

FROST & SULLIVAN

*LUMIRADx*

**2022**  
**TECHNOLOGY**  
**INNOVATION**  
**LEADER**

*EUROPEAN MICROFLUIDICS*  
*POINT-OF-CARE*  
*DIAGNOSTICS INDUSTRY*

## 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 company. LumiraDx excels in many of the criteria in the microfluidics point-of-care diagnostics space.

AWARD CRITERIA	
<i>Technology Leverage</i>	<i>Business Impact</i>
Commitment to Innovation	Financial Performance
Commitment to Creativity	Customer Acquisition
Stage Gate Efficiency	Operational Efficiency
Commercialization Success	Growth Potential
Application Diversity	Human Capital

### ***Microfluidics Point-of-care Diagnostics Market Overview***

The point-of-care testing (POCT) market has witnessed dramatic innovation in the past two decades, allowing physicians to detect and diagnose diseases directly at the patient’s site, thus producing rapid results. Further, microfluidics integration in POCT has revolutionized disease diagnosis, eliminating the need for skilled personnel, large sample volumes, and heavy equipment. Therefore, the COVID-19 pandemic has propelled the demand for microfluidics POCT that scales a laboratory (lab) down into a chip, enables personalized medicine, and ensures better patient outcomes.<sup>1</sup>

LumiraDx uniquely leverages its technology to meet customers’ needs. It is well-positioned to capitalize on new growth opportunities, cementing its leadership in the microfluidics point-of-care (POC) diagnostics space.

### ***Meeting Real-world Client and Market Needs***

Founded in 2014 and headquartered in London, the United Kingdom (UK), LumiraDx provides simple, accessible, and affordable POCT by leveraging microfluidics technology. The company aims to transform community-based healthcare by delivering comprehensive, accurate, and real-time diagnoses to healthcare providers at the point of need. It allows testing for the most common disease states, such as

<sup>1</sup> *Advanced Micro- and Nanofluidics Revolutionizing the Point of Care Diagnostic Industry*, (Frost & Sullivan, April 2021).

cardiovascular, infectious disease, coagulation disorders, and diabetes. Essentially, it facilitates better medical decisions for improved outcomes at lower costs.

LumiraDx has taken various steps to equip customers with the most up-to-date and cutting-edge solutions for POC diagnostics. This orderly and systematic product development journey begins with extensive research and development conducted by tenured industry professionals. Its founders, Ron Zwanziger, David Scott, and Jerry McAleer, boast a successful track record in building and scaling diagnostics and health information technology businesses, such as Medisense, Inverness Medical, and Alere. The team's expertise includes:

- Developing, manufacturing, and commercializing POC diagnostic platforms
- Using cloud-based platforms to transfer patient data and integrate health system networks
- Utilizing the data to build supported self-care plans to improve health outcomes<sup>2</sup>

The company leverages the acquired knowledge to create innovative products that address market needs. While the senior leadership team oversees the design and management of the complex system, LumiraDx has centers of excellence across Stirling and Glasgow (UK) and Boston, San Diego (US), where highly-skilled individual teams focus on specific areas such as qualitative immunoassays, quantitative immunoassays, metabolic, and molecular diagnostics. As a result, the company can drive an array of tests simultaneously.

The company understands the diverse client types' unique requirements and ensures that its offerings meet unaddressed market needs. Traditional POCT has significant limitations such as limited scalability, poor clinical performance, a limited test menu, and a high total ownership cost. The LumiraDx platform consolidates multiple POC systems onto a single instrument and performs as a one-stop diagnostic testing solution. The portable device is the size of a brick, weighs only 1.1 kilos, and uses a rechargeable battery,



<sup>2</sup> LumiraDx, "Who We Are - Leading Edge Innovators in Health It," LumiraDx, 2022, <https://www.lumiradx.com/uk-en/who-we-are>.

while the test strip is smaller than the size of a credit card. Moreover, the simple and intuitive user interface provides a step-by-step testing workflow.

The LumiraDx platform generates rapid lab-comparable results and offers a broad test menu, including severe acute respiratory syndrome coronavirus (SARS-CoV)-2 Antigen (Ag), SARS-CoV-2 Ag pool, SARS-CoV-2 Antibody (Ab), SARS-CoV-2 and Flu A/B, RNA STAR, D-dimer, international normalized ratio (INR), and C-reactive protein (CRP) tests. The company has 30+ assays in development, with some near to launch.

The platform allows multiple sample types (fingerstick blood, venous blood/plasmas/serum, nasal/nasopharyngeal throat swab, saliva, and urine) and test technologies (immunoassay, enzyme, molecular, electrolytes/blood gas) on a common strip architecture for various tests, with eight approved tests currently in the market. The automated web-based manufacturing line requiring only a few human resources produces 28 million tests per month, with the capability to scale further.<sup>3</sup> This low-cost strategy enables the company to offer products at low costs.

Further, the platform innovatively simplifies, scales down, and integrates lab system principles:

**The LumiraDx Platform Simplifies, Scales Down, and Integrates Principles Lab System Principles**

	LumiraDx Platform	Central Lab System
<b>Common Transduction</b>	Fluorescence / electrochemical	Fluorescence / chemiluminescence
<b>Precise Fluidic Control</b>	Piezo bender / test strip bladder	Syringe pumps
<b>No Sample Matrix Bias</b>	Gas wash / liquid-free image	Multiple buffer washes
<b>Non-Specific Binding Control</b>	Particle coating / anti-hama	Assay design / anti-hama
<b>Calibration Bias</b>	Calibration to lab standard	Calibration to lab standard
<b>Assay Precision</b>	Materials, process, assay controls	Chemistry, assay controls

*Source: LumiraDx Presentation, March 2022*

LumiraDx’s Connect Manager cloud-based services enable seamless remote management, instrument configuration, test results viewing, and simplified workgroup provisioning from a mobile, tablet, or personal computer. Data and control mechanisms allow potential future upgrades to connectivity.

<sup>3</sup> Discussion with LumiraDx, 4<sup>th</sup> April 2022.

Additionally, while competing devices in the market demand up to 275 microliters of a blood sample, the LumiraDx platform generally only necessitates about 10 microliters.<sup>4</sup> Furthermore, unlike most of its competitors, the company's system is stable at room temperature. It does not require refrigeration, allowing global shipment and convenient field use.

Frost & Sullivan finds the LumiraDx platform highly impressive and applauds its ability to meet real-world client and market needs.

### ***A Proven Track Record***

By the end of 2021, LumiraDx deployed more than 21,000 instruments.<sup>5</sup> In the first quarter of 2022, it deployed about 25,000 devices across all six continents in almost 100 countries.<sup>6</sup>

The company has a wide variety of tests approved, has achieved the CE mark and the emergency use authorization in the United States (US) from the FDA, and continues to expand its global roll-out. In October 2021, India's Central Drugs Standard Control Organization approved its SARS-CoV-2 Ag test for emergency use.<sup>7</sup> In December 2021, it received Conformité Européenne (CE) marking for its SARS-CoV-2

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*- Ojaswi Rana,  
Best Practices Research Analyst*

and Flu A/B test.<sup>8</sup> Similarly, in February 2022, the UK Medicines and Healthcare Products Regulatory Agency certified the SARS-CoV-2 RNA STAR Complete test.<sup>9</sup> Additionally, in March 2022, it also received approval from the Japanese Ministry of Health (PDMA) for its SARS-CoV-2 and Flu A/B test.<sup>10</sup> The company can now supply products to over 100 countries.

### **COVID-19 Impact**

The COVID-19 pandemic has considerably accelerated LumiraDx's go-to-market strategy. Its comprehensive COVID-19 portfolio includes:

- **RNA Star Open Molecular Systems.** Built on its innovative proprietary qSTAR technology, the single-step method of open channel polymerase chain reaction (PCR) produces results in 20 minutes and completes up to 1,000 tests per hour per machine.<sup>11</sup> It generates results for asymptomatic individuals, detecting the omicron variant with the same sensitivity as other variants. The test is suitable for both pooling and sample home collection.
- **SARS-CoV-2 Ag/Ab LumiraDx Platform:** The microfluidic immunofluorescence technology allows for a high sensitivity Ag test with an impressive 97.6% positive agreement with reverse

<sup>4</sup> Discussion with LumiraDx, 4<sup>th</sup> April 2022.

<sup>5</sup> LumiraDx Presentation, March 2022.

<sup>6</sup> Discussion with LumiraDx, 4<sup>th</sup> April 2022.

<sup>7</sup> LumiraDx, "LUMIRADX Receives Approval for Its COVID-19 Antigen Test for Use in India," PR Newswire, October 20, 2021, <https://www.prnewswire.com/in/news-releases/lumiradx-receives-approval-for-its-covid-19-antigen-test-for-use-in-india-800039047.html>.

<sup>8</sup> Medical Device Network, "LumiraDx Obtains CE Marking for SARS-COV-2 & Flu A/B Antigen Test," Medical Device Network, December 24, 2021, <https://www.medicaldevice-network.com/news/lumiradx-ce-marking-sars-cov-2-flu-a-b-antigen/>.

<sup>9</sup> LumiraDx, "LUMIRADX Receives UK MHRA Approval for SARS-COV-2 RNA Star Complete," PR Newswire, February 22, 2022,

<https://www.prnewswire.co.uk/news-releases/lumiradx-receives-uk-mhra-approval-for-sars-cov-2-rna-star-complete-846466837.html>.

<sup>10</sup> Discussion with LumiraDx, 4<sup>th</sup> April 2022.

<sup>11</sup> LumiraDx Presentation, March 2022.

transcriptase-PCR and a 100% positive agreement in asymptomatic individuals with a cycle threshold of more than 30.<sup>12</sup> It also detects omicron with equal sensitivity to the other variants. LumiraDx also offers an Ab test designed for community care settings to identify individuals with an adaptive immune response to COVID-19, indicating recent or prior infection.

- **SARS-CoV-2 Ag Pool LumiraDx Platform.** Available under the CE mark, the microfluidic immunofluorescence technology enables the pooling of five samples on a single test strip, demonstrating high sensitivity and driving high throughput at a low cost.<sup>13</sup> Pooling and deconvolution are viable on a single POC platform. Like the other products, it detects omicron with equivalent sensitivity to different variants.
- **SARS-CoV-2 and Flu A/B test on LumiraDx Platform.** Available under CE mark and PDMA approval in Japan, this test allows verifying potential infections quickly with a rapid microfluidic assay. It provides actionable and lab-comparable results in 12 minutes for patients suspected of the flu and COVID-19 to assist in decision-making and guide proper treatment.

### Case Studies

**The Rotenburg District Hospital (Kreiskrankenhaus Rotenburg an der Fulda).** The hospital integrated the SARS-CoV-2 Ag LumiraDx Platform into its clinical routine after evaluating its experience and comparing the system against lab-obtained PCR results. It now uses it as part of its rapid testing concept.

*“The LumiraDx test system has helped us substantially during the pandemic to provide safe and smooth care to our patients and have safety measures in place for our staff. The handling is easy, and it has been implemented into our daily routines.”*

*-Karla Krause-Heid, Head Nurse and Human Resources Manager, Rotenburg District Hospital<sup>14</sup>*

**West Coast Health System.** In the second quarter of 2021, the organization started with seven LumiraDx instruments for physician office laboratory and urgent care use. It expanded to pharmacy use in the third quarter, adopting 190 instruments. By the end of 2021, the West Coast Health System also utilized the devices in hospital and reference labs, employing 278 machines. It expanded further into surgery, closing in the first quarter of 2022 with a total of 337 LumiraDx instruments, using more than 48 times as many devices in one year.<sup>15</sup>

*“Grateful for the support and partnership. LumiraDx’s agility has been great.”*

*-Director of Sourcing Laboratory Services, West Coast Health System<sup>16</sup>*

**Southern Sweden Region.** The rapid D-Dimer testing program for thromboembolic conditions in Kalmar, Sweden, was discontinued due to high levels of false-positive causing patients stress and unnecessary

<sup>12</sup> Ibid.

<sup>13</sup> Ibid.

<sup>14</sup> LumiraDx, “LumiraDx SARS-COV-2 Antigen Test Supports COVID-19 Prevention at Rotenburg District Hospital,” LumiraDx SARS-CoV-2 Antigen Test supports COVID-19 prevention at Rotenburg District Hospital, 2021, <https://www.lumiradx.com/uk-en/case-studies/sars-cov-2-antigen-test-supports-covid-19-prevention-at-rotenburg-district-hospital>.

<sup>15</sup> LumiraDx Presentation, March 2022.

<sup>16</sup> Ibid.

hospital admissions. The LumiraDx Program involving fingerstick blood sampling generated lab-comparable performance. The Swedish region implemented the portable, fast, reliable, easy-to-use testing system at 24 sites and general practitioners' offices. Device portability also provided mobile team opportunities.<sup>17</sup>

Frost & Sullivan finds LumiraDx's diverse solutions' use cases compelling and commends its commercialization success and impressive track record.

### ***Customer Acquisition and Retention Strategies Drive Company Growth***

LumiraDx believes that it is \$1 billion and 10 years ahead of its competitors in technology innovation from an overall platform perspective.<sup>18</sup> Its flat organizational structure allows it to start new projects within hours or days, unlike larger competitors that take months. As a result, the company has the edge over other market participants in acquiring and retaining customers.

LumiraDx makes strategic partnerships with prominent healthcare organizations that deploy large-scale programs for a multitude of tests across numerous sites. It partners with Boots in the UK and Europe and CVS in the US to increase its pharmacy customer base.

*"Frost & Sullivan firmly believes that LumiraDx is on an extraordinary growth trajectory fueled by its customer-focused technology and tactful customer acquisition strategies."*

**- Ojaswi Rana,  
Best Practices Research Analyst**

The company also works with US health systems such as Avera Health, the John Hopkins Hospital, and Mayo Clinic in the US to target physician offices. It collaborates with the National Health Service in the UK and the Italian Health Ministry to deploy its instruments for acute and emergency care use. Moreover, its global health partner, the Bill & Melinda Gates Foundation, enabled it to deploy about 5,000 devices across Africa by the end of 2021.<sup>19</sup>

The company demonstrates high-growth potential. LumiraDx is well-positioned in the market, with an industry-leading platform that provides tremendous value in high-demand sectors. The one-stop solution allows it to cater to a global market. For example, it plans to offer tuberculosis (TB) products to African nations while supplying Troponin to the US and the UK. In 2021, it reported revenues of \$421.4 million, tripling from \$139.2 million in 2020.<sup>20</sup>

Furthermore, LumiraDx went public in 2021, through the completion of its merger with the special purpose acquisition company, CA Healthcare Acquisition, valuing the business at \$3 billion.<sup>21</sup>

<sup>17</sup> Ibid.

<sup>18</sup> Discussion with LumiraDx, 4<sup>th</sup> April 2022.

<sup>19</sup> LumiraDx Presentation, March 2022.

<sup>20</sup> LumiraDx, "LUMIRADX Reports Fourth Quarter and Full Year 2021 Results," PR Newswire, March 10, 2022, <https://www.prnewswire.com/news-releases/lumiradx-reports-fourth-quarter-and-full-year-2021-results-301499787.html>.

<sup>21</sup> Medical Device Network, "LumiraDx Completes Merger with CA Health Acquisition," Medical Device Network, September 29, 2021, <https://www.medicaldevice-network.com/news/lumiradx-merger-ca-health-acquisition/>.

***“Now, as a publicly-traded company, we can accelerate our expansion across geographies and health conditions, impacting global healthcare and testing access and bringing value to our shareholders and customers.”***

***-Ron Zwanziger, Chairman and Chief Executive Officer, LumiraDx<sup>22</sup>***

In 2022, the company will focus on cardiac testing and completing its respiratory portfolio and aims to operate in about 150 to 160 countries. It plans to offer a menu of more than 30 tests on a single platform in the next two years. Its three-year roadmap includes addressing diverse areas such as sexual health, diabetes, cardiovascular, respiratory, cardiac, hospital-acquired infection, virology, and vector-borne diseases.

Frost & Sullivan firmly believes that LumiraDx is on an extraordinary growth trajectory fueled by its customer-focused technology and tactful customer acquisition strategies.

## Conclusion

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Technology is a critical success factor for the microfluidics point-of-care diagnostics industry. Yet, with many options available, market stakeholders need to leverage the most appropriate and best technology-based solutions to optimize their market impact. With its LumiraDx platform, LumiraDx delivers a scalable one-stop solution with a broad test menu and low total ownership cost that generates rapid laboratory-comparable results.

The company stands out from competitors based on its commitment to innovation and creativity while achieving commercial success. Deploying over 21,000 point-of-care devices by the end of 2021 to physician offices, pharmacies, acute and emergency care, and global health systems underscores its immense growth potential.

For its strong overall performance, LumiraDx is recognized with Frost & Sullivan’s 2022 European Technology Innovation Leadership Award in the microfluidics point-of-care diagnostics industry.

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<sup>22</sup> Ibid.



## What You Need to Know about the Technology Innovation Leadership Recognition

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Frost & Sullivan's Technology Innovation Leadership 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

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### 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 6 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)**

