008 recall was the result of the company’s failure to detect trends:

It was a failure to analyze test data that we weren’t even obligated to collect—a failure on our part to analyze that data and look for root-cause analysis, investigate and follow-up on individual trends, to look for patterns so that we could find the bacteria that we couldn’t see inside these facilities, and end up with a different result. It was more a failure to analyze those findings for a root cause, and a failure of those protocols, than it was a failure of inspection, per se.⁵⁴

Many food companies were using “homegrown” data analysis systems, including manual-entry systems in Microsoft Excel or even pen and paper. According to Acheson, however, these companies would likely be looking to upgrade their systems to better comply with FSMA: “Today food companies are looking for software solutions. They’re looking for technological solutions to help manage all that paperwork—sophisticated solutions that can map where you’ve tested. Think of a 2D or highly sophisticated 3D map of your facility. You know where you’ve tested. More importantly, you know where you haven’t.”⁵⁵

A New Player: Sample6

Sample6 was founded in 2009 following a scientific breakthrough in the field of synthetic biology. MIT Professor Tim Lu and Dr. Michael Koeris developed a proprietary Bioillumination Platform that utilized engineered bacteriophages and naturally occurring bioluminescence to selectively “light up” specific types of bacteria, which could be detected in a machine called a luminometer. This novel technology allowed for the reliable detection of bacteria in a very short period of time—only four hours.

After winning several business plan competitions and receiving seed funding from Boston University, Sample6 raised \$5.75 million in Series A funding in 2011 from Chevron Technology Ventures, Flybridge Capital, The Kraft Group, and Founder Collective. The company thus embarked upon its mission to “improve the health and safety of global consumers by building integrated systems that can quickly and easily detect harmful and unwanted bacteria.”⁵⁶ Although the founders envisioned diverse applications of their technology in health-care and other consumer industries

(such as cruise ships), they decided to focus their initial commercialization efforts on the food industry.

Within food safety, Sample6 focused its initial product development on creating an easy-to-use environmental diagnostic kit for *Listeria* called DETECT/L (with plans to eventually expand into other pathogens such as *Salmonella* and *E. coli*). The testing kit was simple and self-contained (see **Exhibit 4** for photos). First, the tester used a pre-moistened sponge to swab an environmental surface of interest (such as a piece of equipment or a drain). After swabbing, the sponge was placed into a plastic bag and the liquid was transferred to a test tube prefilled with reagents. After approximately three hours, the sample could be read in a luminometer.

In addition to this diagnostic assay, Sample6 developed a cloud-based data-monitoring system called Sample6_{ANALYZE} (see **Exhibit 5** for screenshots of the tool). This software platform enabled companies to analyze and track their tests and results. First, it helped food companies define a customized testing schedule, including floor plans and digital pictures to identify testing points. Second, all assays were tagged with a unique QR code, allowing results to be automatically scanned and transferred into the data monitoring system. Sample6_{ANALYZE} thus provided a real-time visual “heat map” of all tests and results, allowing food companies to monitor, evaluate, and model their food safety needs. In the event of a positive test result, Sample6_{ANALYZE} provided remediation support according to the company’s custom operating procedures.

Together, Sample6’s test kit and data platform provided rapid, targeted, and actionable bacterial information. It was a significant step toward Sample6’s vision “to move microbial monitoring away from small numbers of samples, to a platform that enables continuous pathogen sensing.”⁵⁷ In this way, the Sample6 solution functioned like a smoke detector for food safety, alerting companies as soon as any sign of trouble arose so that they could take immediate action and prevent problems from escalating. Koeris described its potential impact on the food industry: “Our desire as founders is to help humanity by reducing morbidity and mortality—sickness and death. The beauty of targeting the food system is that we are significantly reducing the morbidity and mortality that is associated with food-borne infections.”⁵⁸

As of May 2013, the company had launched beta testing with 10 different companies across different food segments (dairy, meat, seafood, fresh produce, etc.) and eagerly approached its commercial launch after. It planned to raise Series B financing in the next quarter.

Benefits to Customers

The Sample6 food safety platform offered numerous benefits to customers, and Curran wondered which of these value propositions his team should focus on as they targeted initial customers. (See **Exhibit 6** for a summary of a survey with potential customers.)

Faster testing time The Sample6 assay could be performed in less than 4 hours, whereas other available methodologies required a minimum of 24 hours to return results (see **Exhibit 7** for some comparisons with other methods).⁵⁹ Moreover, some tests could take as long as two to three days, including PCR tests (56 hours) and immunoassays (72 hours).⁶⁰ Sample6’s increased speed offered several potential benefits to customers. First, by providing same-day (versus overnight) results, any positive test results could be immediately corrected while a company’s sanitation crew was still on shift. Likewise, fewer products would have to be withheld or recalled pending investigation. Finally, for companies that held their finished goods pending the results of environmental tests, the rapid results could dramatically reduce inventory carrying costs and spoilage.

No enrichment Many culture-based microbiology assays required *growing more of the bacteria* in order to detect it. Because this process actually increased the presence of harmful pathogens, they could not be performed on site in food processing plants. Sample6's process did not involve any such bacterial enrichment and thus could be performed on site. This feature further saved time and could allow some companies to have their own employees perform the testing rather than outsourcing to a costly external lab.

High sensitivity and specificity The Sample6 assay was shown to have "exquisite sensitivity"⁶¹—that is, it yielded very few false negatives and very few false positives. The test was robust, reliable, and targeted, potentially imparting increased confidence to food manufacturers and regulators.

Cost effective Sample6 planned to charge less per test than most outside labs, which often charged \$20–\$30 per test. Given that some food companies performed hundreds of tests per day per plant, Sample6's lower price point could have a significant impact on savings.⁶² Ricker (COO of Pacific Cheese Company) noted that food safety testing was "a significant financial investment."⁶³ Cost efficacy was especially important since food tended to be a low-margin, high-volume industry.

Increased visibility Many food companies still tracked their food safety testing manually, using paper and pen or basic spreadsheets to record tests and results. However, the 2011 passage of FSMA demanded increased documentation. Sample6's data monitoring platform helped achieve the increased level of record keeping expected by the FDA. Additionally, the visual mapping of tests and results helped processors better understand where they needed to test for pathogens and to home in on the source of contamination in the event of a positive result.

Brand protection and differentiation Lastly, Sample6 felt that its innovative solution had the potential to transform food safety testing from "a necessary evil" to a brand-enhancing differentiator. Impeccable food safety was clearly essential to protect brands in an age of food recalls and Internet consumerism. But Curran also believed that partnering with Sample6 could help food growers, processors, and manufacturers win business and generate higher revenues in a competitive industry. Much like *Consumer Reports*, Sample6 could become a "gold-standard seal-of-approval" in the eyes of consumers, retailers, and restaurants. While Sample6's food safety program could thus be a competitive advantage for early adopters, Curran also hoped that it would one day become a standard operating procedure for food companies and regulators.

Potential Customers

As Curran prepared for his meeting, he reflected on the diversity of food companies that Sample6 had been fortunate to work with so far. Each of the players had a different history and approach to food safety, and therefore slightly different needs. And yet they were all bound by their commitment to adopt new technologies to improve food safety.

Pacific Cheese Company

Pacific Cheese Company was a premier manufacturer and supplier of fine cheeses on the West Coast. Founded in 1970 as "industry pioneers," Pacific Cheese was "instrumental in the expansion of the California cheese industry and laid the groundwork for the company's growth into one of the country's leading suppliers of premier-quality, natural cheeses."⁶⁴ In 2013, Pacific Cheese was a privately held company servicing retailers, manufacturers, restaurants, and food-service distributors.

Ricker described the company's quest to become "the best of the best in food safety."⁶⁵ Indeed, a 2011 firm-initiated recall of 3,700 pounds of product found to be contaminated with *Listeria monocytogenes*⁶⁶ validated the direction being taken by the company to overhaul its food safety program and become the "gold-standard for the whole food universe—we're not there yet." Ricker stated that Pacific Cheese's launch of the Safe Quality Food ("SQF") certification initiative in late 2010 was the appropriate strategy to achieve that "gold standard" in all plant locations. Additionally, his vision was for all employees to be well informed, well trained and empowered with food safety awareness and behaviors "from the most senior level down to entry level associates."⁶⁷

Logistically, Pacific Cheese took a unique precaution to ensure the safety of its products: it held its finished goods in inventory until receiving both product test results (required) and environmental test results (not required). This process of waiting for test results before releasing product, known as "positive release," underscored Pacific Cheese's commitment to environmental pathogen monitoring. Pacific Cheese used third-party labs to perform environmental testing, which could take two to five days, including an extra two to three days to perform confirmation testing if needed.⁶⁸ This extra time increased inventory-holding costs and reduced product shelf life, and also hampered Pacific Cheese's flexibility to react to short-lead orders or correct mistaken orders. Additionally, the extra days required for confirmation testing could lead to delivery delays to customers.⁶⁹

While Sample6's faster testing solution offered obvious benefits to Pacific Cheese, given these operational considerations, the company's interest in them went much deeper. As an innovative pioneer in the cheese market, Ricker wanted his company to be "ahead of the curve" in food safety: "How can we be assured that we are not only in compliance but also on the leading edge? . . . How can we help grow the dairy category as an industry? How do we come up with new offerings in this commodity category? . . . We need the help of third-parties and industry experts."⁷⁰

Ricker looked forward to taking a collaborative approach with Sample6 to help it test and prove the technology. "We are going to be involved," he said. "We want to see it and touch it and feel it."⁷¹ Additionally, Carol Dudick, Sr. Director of Quality Assurance at Pacific Cheese, noted that the kit's ease of use and lack of enrichment would enable Pacific Cheese to perform testing on site with its own technicians. The data monitoring program would also allow it "to take [its] Excel spreadsheet to the next level" to notice trends and pinpoint problems.⁷²

Earthbound Farm

Founded in California in 1984, Earthbound Farm was the largest grower of organic produce in the United States.⁷³ With a focus on natural nourishment, Earthbound Farm pioneered the sale of prewashed, packaged salad and mixed baby greens ("spring mix") in the 1980s. Its product lines included salads; fresh and frozen vegetables; fresh, frozen, and dried fruits; herbs; and packaged snacks. All Earthbound Farm foods were USDA-certified organic, "not just because it tastes better, but because it's healthier to eat and friendlier to the environment."⁷⁴

As suggested by its commitment to organic produce, food integrity was of the utmost importance to the Earthbound Farm brand. In fact, Will Daniels, Earthbound Farm's top operations manager, held the title of "SVP of Operations and Organic Integrity." In addition to its dedication to healthy and sustainable eating, Earthbound Farm publicly expressed its concerns with issues such as GMOs in food, irradiation of lettuce and spinach, and the use of toxic pesticides in farming.⁷⁵ Earthbound Farm's strong consumer brand helped it become a major supplier to retail chains, including Walmart, Costco, Safeway, and Whole Foods.

Food safety was an integral component of Earthbound Farm's premium brand strategy. Daniels said, "We want consumers to be able to trust our brand and know that when they purchase Earthbound Farm, they are getting a safe and wholesome product."⁷⁶ Like Pacific Cheese Company, Earthbound Farm renewed its focus on food safety in the wake of a food recall. In this case, an Earthbound Farm partner company—Natural Selection Foods—was the source of the massive fresh spinach recall of 2006 referenced earlier in this case. Daniels described how this recall affected the approach to food safety:

Since the spinach outbreak in 2006, we took a deep dive into our program and realized that we were operating at industry best standards back then—and that wasn't good enough. So we were determined to re-envision our food safety program and come up with a multi-hurdle program that includes pathogen testing in and around our products.

The company's website publicly detailed its food safety and traceability procedures, from planting to growing to processing. It described this program as "unparalleled in integrity and scope" and "the most rigorous in the industry."⁷⁷ However, Daniels noted that the Sample6 product offered several improvements. First, Earthbound Farm's current *Listeria* testing procedures took 48 hours to return results—and another 3 to 5 days to obtain culture confirmation of these results if necessary—which could be costly for perishable fresh produce. "With fresh-cut salads, we have about 21 days from harvest to degradation so it's really important that we move the product through our processes and to our consumers as quickly as possible . . . especially since we have to ship the product across the country. It can take as long as 5 days to deliver the product."⁷⁸

Additionally, Daniels noted that Sample6's rapid and easy-to-use testing kit would allow Earthbound Farm to bring environmental testing in-house and substantially increase the amount of *Listeria* testing performed. Finally, he spoke very highly of the Sample6^{ANALYZE} data monitoring and mapping feature, a tool that he believed would allow Earthbound Farm to identify and focus on "hot spots" within its processing environment.⁷⁹

Legal Sea Foods

Legal Sea Foods was a Boston-based seafood restaurant group with an online fish market and a retail products division. Originally started as a fish market in Cambridge, Massachusetts, in 1950, Legal Sea Foods currently operated over 30 restaurants.⁸⁰ From its earliest days, Legal Sea Foods obsessed over the freshness and quality of its seafood; hence, its motto, "If it isn't fresh, it isn't Legal!" This quality assurance proposition remained a key tenet of Legal Sea Foods' business model.

Legal Sea Foods President & CEO Roger Berkowitz, whose father founded the company, ensured that "Legal sets the industry standard for freshness and purity"⁸¹ even as it continued to expand. Legal Sea Foods bought only the freshest fish—either "top of catch" or day boat fish.⁸² Additionally, Legal Sea Foods strongly emphasized food safety, sanitation, and controls. For example, the company built a "state-of-art fish processing plant and food safety laboratory," called the Quality Control Center, at the company's headquarters (and described on the restaurant placemats).⁸³ Here, the company ran "a boatload of scientific tests," including pathogen and mercury testing, to ensure safety "from pier to plate."⁸⁴

Legal Sea Foods emphasized the importance of staying on the leading edge of new food safety technologies and regulation. Again, this commitment had deep roots; in the 1990s, Legal Sea Foods partnered with the FDA to develop the Hazard Analysis and Critical Control Points (HACCP) seafood inspection process.⁸⁵ Berkowitz said, "Businesses must evolve over time, and as more information on food safety becomes available to the public, those that pro-act to new advances are

going to be in a better position I think. Those that choose not to act, or react very late, will be out of the game very quickly.”⁸⁶ John Ciarametaro, Assistant Director of Quality Assurance at Legal Sea Foods, added, “One of the ways that we’ve stayed ahead of the game is by working with companies such as Sample6 to keep these types of hazard from occurring.”⁸⁷

OSI Group

OSI Group (OSI) was a privately held global food supplier. While OSI was involved in the manufacturing of many different types of foods—including pizza, sandwiches, soups, and snacks—it was one of the world’s largest suppliers of raw and processed meats (beef, pork, chicken, hot dogs, bacon, etc.). Notably, OSI was a leading supplier of beef, bacon, and breakfast sausage to a major fast-food chain in the United States and abroad.⁸⁸ OSI worked with other food retailers and private-label brands, providing a diverse mix of products and distribution services.⁸⁹ Based outside of Chicago, OSI had over 50 facilities across 17 countries.⁹⁰

According to Sharon Birkett, VP North American Quality and Food Protection at OSI, its mission was to be a “premier, indispensable food supplier . . . and in order to be indispensable, we need to ensure that our foods are safe and free from pathogens.”⁹¹ As such, OSI developed a comprehensive pathogen-testing program across its numerous facilities. OSI had tremendous success in its food safety program, culminating in accolades from customers, including a quality award from a major fast-food chain.⁹²

However, Birkett acknowledged that despite its success, OSI “definitely has room for continuous improvement. . . . You feel like you’re doing all the right things, but how do I know what I don’t know?”⁹³ In particular, she said, data analytics represented an “area of opportunity.” OSI currently plotted test results—“only if it’s something other than a negative”—in an Excel spreadsheet.⁹⁴ The Sample6 solution, she said, was visually appealing, and she felt that it would be easier to purchase such a software solution “off the shelf” than try to create her own version with limited IT resources.

Hurckes agreed, saying, “We collect massive amounts of data and have a definite need to make that data more usable and accessible.” She added, “Everyone is trying to come up with the quickest test. Sample6 is the only one trying to understand what to do with the data once we get it.”⁹⁵ Finally, she noted that OSI’s data monitoring—albeit rudimentary—was nonetheless expensive to maintain. “Everyone would love to cut down on that cost, but if you get into a problem situation, you can blow your budget in a month trying to figure out where it is coming from.”⁹⁶

Additionally, Hurckes articulated some specific benefits OSI would capture from a faster environmental pathogen test. It took OSI two to three days to receive environmental test results from external labs. During this wait, food production continued. “That’s the kicker,” Hurckes said. “That’s two days that we could be contaminating our product. That’s two days that we could be making improvements. . . . That’s two days of peril that you put yourself into.”⁹⁷ OSI performed a complete sanitation program each night, in which equipment was taken apart and cleaned. A faster test could yield actionable results before the sanitation crew left and before the machines were put back together.

Questions Moving Forward

As Curran prepared for his meeting with the top food executives, he couldn’t help but reflect on the incredible progress Sample6 had made—and the challenges that lay ahead. Indeed, the food industry was changing. Trends such as globalization, shifting consumer tastes, and technological

breakthroughs required that food companies keep up—or get left behind. He knew that the leaders of major food companies were wondering, what can I be doing to stay successful and competitive?

Fueled by recent food recalls and heightened consumer awareness, food safety was definitely an important consideration for all industry players. And, he felt, Sample 6 had a technological breakthrough and sophisticated solution. But how could large food companies partner with start-up companies like Sample6 to drive meaningful change? Could they afford to? Could they afford *not* to?

Furthermore, Curran wondered which of the myriad customers and value propositions he should focus Sample6's limited resources on. Should Sample6 focus on a particular food category, such as fresh produce or seafood or dairy? And which product benefits were most important to customers? He had hoped that he could establish the importance of food safety to branding, and that pathogen testing was not just good for business, but critical. He also wondered to what extent data analytics would be a part of the food safety solution moving forward.

Finally, as Curran walked out of his office and headed toward the conference room, he couldn't help but wonder if there was someone missing from the conversation—the regulatory agencies. Should they be a part of this conversation? What was the best way for Sample6 and its customers to work with them? He let out a deep breath and walked into the room.

Exhibit 1 Selected Pathogens Causing Food-borne Illness

Type	Pathogen	Estimated Annual:			Deaths	Common Food Sources
		Illnesses	Hospitalizations			
Bacteria	<i>Bacillus cereus</i>	63,000	20	0		Rice, leftovers, sauces, soups
	<i>Brucella</i> spp.	840	55	1		Raw milk, unpasteurized dairy
						Raw / undercooked poultry, unpasteurized dairy, contaminated water
	<i>Campylobacter</i> spp.	850,000	85,000	76		Beef, poultry, gravy
	<i>Clostridium perfringens</i>	970,000	440	26		
	<i>E. Coli</i> (STEC) O157	63,000	2,100	20		
	<i>E. Coli</i> (STEC) non-O157	110,000	270	1		Ground beef, unpasteurized milk and juice, soft cheeses, raw fruits and vegetables
	<i>E. Coli</i> (ETEC)	18,000	12	0		
	<i>E. Coli</i> - other	12,000	8	0		
	<i>E. Coli</i> - total	203,000	2,390	21		
Parasites	<i>Listeria monocytogenes</i>	1,600	1,500	250		Deli meats, smoked seafood, unpasteurized dairy, raw sprouts
	<i>Mycobacterium bovis</i>	60	31	3		Unpasteurized dairy
	<i>Salmonella</i> spp.	1,000,000	19,000	380		Eggs, poultry, meat, unpasteurized milk and juice, cheese, raw fruits and vegetables, nuts
	<i>Shigella</i> spp.	130,000	1,500	10		Prepared foods, raw fruits and vegetables, contaminated water
	<i>Streptococcus</i> spp.	251,000	1,101	6		Prepared foods
	<i>Vibrio</i> spp.	53,180	278	48		Seafood
	<i>Yersinia enterocolitica</i>	98,000	530	29		Pork, unpasteurized milk, oysters
	<i>Cryptosporidium</i> spp.	58,000	210	4		Raw fruits and vegetables, contaminated water
	<i>Giardia intestinalis</i>	77,000	230	2		Raw fruits and vegetables, contaminated water
	<i>Toxoplasma gondii</i>	87,000	4,400	330		Raw or undercooked meat
Viruses	Hepatitis A	1,600	99	8		Shellfish, raw produce, contaminated water
	Norovirus	5,500,000	15,000	150		Shellfish, raw seafood, prepared foods

Source: U.S. Centers for Disease Control and Prevention^a, and Kalorama Research.^b

^a Centers for Disease Control and Prevention, "Pathogens causing US foodborne illnesses, hospitalizations, and deaths, 2000-2008," <http://www.cdc.gov/foodborneburden/PDFs/pathogens-complete-list-01-12.pdf>, accessed April 2013.

^b Salazar, "Food Safety Diagnostics: The World Market," Table 2-1.

Exhibit 2 CDC Food Safety Progress Report, 2012

Pathogen	% Change: 2012 vs. 2006-2008	2012 Rate per 100,000	2020 Target per 100,000	Ratio of Reported : Undiagnosed Cases
<i>Campylobacter</i> spp.	+14%	14.30	8.50	1 : 30
<i>E. Coli</i> (STEC) O157	No change	1.12	0.60	1 : 26
<i>Listeria monocytogenes</i>	No Change	0.25	0.20	1 : 2
<i>Salmonella</i> spp.	No Change	16.42	11.40	1 : 29
<i>Vibrio</i> spp.	+43%	0.41	0.20	1 : 142
<i>Yersinia enterocolitica</i>	No change	0.33	0.30	1 : 123

Source: U.S. Centers for Disease Control and Prevention.^a

^a Centers for Disease Control and Prevention, “Trends in Foodborne Illness in the United States, 2012.”

Exhibit 3 Top Food Safety Diagnostics Companies (U.S.)

Company	2011 Revenue (\$ million)	Market Share
bioMérieux	335	11%
3M	230	8%
DuPont Qualicon	65	2%
<i>Other</i>	2,313	79%
Total	2,943	100%

Source: Data from Kevin Gainer, "Global Markets and Technologies for Food Safety Testing," *BCC Research FOD011G* (August 2012), Figures 20-21, <http://www.bccresearch.com>, accessed April 2013.

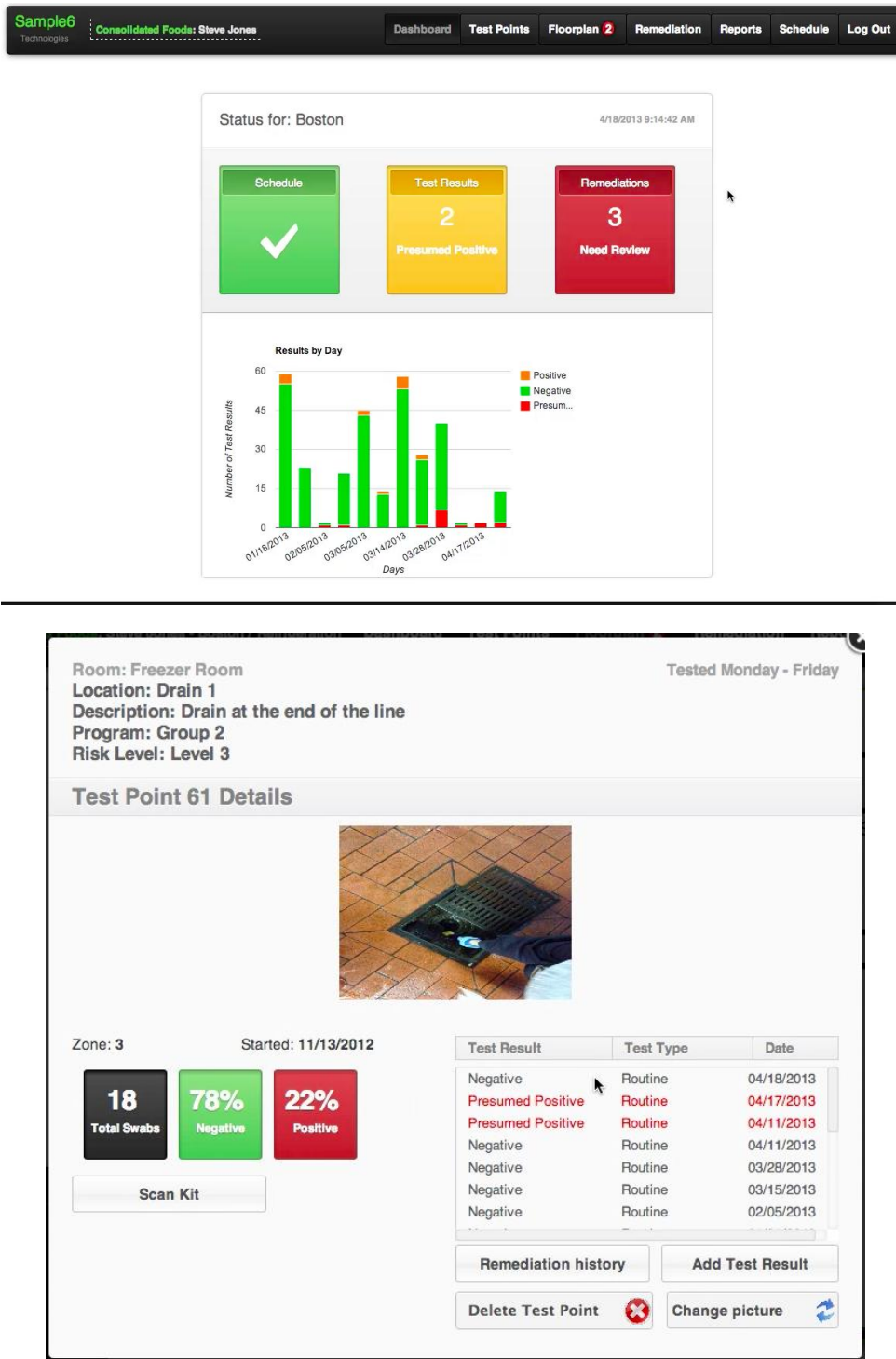
Exhibit 4 Images of Sample6 Environmental Testing Kit and Luminometer



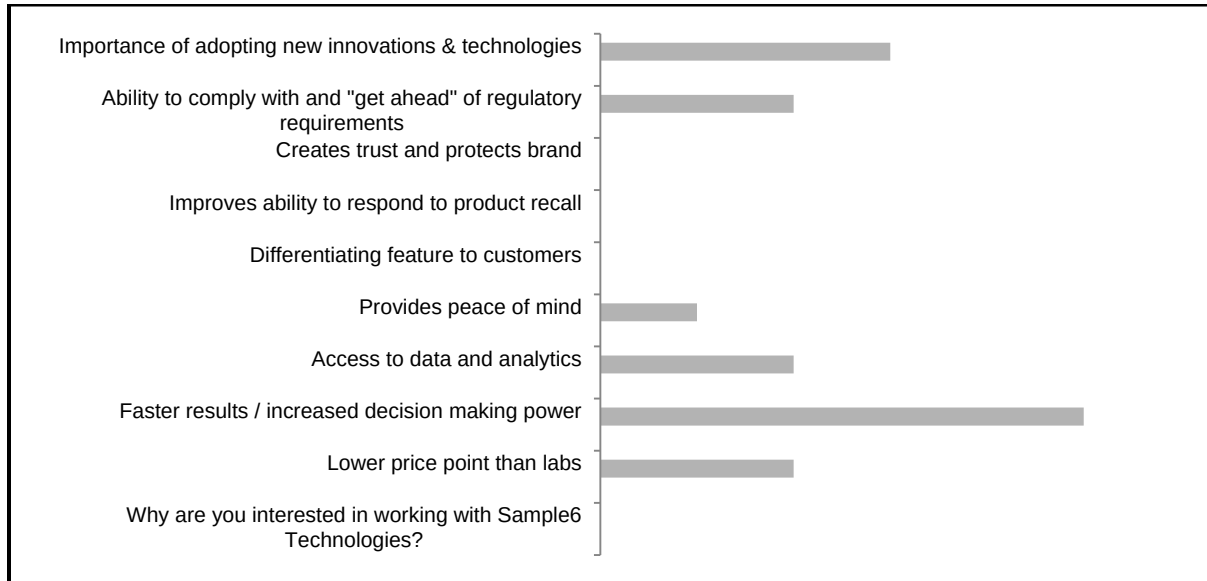
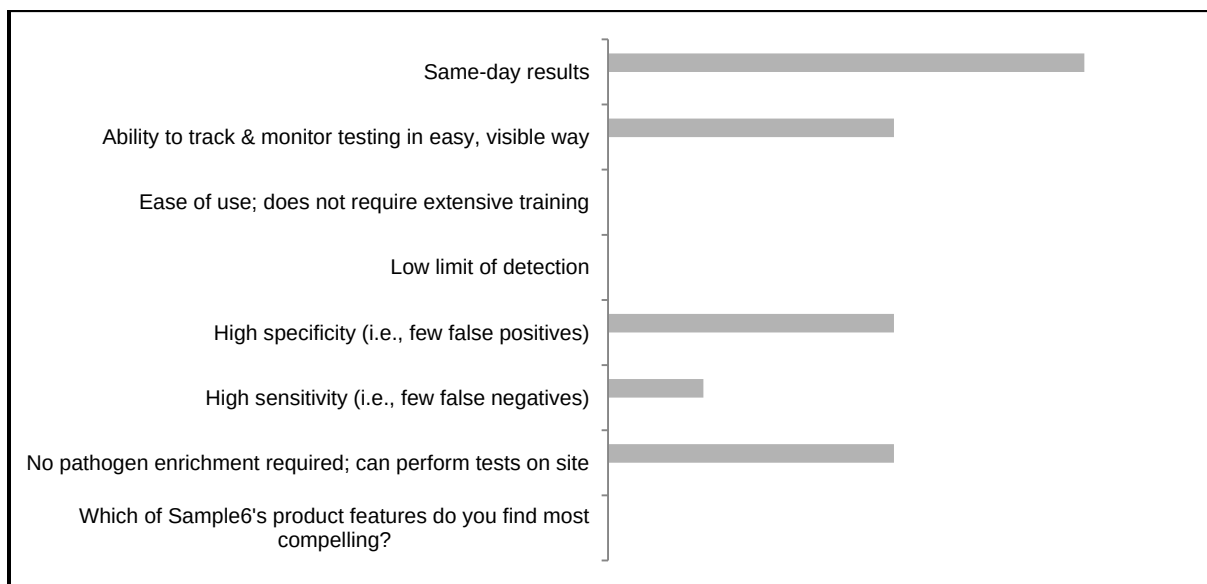
Source: Company documents.

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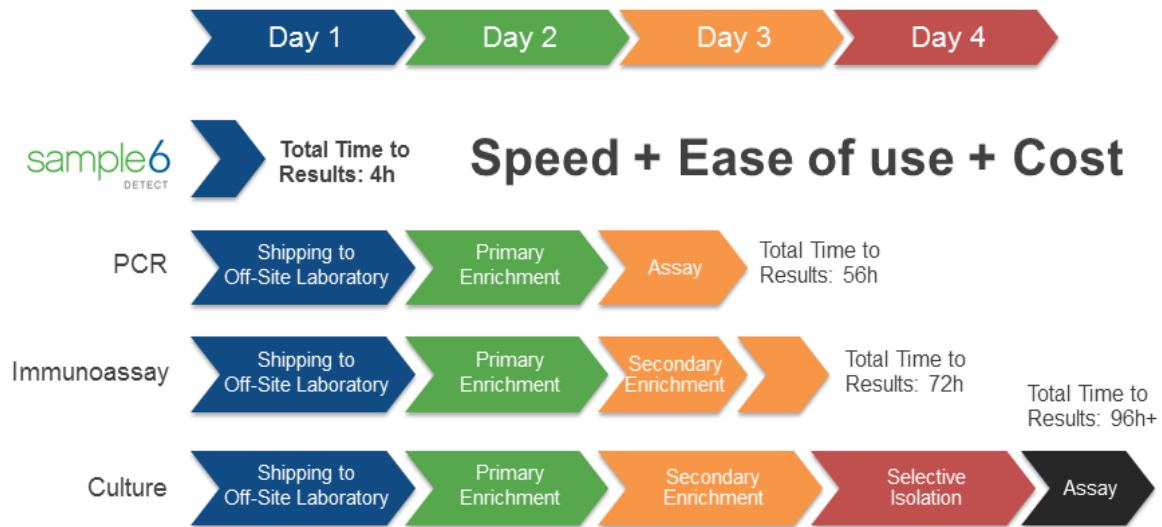
Exhibit 5 Screenshots of Sample6_{ANALYZE} Data Analysis Tool

Source: Company documents.

Exhibit 6 Sample6 Prospective Customer Survey Results**Why are you interested in working with Sample6?****Which of Sample6's product features do you find most compelling?**

Source: Survey by author.

Exhibit 7 Sample6 Time to Results versus Other Methodologies



Source: Company documents.

Endnotes

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