2021

Technology Innovation Leadership

Global

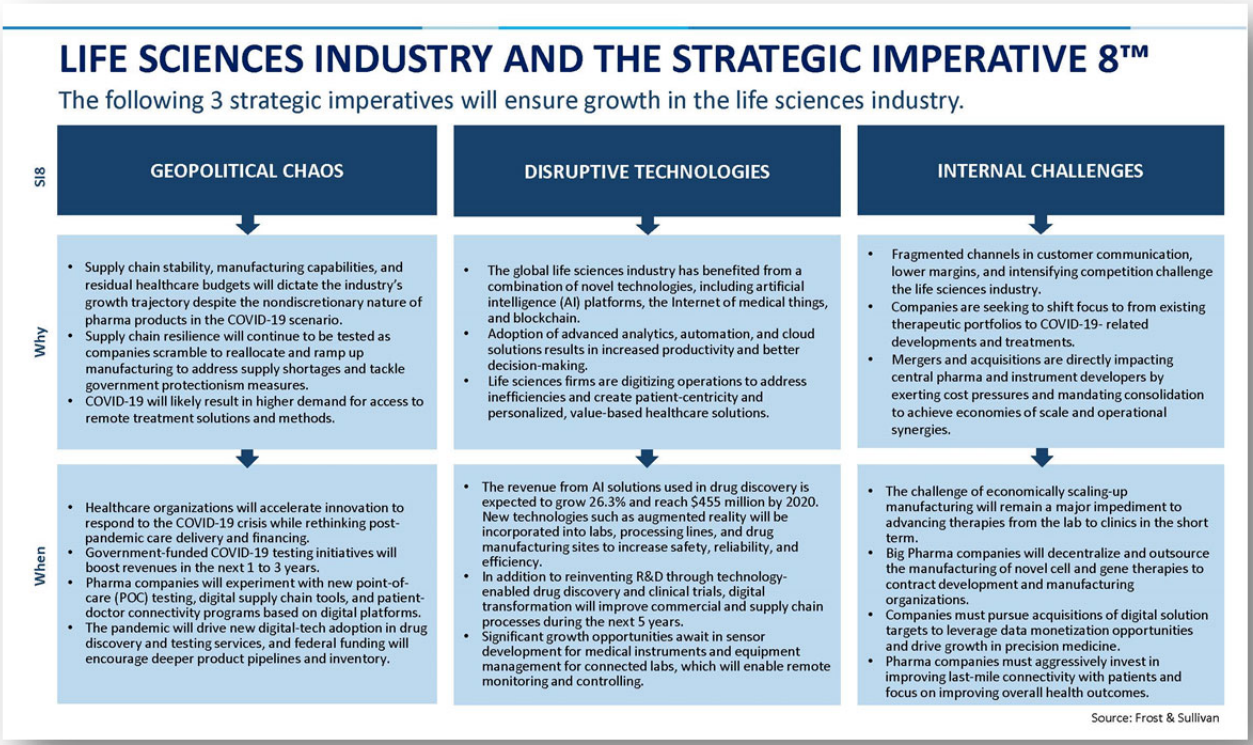
Molecular Testing Industry

Excellence in Best Practices

FROST & SULLIVAN

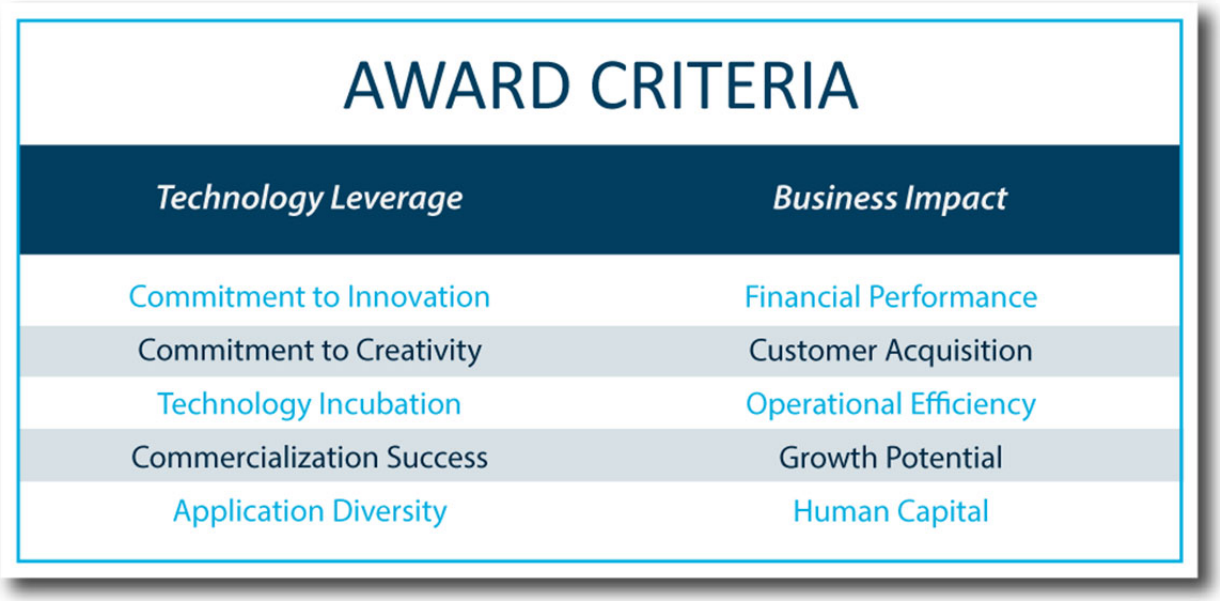
Strategic Imperatives

Frost & Sullivan identifies three key strategic imperatives that impact the life sciences industry: geopolitical chaos, disruptive technologies, and internal challenges. Every company that is competing in the life sciences space is obligated to address these imperatives proactively; failing to do so will almost certainly lead to stagnation or decline. Successful companies overcome the challenges posed by these imperatives and leverage them to drive innovation and growth. Frost & Sullivan's recognition of PathogenDx is a reflection of how well it is performing against the backdrop of these imperatives.



Best Practices Criteria for World-Class Performance

Frost & Sullivan applies a rigorous analytical process to evaluate multiple nominees for each award category before determining the final award recipient. The process involves a detailed evaluation of best practices criteria across two dimensions for each nominated companies. PathogenDx excels in many of the criteria in the Molecular Testing space.



Coupling RT-PCR and DNA Multiplexing to Design Highly Accurate Cost-effective Respiratory Diagnostics with Broad Coverage

Founded in 2014, and headquartered in Scottsdale, Arizona, PathogenDx offers disruptive Nucleic Acid-based tests that use a multiplex microarray to identify, detect, and quantify multiple pathogens and viral strains more rapidly and cost-effectively when compared to other molecular based platforms. The proprietary and patented technology is applicable for small and medium testing facilities and is applicable across industries such as the health diagnostics, agriculture, and food markets.

The ongoing novel coronavirus (COVID-19) crisis demands a unique long-term diagnostic solution to address the pandemic. COVID-19, for example, has become a persistent problem involving a mutant virus that has created four mutations EU, UK, South African and Brazilian versions within a span of just seven to eight months. While competing existing technologies lack the accuracy and ability to track several mutations at once, PathogenDx's DetectX-Rv test stands out. It holistically addresses the COVID-19 challenge for individual patient diagnosis of COVID-19, as well as delivering Clade-Variant Adaptive Surveillance of the major mutations. It is proven that COVID-19 infection transmits SARS-CoV-2 virus in the environment via aerosolization to humans ultimately resulting in community-wide spread. In light of this, the company developed the technology to also test for SARS-CoV-2 in the environment both in the air and on surfaces cost-effectively.

> *"The company's testing technology harnesses all the different historical mutations and robustly expands and evolves over time to quickly add necessary probes within a market-disruptive three to four weeks, capturing new mode mutations without having any significant linear cost increase."*
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> ***- Supriya Lala Kundu, Best Practices Research Analyst***

The company's testing technology harnesses all the different historical mutations and robustly expands and evolves over time to quickly add necessary probes within a market-disruptive three to four weeks, capturing new mode mutations without having

any significant linear cost increase. One among the top companies selected by the National Institutes of Health (NIH), PathogenDx received grants from the National Institute of Allergy and Infectious Diseases under the NIH.

The grant helped the company to scale up its technology for COVID-19 testing and expand platform capabilities to test for all respiratory viral infections, including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) commonly referred to as COVID-19, as well as Influenza A+B, and other respiratory pathogens all in the same sample.

Detectx-Rv utilizes nasopharyngeal swabs, nasal aspirate or fluids, and viral RNA purification kits. It also contains up more probes on its microarray to drive 100% specificity in the test, higher than all current Food & Drug Administration (FDA) authorized COVID-19 tests. The technology distinguishes Corona-like-viruses from SARS-CoV-2 to deliver market-leading accuracy. It identifies N1, N2, genes for SARS-CoV-2, and the RNase P gene as the positive control. The company's platform leverages the end-point reverse transcription-polymerase chain reaction (RT-PCR) technology that detects RNA in the sample. However, q-RT-PCR diagnostic methods have limitations related to sensitivity and specificity that prevent distinguishing between several pathogen strains. Besides, identifying target sequences in low copy numbers (present in asymptomatic or mildly symptomatic patients) is a challenge. To that end, PathogenDx adapted its unique technology by combining RT-PCR technology with the powerful DNA microarray hybridization technique to improve specificity and unleash the possibilities for multiplex testing for qualitative viral detection. The coupling of these two technology elements delivers discrimination power of testing that is 10x greater than the conventional real-time reverse transcription PCR (qRT-PCR) technologies currently being used on a mass scale for COVID-19 testing.

The combined approach can robustly triage patients by distinguishing between several other flu-like symptoms, such as bad cold, influenza A or B from COVID-19. The platform detects multiple RNA target sequences simultaneously and identifies distinct signs relative to a large number of specificity controls. The assay kit contains five SARS-CoV-2 primer sets and four SARS-CoV-2probes targeting each N1, and N2 genes. After the RNA extraction and PCR amplification, a fluorophore marks the resulting amplified COVID-19 cDNA, followed by hybridizing the amplified sample in the DNA microarray. The microarray holds 144 synthetic single stranded DNA probes, SARS-CoV-2, Influenza A+B, and Variant probes and an internal (RNase P) positive control organized in a 12 x 12 configuration (acts as a set of multiple tests), leading to increased specificity. The cDNA then hybridizes with all 144 probes (in parallel) to provide rapid results within five hours.[1]

High-throughput Ultra-Rapid Test with Superior Detection Sensitivity Enabling to Diagnose Asymptomatic Transmission

PathogenDx's testing platform's high throughput capability allows running 96 tests per kit. The current manual process has a testing throughput of 576 samples in 8 hours on a 96-well plate with two lab-technicians. The company aims to scale and maximize throughput by enabling pooled sample testing to accommodate up to 3,456 tests on six plates of the 96-well Microarray and deploy continuous processing either manually with four lab-technicians or via automation. By providing an ultra-rapid

[1] https://www.labmanager.com/big-picture/during-covid-19/microarray-technology-enhances-covid-19-testing-22575

sample-to-result testing turnaround time of four and half hours (4.5 Hours), PathogenDX aims to simplify and quicken COVID-19 detection, unlike any existing technology, providing it a competitive advantage. The company aims to develop its novel platform to enhance COVID-19 detection accuracy and efficacy without compromising sensitivity and specificity, to diagnose asymptomatic transmission, and limit infection spread.

PathogenDx points out that the test's sensitivity and specificity for COVID-19 (SARS-CoV-2) are superior to other comparable FDA-approved competitive tests (Q-RT PCR technology) that suffer from concerning false-negative rates ranging from 15% to 48%.

> *"By providing an ultra-rapid sample-to-result testing turnaround time of four and half hours (4.5 Hours), PathogenDX aims to simplify and quicken COVID-19 detection, unlike any existing technology, providing it a competitive advantage. The company aims to develop its novel platform to enhance COVID-19 detection accuracy and efficacy without compromising sensitivity and specificity, to diagnose asymptomatic transmission, and limit infection spread."*
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In other approaches, a single-step qRT-PCR reaction limits DNA amplification and results in reduced detection sensitivity of nearly 55 copies per reaction with a poor signal-to-background noise. In comparison, PathogenDx's high-performing test applies its One-step PCR that maximizes DNA amplification using similar amplification technology like next generation sequencing or Droplet Digital-PCR, leading to a superior lower limit of detection and ten times better accuracy than other FDA-approved similar PCR-based tests. Studies validated that the lowest concentration with observed positive rates for analytical sensitivity was 0.3 copies per reaction (and 3.64 copies per reaction post RNA extraction). Such low detection limits are clinically relevant in testing asymptomatic individuals to restrict infection spread. Furthermore, studies conducted to evaluate wet testing cross-reactivity and determine the DetectX-Rv assay specificity against closely related viruses depicted no cross-reactivity. The test also showed a high signal-to-background noise.

Environmental Screening and Monitoring Test to Prevent Airborne Infection Spread

With an increased percentage of time spent indoors during 2020, air purification within enclosed spaces has become necessary as part of combating the spread of COVID-19. Therefore environmental screening tests aimed to improve air quality in homes and commercial buildings are vital.

PathogenDx's environmental screening and monitoring EnviroX-Rv test provides public facilities and buildings lacking ventilation with a fast and accurate approach to screen the air for contaminants, such as aerosolized SARS-CoV-2 and other viruses. It can detect viruses that spread through transmitted droplets and remain either air-suspended for hours or stuck for up to three days on surfaces. Detecting the contaminants leads to conducting air sanitation or disinfection procedures within the facility to protect public health and prevent disease spread.

The company collaborated with Bertin Technologies, coupling its technology to Bertin's Coriolis Air Sampler; PathogenDx then applied its highly sensitive and specific DNA microarray to examine the air sample to ascertain viral presence in the air. With at least ten times more sensitivity than existing viral

detecting technologies and a threshold detection limit of 62 copies of the virus, EnviroX-Rv delivers 98% accuracy and detects minimal viral load, which is as low as a single copy.

"As the public reintroduces itself back into society, this innovative solution can help facility managers monitor buildings and confirm that the sanitation and remediation solutions they are using are effective, so we can safely restart our economy."

Milan Patel, Co-founder & CEO of PathogenDx[2]

For example, a study evaluated SARS-CoV-2 surface and air contamination at North Western London hospital utilizing the Bertin's Carolis Air Sampler. The research revealed detection of viral RNA in 114/218 (52.3%) of surface samples (in hospital's public places) and viral DNA in 14/31 (38.7%) air samples.[3]

EnviroX-Rv is the first test to receive an international validation from the globally-recognized Association of Official Analytical Collaboration (AOAC) Research Institute's Performance Tested Methods℠ Program. It demonstrates more sensitivity than the World Health Organization's sampling guidance methods and the Centers for Disease Control and Prevention assays. The test can determine the presence of dead virus particles and ascertain prior contamination, owing to its ability to detect RNA fragments on concrete, plastic, and other non-porous high-use surfaces. Such market-disruptive sensitivity plays a vital role in ensuring pathogen-free environments for employees, patients, and consumers across facilities.

Marketing and Product Adoption Focus

Priced at one-fifth to one-tenth the equipment cost of other established players that provide similar test platforms with multiplexing capabilities, PathogenDx's price-performance value stems from its ability to enable superior diagnostic coverage for several respiratory pathogens. Providing a cost-effective surveillance technology that fits the economy of small and medium-sized clinical and diagnostic labs, the FDA-EUA-validated test is currently applicable for research-use only and pending FDA approval for COVID-19 with multiplexing capabilities of Clade Variants.

The company's current test volume ranges between 250,000 tests per month and is scaling up to 750,000 tests per month. PathogenDx aims to market the test to private small and medium-sized diagnostic labs and expand reach to rural communities to serve high-risk, underserved groups, simultaneously increasing awareness and educating government and private entities to bolster adoption rates.

[2] https://www.prnewswire.com/news-releases/pathogendx-announces-partnership-with-bertin-instruments-to-combat-spread-of-covid-19-301081320.html
[3] Zhou, J. (2020). Investigating SARS-CoV-2 surface and air contamination in an acute healthcare setting during the peak of the COVID-19 pandemic in London. Medrxiv

Conclusion

PathogenDx adapted its unique testing platform by combining multiplexed end-point real-time polymerase chain reaction (RT-PCR) with DNA microarray technology to enable testing for coronavirus (COVID-19) in people, air, and contact surfaces. For respiratory diagnostics, the DetectX-RV allows qualitative viral detection and management with a rapid result turnaround time of less than five hours. The EnviroX-Rv test screens airborne and surface-based COVID-19 transmission at commercial facilities, leading to rapid sanitization and limit infection spread. By enabling a One-step PCR separating the hybridization of the amplified sample on the microarray probes,, the company delivers ten times higher accuracy than commercially available quantitative real-time PCR tests, thus, eliminating high false-negative limitations.

The highly accurate, specific, and ultra-sensitive DetectX-RV supports complex multiplexed testing. It identifies N1, and N2, genes for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), all the major COVID-19 Clade Variants identified so far, and the RNase P gene, and other respiratory pathogens such as Influenza A/B, and the next wave of coronavirus in the same sample, creating new possibilities for respiratory testing. The matchless sensitivity enables an exceptional lower limit of viral load detection, vital to diagnose and prevent asymptomatic transmission. The scalable platform design increases throughput with pooled samples testing that raises tests conducted per substrate footprint for a lower test cost.

With its strong overall performance, PathogenDx earns Frost & Sullivan's 2021 Global Technology Innovation Leadership Award in the molecular testing industry.

What You Need to Know about the Technology Innovation Leadership Recognition

Frost & Sullivan's Technology Innovation Award recognizes the company that has introduced the best underlying technology for achieving remarkable product and customer success while driving future business value.

Best Practices Award Analysis

For the Technology Innovation Leadership Award, Frost & Sullivan analysts independently evaluated the criteria listed below.

Technology Leverage

Commitment to Innovation: Continuous emerging technology adoption and creation enables new product development and enhances product performance

Commitment to Creativity: Company leverages technology advancements to push the limits of form and function in the pursuit of white space innovation

Stage Gate Efficiency: Technology adoption enhances the stage gate process for launching new products and solutions

Commercialization Success: Company displays a proven track record of taking new technologies to market with a high success rate

Application Diversity: Company develops and/or integrates technology that serves multiple applications and multiple environments

Business Impact

Financial Performance: Strong overall financial performance is achieved in terms of revenues, revenue growth, operating margin, and other key financial metrics

Customer Acquisition: Customer-facing processes support efficient and consistent new customer acquisition while enhancing customer retention

Operational Efficiency: Company staff performs assigned tasks productively, quickly, and to a high-quality standard

Growth Potential: Growth is fostered by a strong customer focus that strengthens the brand and reinforces customer loyalty

Human Capital: Commitment to quality and to customers characterize the company culture, which in turn enhances employee morale and retention

About Frost & Sullivan

Frost & Sullivan is the Growth Pipeline Company™. We power our clients to a future shaped by growth. Our Growth Pipeline as a Service™ provides the CEO and the CEO's growth team with a continuous and rigorous platform of growth opportunities, ensuring long-term success. To achieve positive outcomes, our team leverages over 60 years of experience, coaching organizations of all types and sizes across 6 continents with our proven best practices. To power your Growth Pipeline future, visit Frost & Sullivan at http://www.frost.com.

The Growth Pipeline Engine™

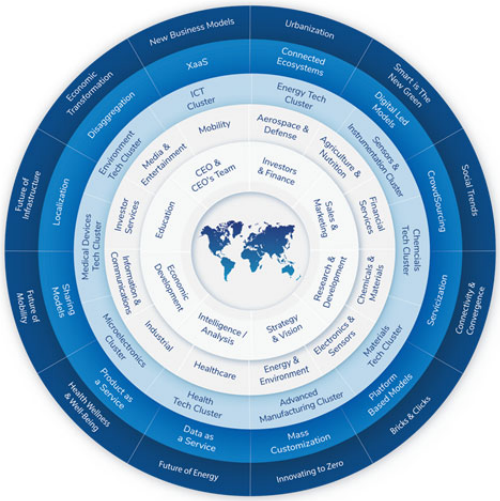
Frost & Sullivan's proprietary model to systematically create on-going growth opportunities and strategies for our clients is fuelled by the Innovation Generator™. Learn more.

Key Impacts:

- **Growth Pipeline:** *Continuous flow of Growth opportunities*
- **Growth Strategies:** *Proven Best Practices*
- **Innovation Culture:** *Optimized Customer Experience*
- **ROI & Margin:** *Implementation Excellence*
- **Transformational Growth:** *Industry Leadership*

The Innovation Generator™

Our six analytical perspectives are crucial in capturing the broadest range of innovative growth opportunities, most of which occur at the points of these perspectives.



Analytical Perspectives:

- Mega Trend (MT)
- Business Model (BM)
- Technology (TE)
- Industries (IN)
- Customer (CU)
- Geographies (GE)