FROST & SULLIVAN

FROST & SULLIVAN BEST PRACTICES AWARD

RAPID DIAGNOSTICS - NORTH AMERICA

Technology Innovation 2019

FIRST LIGHT DIAGNOSTICS

Contents

Background and Company Performance

Industry Challenges

The global infectious disease diagnostics market was valued at $14.73 billion in 2017 and is projected to grow at a compound annual growth rate of 5.6%, reaching $19.35 billion in 2022. The World Health Organization reports that about 17 million people worldwide die from infectious diseases each year, which can be attributed to viral, bacterial, and fungal sources. In the United States, 30 million people suffer from 7,000 types of such diseases. An average of 10,000 cases of tuberculosis (TB) has been reported, about 2 million people become infected from bacterial infections every year, and about 51,455 cases of salmonella were reported in 2017 alone. In addition, the geriatric population is more prone to such infections, and because this US population is expected to increase from 46 million to over 98 million by 2060, the United States will likely have the largest market for infectious disease diagnostics.

The current infectious disease diagnostics market has the following challenges:

Life-threatening infections, such as respiratory and blood infections, are caused by pathogens that are difficult to treat because they are multi-drug resistant, and available antimicrobial susceptibility testing (AST) methods to determine appropriate antibiotics are slow. Culture-based methods require more than a day to produce results, which means patients are treated empirically with broad-spectrum of antibiotics that can spread antibiotic resistance. Rapid AST technologies in the market have low throughput and high costs and cannot be used for the majority of human samples which contain non-disease-causing bacteria or for polymicrobial infections.

Furthermore, several infections are best diagnosed by ultrasensitively detecting key molecules and not cells. For instance, *Clostridium difficile* (*C. difficile*) can be diagnosed by detecting a protein toxin. *C. difficile* diagnostic tests available in the market, such as enzyme immunoassay tests specific for this disease, lack the sensitivity and miss infected patients. Highly sensitive nucleic acid amplification tests, such as the polymerase chain reaction (PCR), are non-specific because they cannot distinguish between colonization and active infection.

Healthcare-acquired infections (HAIs) have emerged as a crucial health concern worldwide. According to the Centers for Disease Control and Prevention (CDC), one in 31 patients in a hospital is affected by HAIs. Superbugs, or bacteria resistant to common antibiotics, can enter the body and cause serious infections during surgeries. Genetic tests are quicker than traditional culture-based tests in identifying the infectious pathogen, but these test are not practical for determining the right targeted therapy, incur high costs, and some platforms are not designed for conducting a large number of tests at the same time. Moreover, the Hospital Readmissions Reduction Program (HRRP) reduces excessive hospital readmissions and penalizes hospitals for readmissions because of a variety of

reasons (e.g., HAIs). Given the high prevalence of HAIs, hospitals often suffer financially; therefore, a platform is urgently needed that can rapidly detect infections, identify pathogens, and determine the appropriate antibiotics at the onset of infection. In addition, such a platform should be capable of rapid diagnosis and must be primed for scaling (i.e., to conduct as many tests as possible at the same time).

Frost & Sullivan has identified First Light Diagnostics Inc, a US-based diagnostics company for infectious diseases, as a company that has successfully and effectively tackled all these challenges.

Technology Attributes and Future Business Value

Industry Impact

First Light's MultiPath™ technology addresses important market gaps. For example, the platform provides pathogen identification in 30 minutes and AST results in four hours directly from the patient sample, thereby enabling treatment decisions one or two days quicker than with traditional AST methods. This shorter time period is significant because it allows for the correct treatment to be administered during the onset of infection. Direct-from-specimen testing eliminates the need for an intermediate culture step, while the ultra-sensitive detection feature identifies the low number of cells that might be present in uncultured patient samples. Moreover, the patented MultiPath technology is unaffected by samples containing multiple species of pathogens that contaminate microbes and sample matrices. The platform is a fully automated sample-to-result solution and can perform up to 20 ASTs simultaneously, which dramatically improves throughput and workflow. Based on Frost & Sullivan research, First Light's MultiPath technology is an efficient platform for infection diagnoses and provides rapid antimicrobial susceptibility testing that radically reduces time and costs for hospitals.

Furthermore, First Light's technology provides the ultra-sensitive detection of toxins and disease biomarkers. For instance, the company provides a cost-effective, ultra-sensitive, and specific test for diagnosing *C. difficile* infection. By being both highly sensitive and specific the test is differentiated from insensitive enzyme immunoassays and non-specific nucleic acid amplification tests.. The company's test is up to 60 times more sensitive than other available tests and detects the toxin at levels corresponding to clinical thresholds for the infection. Because First Light's test has higher specificity than nucleic acid amplification tests because it detects the disease-causing toxins that are made by the growing bacteria but not the dormant spores found in colonized patients. This specificity is one of the platform's strongest selling points. In addition, the technology is easy to use because it detects the toxin directly from stool samples, without the need for additional processing steps. Because the test takes only 30 minutes, hospitals can quickly identify infections and avoid over treatment and over diagnosis, thus eliminating the risk of not being able to distinguish between a true infection and patient colonization.

Application Diversity and Scalability

First Light's MultiPath platform addresses the challenge with HAIs as well. The technology enables rapid, high throughput and cost-effective patient screening tests for a wide variety of superbugs and is not confounded by the multiple genes and mutations that cause antibiotic resistance. The tests identify resistance phenotypically by determining whether the antibiotic stops the cells from growing. This approach works well even if the genetics of the resistance mechanisms are complex.

Future applications of the platform's menu include screening tests for superbugs including methicillin-resistant Staphylococcus aureus (MRSA). This bacterial pathogen causes a large number of life-threatening hospital infections and is resistant to commonly used antibiotics. The ability to detect HAIs in a timely fashion is a market challenge that when addressed, impacts patient lives and reduces hospitals' expenditure in Human Research Protection Program (HRPP) costs. Improved patient outcomes for the most common HAIs are expected to shorten a patient's length of stay, thus saving hospitals an average of about $20,000 per day. In 2016, the North American HAI diagnostics market was valued at $1.9 billion and is expected to reach $4.9 billion by 2020.

First Light will initially leverage its highly differentiated MultiPath platform in the HAI segment of the North American infectious disease diagnostics market. *C. difficile* testing accounts for 37% of the healthcare spending in this segment, MRSA accounts for 25%, vancomycin-resistant enterococci (VRE) accounts for 11%, and screening for carbapenem-resistant enterobacteriaceae (CRE) accounts for 4%. The remaining 23% is spent on detecting life-threatening syndromic infections, such as urinary tract infections, sepsis, pneumonia, and surgical-site infections.

First Light plans to launch the MultiPath platform by the end of 2020, along with a test for *C. difficile* and a second rapid phenotypic AST for antimicrobial susceptibility testing for gram-negative infections. By the end of the first quarter 2019, the company will begin clinical studies for the *C. difficile* test at three independent clinical sites. By the third quarter 2019, First Light plans to submit the MultiPath platform and the *C. difficile* test to the US Food and Drug Administration (FDA) for regulatory clearance, and the product is expected to enter the market by 2020.

The recently revised US and European practice guidelines emphasize the importance of toxin tests in identifying the *C. difficile* infection accurately. These new guidelines will benefit toxin testing and First Light's *C. difficile* testing platform. By 2020, the company expects to begin taking market share for *C. difficile* toxin and DNA testing. In addition, First Light will launch the rapid AST test, enabling the company to begin taking a share of the rapid AST test market in 2021. Frost & Sullivan believes that First Light is making commendable progress in scaling its business across the infectious disease diagnostics market.

Financial Performance

First Light has secured a government contract with the Biomedical Advanced Research and Development Authority (BARDA) for up to $43 million to develop and provide the MultiPath platform and an ultrasensitive test for detecting anthrax.

Subsequently, in November 2018, the company relocated to a new facility, thus enabling new development and manufacturing capabilities. To meet the challenge of financing the commercialization of such a novel clinical diagnostics platform, First Light has been receiving funding from a diverse array of sources, including government grants, contracts, and equity financing.

In January 2019, First Light closed a Series A Equity financing for $13.5 million, and in 2019, the company closed a debt financing package for $4.5 million. Frost & Sullivan expects First Light to leverage this funding toward introducing its technologies in the infectious disease diagnostics market.

Customer Acquisition

First Light's technology can detect infections, toxins, biomarkers, and diagnostically informative human cells and identify pathogens in only 30 minutes, which is twice as quick as the time taken to detect toxins by other tests and up to one or two days quicker than the time taken to identify pathogens. In only four hours, MultiPath determines susceptibility profiles by phenotypic AST.

The MultiPath platform's applications are diverse. For example, 64 targets can be detected per cartridge, and phenotypic susceptibility can be tested for up to 14 microbials per cartridge.

These cartridges are a low-cost consumable and allow for on-demand testing, whereby up to 20 cartridges can be loaded simultaneously, including in mixed applications and while processing other samples. Other easy-to-use features include the need for little-to-no sample preparation; no liquid handling on the analyzer; no analyzer replenishing because of no reagents or pipette tips; and fully automated sample tracking, which means that typing is not required. In addition, internal controls create accurate results.

Therefore, healthcare facilities and other customers are expected to switch from competitors' products to First Light's products because the company's AST results are rapid and can be taken from different sample types; ultrasensitive tests for toxins and biomolecules are more accurate; and products provide high throughput and high performance at a low cost and a small footprint.

Conclusion

First Light effectively addresses market challenges by leveraging technology and providing the MultiPath platform and diagnostics tests that can significantly impact the infectious disease diagnostics industry. First Light has successfully built a scalable business because its products can be used across diverse applications. In addition, the company has received grants and funding from various sources and will acquire customers based on its products' diverse, attractive features.

With its strong overall performance, First Light Diagnostics has earned Frost & Sullivan's 2019 Technology Innovation Award in the North American rapid diagnostics industry.

Significance of Technology Innovation

Ultimately, growth in any organization depends on finding new ways to excite the market and maintaining a long-term commitment to innovation. At its core, technology innovation, or any other type of innovation, can only be sustained with leadership in 3 key areas: understanding demand, nurturing the brand, and differentiating from the competition.

Understanding Technology Innovation

Technology innovation begins with a spark of creativity that is systematically pursued, developed, and commercialized. That spark can result from a successful partnership, a productive in-house innovation group, or a bright-minded individual. Regardless of the source, the success of any new technology is ultimately determined by its innovativeness and its impact on the business as a whole.

Key Benchmarking Criteria

For the Technology Innovation Award, Frost & Sullivan analysts independently evaluated 2 key factors—Technology Attributes and Future Business Value—according to the criteria identified below.

Technology Attributes

Criterion 1: Industry Impact
Criterion 2: Product Impact
Criterion 3: Scalability
Criterion 4: Visionary Innovation
Criterion 5: Application Diversity

Future Business Value

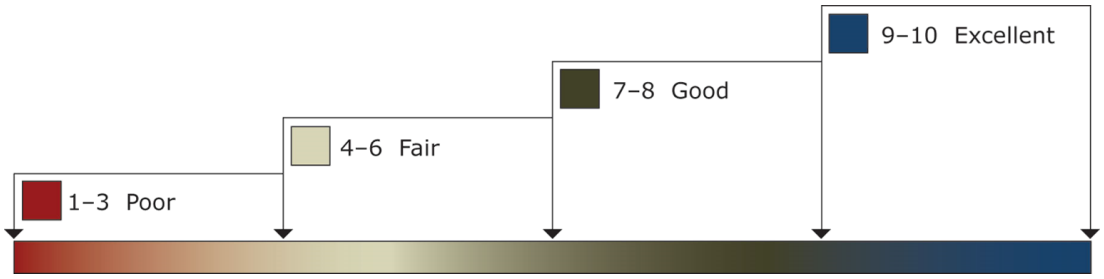
Criterion 1: Financial Performance
Criterion 2: Customer Acquisition
Criterion 3: Technology Licensing
Criterion 4: Brand Loyalty
Criterion 5: Human Capital

Best Practices Award Analysis for First Light Diagnostics

Decision Support Scorecard

To support its evaluation of best practices across multiple business performance categories, Frost & Sullivan employs a customized Decision Support Scorecard. This tool allows research and consulting teams to objectively analyze performance according to the key benchmarking criteria listed in the previous section, and to assign ratings on that basis. The tool follows a 10-point scale that allows for nuances in performance evaluation. Ratings guidelines are illustrated below.

RATINGS GUIDELINES



The Decision Support Scorecard considers Technology Attributes and Future Business Value (i.e., the overarching categories for all 10 benchmarking criteria; the definitions for each criterion are provided beneath the scorecard). The research team confirms the veracity of this weighted scorecard through sensitivity analysis, which confirms that small changes to the ratings for a specific criterion do not lead to a significant change in the overall relative rankings of the companies.

The results of this analysis are shown below. To remain unbiased and to protect the interests of all organizations reviewed, Frost & Sullivan has chosen to refer to the other key participants as Competitor 1 and Competitor 2.

Measurement of 1–10 (1 = poor; 10 = excellent)			
Technology Innovation	Technology Attributes	Future Business Value	**Average Rating**
First Light Diagnostics	**9.5**	**9.5**	**9.5**
Competitor 1	8.5	8.5	8.5
Competitor 2	7.8	7.6	7.7

Technology Attributes

Criterion 1: Industry Impact

Requirement: Technology enables the pursuit of groundbreaking ideas, contributing to the betterment of the entire industry.

Criterion 2: Product Impact

Requirement: Specific technology helps enhance features and functionalities of the entire product line for the company.

Criterion 3: Scalability

Requirement: Technology is scalable, enabling new generations of products over time, with increasing levels of quality and functionality.

Criterion 4: Visionary Innovation

Requirement: Specific new technology represents true innovation based on a deep understanding of future needs and applications.

Criterion 5: Application Diversity

Requirement: New technology serves multiple products, multiple applications, and multiple user environments.

Future Business Value

Criterion 1: Financial Performance

Requirement: Potential is high for strong financial performance in terms of revenue, operating margins, and other relevant financial metrics.

Criterion 2: Customer Acquisition

Requirement: Specific technology enables acquisition of new customers, even as it enhances value to current customers.

Criterion 3: Technology Licensing

Requirement: New technology displays great potential to be licensed across many verticals and applications, thereby driving incremental revenue streams.

Criterion 4: Brand Loyalty

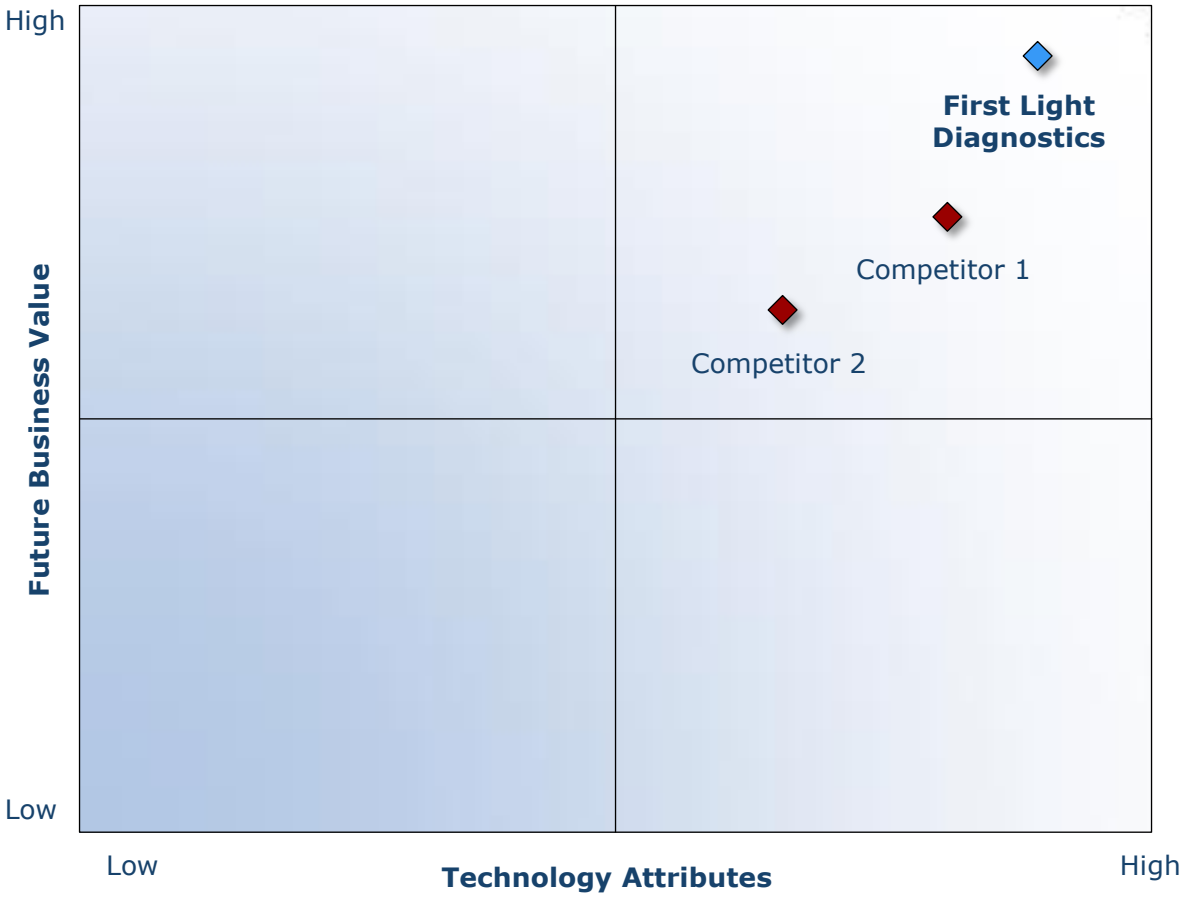
Requirement: New technology enhances the company's brand, creating and/or nurturing brand loyalty.

Criterion 5: Human Capital

Requirement: Customer impact is enhanced through the leverage of specific technology, translating into positive impact on employee morale and retention.

Decision Support Matrix

Once all companies have been evaluated according to the Decision Support Scorecard, analysts then position the candidates on the matrix shown below, enabling them to visualize which companies are truly breakthrough and which ones are not yet operating at best-in-class levels.



Best Practices Recognition: 10 Steps to Researching, Identifying, and Recognizing Best Practices

Frost & Sullivan analysts follow a 10-step process to evaluate award candidates and assess their fit with select best practices criteria. The reputation and integrity of the awards are based on close adherence to this process.

	STEP	OBJECTIVE	KEY ACTIVITIES	OUTPUT
1	**Monitor, target, and screen**	Identify award recipient candidates from around the world	• Conduct in-depth industry research • Identify emerging industries • Scan multiple regions	Pipeline of candidates that potentially meet all best practices criteria
2	**Perform 360-degree research**	Perform comprehensive, 360-degree research on all candidates in the pipeline	• Interview thought leaders and industry practitioners • Assess candidates' fit with best practices criteria • Rank all candidates	Matrix positioning of all candidates' performance relative to one another
3	**Invite thought leadership in best practices**	Perform in-depth examination of all candidates	• Confirm best practices criteria • Examine eligibility of all candidates • Identify any information gaps	Detailed profiles of all ranked candidates
4	**Initiate research director review**	Conduct an unbiased evaluation of all candidate profiles	• Brainstorm ranking options • Invite multiple perspectives on candidates' performance • Update candidate profiles	Final prioritization of all eligible candidates and companion best practices positioning paper
5	**Assemble panel of industry experts**	Present findings to an expert panel of industry thought leaders	• Share findings • Strengthen cases for candidate eligibility • Prioritize candidates	Refined list of prioritized award candidates
6	**Conduct global industry review**	Build consensus on award candidates' eligibility	• Hold global team meeting to review all candidates • Pressure-test fit with criteria • Confirm inclusion of all eligible candidates	Final list of eligible award candidates, representing success stories worldwide
7	**Perform quality check**	Develop official award consideration materials	• Perform final performance benchmarking activities • Write nominations • Perform quality review	High-quality, accurate, and creative presentation of nominees' successes
8	**Reconnect with panel of industry experts**	Finalize the selection of the best practices award recipient	• Review analysis with panel • Build consensus • Select recipient	Decision on which company performs best against all best practices criteria
9	**Communicate recognition**	Inform award recipient of recognition	• Present award to the CEO • Inspire the organization for continued success • Celebrate the recipient's performance	Announcement of award and plan for how recipient can use the award to enhance the brand
10	**Take strategic action**	Upon licensing, company is able to share award news with stakeholders and customers	• Coordinate media outreach • Design a marketing plan • Assess award's role in strategic planning	Widespread awareness of recipient's award status among investors, media personnel, and employees

The Intersection between 360-Degree Research and Best Practices Awards

Research Methodology

Frost & Sullivan's 360-degree research methodology represents the analytical rigor of the research process. It offers a 360-degree view of industry challenges, trends, and issues by integrating all 7 of Frost & Sullivan's research methodologies. Too often companies make important growth decisions based on a narrow understanding of their environment, resulting in errors of both omission and commission. Successful growth strategies are founded on a thorough understanding of market, technical, economic, financial, customer, best practices, and demographic analyses. The integration of these research disciplines into the 360-degree research methodology provides an evaluation platform for benchmarking industry participants and for identifying those performing at best-in-class levels.

360-DEGREE RESEARCH: SEEING ORDER IN THE CHAOS

About Frost & Sullivan

Frost & Sullivan, the Growth Partnership Company, helps clients accelerate growth and achieve best-in-class positions in growth, innovation, and leadership. The company's Growth Partnership Service provides the CEO and the CEO's growth team with disciplined research and best-practices models to drive the generation, evaluation, and implementation of powerful growth strategies. Frost & Sullivan leverages nearly 60 years of experience in partnering with Global 1000 companies, emerging businesses, and the investment community from 45 offices on 6 continents. To join Frost & Sullivan's Growth Partnership, visit http://www.frost.com.