FROST & SULLIVAN

2024 NEW PRODUCT INNOVATOR

IN THE NORTH AMERICAN MULTIPLEXED URINARY TRACT INFECTION DETECTION INDUSTRY

PathogenDx

Setting the standard in molecular testing

FROST & SULLIVAN

2024 BEST PRACTICES AWARD

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. PathogenDx excels in many of the criteria in the multiplexed urinary tract infection detection space.

Overcoming Challenges in Urinary Tract Infection Detection with a Microarray Detection Platform

The global burden of urinary tract infections (UTIs) is on the rise. UTIs are now recognized as one of the most common infectious diseases worldwide. The incidence of UTIs is higher in women than in men, with 50 to 60% of women experiencing a UTI at least once in their lifetime. This incidence is even higher during pregnancy, affecting 20% of pregnant women. Over the last decade, women's health, previously a neglected area, has gained more attention. However, there have been minimal research developments contributing to early and precise UTI diagnosis methods globally.

Conventional tests for UTI detection, performed using urine culture, have low sensitivity and can take several days to a week for results. Currently, there are various molecular diagnostics UTI detection tests available on the market. These tests use technologies like microarray, quantitative polymerase chain reaction (qPCR), and next-generation sequencing (NGS) for detecting bacterial pathogens and antibiotic-resistant genes. qPCR, a high-cost rapid detection test, is widely used for UTI detection, however, it faces challenges with multiplexing tests and its sensitivity is lower than NGS and microarray-based detection. NGS, another method for clinical pathogen detection and UTI diagnostics, requires longer timelines for data analysis. NGS can also require extensive sample preparation steps and needs dedicated costly instrumentation. microarray-based pathogen detection is the fastest and most cost-effective method, but traditional microarrays can be challenged by steric-effects, limiting binding capabilities between the probe and target.

The challenges associated with timelines, cost-effectiveness, and accurate pathogen detection in UTI diagnosis highlight the demand for a new, efficient test. To address these ongoing challenges, PathogenDx, founded in 2014 and headquartered in the United States, has designed and developed a simple, comprehensive detection test based on their proprietary D3 Array, its core technology platform. This product is aimed at meeting the current needs in UTI detection.

High-Throughput Accurate UTI Pathogen Detection in Accelerated Timeframes

PathogenDx launched its D3 Array-UTI detection test in February 2024, offering a more comprehensive solution compared to standard UTI diagnostic tests. The D3 Array-UTI detection test has been developed using PathogenDx's core technology platform, the D3 Array—a dynamic, three-dimensional, detection self-assembled spatial assay. This proprietary technology platform underpins the UTI detection test, enabling it to identify 26 pathogens and 12 ARGgenes in each well of a 96-well plate. This makes it one of the most effective methods for pathogen detection. The tests can process 48 clinical samples per 96-well plate, providing high throughput UTI detection without requiring multiple runs, unlike standard microarrays.

The D3 Arrays contain molecular probes associated with specific targets, pathogens, and biomarkers. Each array has 324 to 576 probes printed in a well. Compared to qPCR assays, the D3 Array-UTI offers greater accuracy, lower costs, and higher throughput. The entire process can be completed in about 6 to 7 hours for 48 samples. While some competitors can complete their process in 5 hours, they are limited to between 8-14 samples, whereas the D3 Array can process 48. The D3 Array provides a 100 times greater binding area compared to traditional microarray technology and delivers 6 times more data points than competitors' array. Additionally, the D3 Array-UTI detection assay ensures accurate results by conducting triplicate testing per target, confirming pathogen detection thrice per sample. Its accuracy makes the test highly reliable.

> *"The microarray model of the test makes it one of the easiest UTI tests to adopt. Unlike the industry standard two-dimensional microarray tests, which have lengthy hybridization times of 12 to 18 hours, PathogenDx has developed a fast three-dimensional microarray solution, providing 100 times more surface area for the amplified PCR strand to bind without encountering steric hindrances."*
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> ***- Neeraja V,***
> ***Senior Research Analyst***

The D3 Array-UTI test is instrument-agnostic, making it compatible with a range of molecular instruments, such as PCR thermocyclers and liquid handling systems, providing great flexibility and reducing capital expenditure for labs. The only additional component required to analyze or detect the pathogens is a red-green channel imager, which can be easily sourced.

The UTI detection test developed by PathogenDx costs significantly less than standard detection tests, as it consolidates all targets into a single well. The microarray model of the test makes it one of the easiest UTI tests to adopt. PathogenDx has developed a fast three-dimensional microarray solution that uses standard, off-the-shelf nucleic acid chemistry, "flattening" the cost, and providing 100 times more surface area for the amplified PCR strand to bind without encountering steric hindrances. As a result, this platform provides single-gene sensitivity.

For successful pathogen detection, PathogenDx's test targets the 16S rDNA region, spanning 1,500 bases, to cover the most variable regions of the bacteria, enabling the identification of pathogens . Using a single primer, all organisms present in the sample are amplified, and hybridization is conducted at room temperature. This eliminates the need for heating and cooling mechanisms required by other microarrays.

For the designed probes, there is a pre-added concentration at the bottom of the well. For each pathogen, if its concentration exceeds that of the control, it yields a ratio value ranging from 1 to 10,000 for a high microbial payload. Clinicians can now quantify the infection and identify the specific pathogens causing UTIs using the D3 Array-UTI detection test. Frost & Sullivan applauds PathogenDx for upgrading its core D3 technology to address the unmet needs in accurate pathogen detection and quantification in UTI diagnosis.

Low-Cost Microarray Technology to Witness Higher Adoption Potential in UTI Detection

The D3 Array-UTI detection is already available and gaining traction among small to mid-sized labs due to its ability to perform multiplexed tests and achieve cost savings with the help of cloud-based data analytics, leading to cost reduction and enhanced content capabilities. Automation of data management streamlines diagnostic tests and results. By leveraging cloud-based data analytics and reporting, the diagnostic analysis process becomes more customer-friendly. As a result, the demand for the D3 Array-UTI detection test from small to mid-sized labs is expected to rise in the near future.

The biggest advantage of adopting microarray-based UTI pathogen detection tests over qPCR tests and NGS is the ease of multiplexing for larger sample sizes. Additionally, the D3 Array-UTI eliminates the need for additional instrumentation costs, as it can be easily integrated on existing molecular laboratory equipment . The D3 Array-UTI detection test helps improve the speed of sample diagnostics, enabling labs to process 48 samples in a shift, more if needed, with additional instrumentation workflow set ups .

> *"PathogenDx's microarray-based UTI pathogen detection test was developed based on the 26 pathogens identified from clinical data of 15,000 clinical samples. The array has demonstrated a high pathogen sensitivity of 96.3% with 10 copies of pathogen per reaction. There are no cross-reactions with other organisms, ensuring the diagnostic test's reliability and enhancing the customer experience with ease and accuracy."*
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PathogenDx has filed for 35 patents covering its D3 microarray platform and the diagnostic tests, establishing strong exclusivity for its technology. Previously, the company received emergency (EUA) FDA approval for its COVID-19 testing kit in 2021.

In addition to healthcare kits, PathogenDx offers a range of microorganism detection tests for food and agriculture. Since its inception, the company has raised nearly $11.83 million across 5 funding rounds. In

2023, it reported substantial 2-year revenue growth of 276%, establishing itself as one of the fastest-growing companies in North America with key products such as Detectx™, Quantx™, and Envirox™, used for bacterial and fungal testing.

Conclusion

PathogenDx is a microarray-based diagnostics company that has developed a dynamic platform capable of efficiently detecting a wide array of pathogens. This platform caters to several applications in clinical diagnostics, food safety, and agriculture. PathogenDx's UTI detection test is an innovative breakthrough, providing comprehensive and rapid detection of 26 pathogens responsible for causing UTIs. The D3 platform has shown promising results in clinical applications, including detection of COVID-19 and now in UTI diagnosis. PathogenDx is a promising industry participant, developing advanced and targeted versions of a new generation of microarray-based technology poised for widespread adoption in diagnostics. The company's commitment to developing cost-effective diagnostics is highly commendable.

With its strong overall performance, PathogenDx earns Frost & Sullivan's 2024 New Product Innovation Award in the North American multiplexed UTI detection industry.

What You Need to Know about the New Product Innovation Recognition

Frost & Sullivan's New Product Innovation Award recognizes the company that offers a new product or solution that uniquely addresses key customer challenges.

Best Practices Award Analysis

For the New Product Innovation Award, Frost & Sullivan analysts independently evaluated the criteria listed below.

New Product Attributes

Match to Needs: Customer needs directly influence and inspire product design and positioning

Reliability: Product consistently meets or exceeds customer performance expectations

Quality: Product offers best-in-class quality with a full complement of features and functionality

Positioning: Product serves a unique, unmet need that competitors cannot easily replicate

Design: Product features an innovative design that enhances both visual appeal and ease of use

Customer Impact

Price/Performance Value: Products or services provide the best value for the price compared to similar market offerings

Customer Purchase Experience: Quality of the purchase experience assures customers that they are buying the optimal solution for addressing their unique needs and constraints

Customer Ownership Experience: Customers proudly own the company's product or service and have a positive experience throughout the life of the product or service

Customer Service Experience: Customer service is accessible, fast, stress-free, and high quality

Brand Equity: Customers perceive the brand positively and exhibit high brand loyalty

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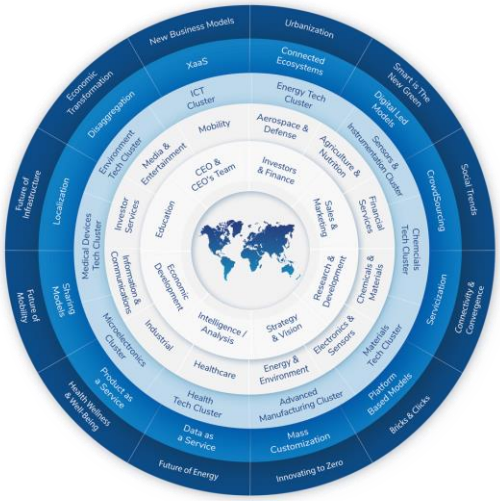
Key Impacts:

- **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)