

F R O S T & S U L L I V A N



**2017 North American  
Microarrays in Molecular Diagnostics  
New Product Innovation Award**

F R O S T & S U L L I V A N

**BEST**  
**2017** **PRACTICES**  
**AWARD**

**NORTH AMERICAN  
MICROARRAYS IN MOLECULAR DIAGNOSTICS  
NEW PRODUCT INNOVATION AWARD**

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## Background and Company Performance

### *Industry Challenges*

In recent years, microarrays have increased in importance among biologists and biomedical researchers because of the technology's ability to monitor thousands of genes on a single chip. This emerging technology aids scientists in tracking thousands of genes within a living organism and it offers an understanding of the functionality and interaction between them. In particular, microarrays have become very popular in oncology, pharmacology, and assay applications; however, some of the major challenges in addition to technical difficulty, specificity, and reliability include the following:

- Microarrays can generate large data sets with the aid of the chip used, but detailed new statistical and informatics-related complexity is still a challenge for biotechnologists.
- Standard protocols for microarray data analysis do not exist.
- No consistent systems are available to manage the disbursement point for microarray data and for the products of various data-mining techniques or their applications, since microarrays still pose informatics challenges.
- Though some microarrays currently available commercially promise real-time results, most are not able to live up to the expectation of both doctors and biotechnologists in terms of turn-around time and results.
- Microarray platforms are not flexible enough to handle multiple forms of assays.
- The high cost of this technology provides barriers to adoption in emerging countries.

Ultimately, each of these challenges must be addressed for the end user base to realize the full technical potential of microarrays in the healthcare space.

### *New Product Attributes and Customer Impact*

#### **Match to Needs**

Akonni Biosystems Inc. (Akonni) is a US company and leader in the molecular diagnostics (MDx) space that has made strides in addressing the aforementioned challenges. The company developed a unique, near-point-of-care molecular testing platform, TruDiagnosis®. This product platform is based on the gel-drop microarray technology called TruArray® that the company has exclusively licensed from Argonne National Laboratory in the United States. The 3D gel drop technology has an efficient immobilization capacity, due to the innovative spacing design of the immobilized molecules throughout the volume of the gel drop. To enhance the hybridization specificity,

it is important to quantify the extent of the specificity at an individual hybridization level of the microarrays to gain highly accurate data. Akonni's technology design ensures this hybridization efficiency, which is reflected in the performance of its TruDiagnosis molecular product platform. The platform is capable of analyzing hundreds of targets (genes, proteins, or metabolites) in a single rapid, self-contained, easy-to-use, and low-cost real-time test.

TruDiagnosis has broad potential from an application perspective and represents a substantial, scalable solution as compared to other molecular microarrays resulting in accurate analysis at a lower overall cost. The platform consists of Akonni's proprietary TruDx® Imagers, TruArray Assays, TruTip® Kits, and has been designed to include nucleic acid extraction, as well as fully-automated gridding and data analysis software for patient reporting. The low-density microarrays are the result of Akonni's long yet thorough research process that ensures that it meets the needs of biotechnologists and healthcare practitioners. Of particular value to users, the microarrays can carry a wide range of 5 to 400 3D gel-drops per array. To enhance the platform's competitiveness Akonni has made several improvements to the microarray manufacturing, for faster hardware/software functioning and in-depth analysis of the microarray tests.

## **Reliability**

TruDiagnosis' easy mode of operation and accurate results enhance its reliability. A few microliters of the DNA sample are dropped onto a microfluidic test slide the size of a stick of chewing gum. The sample then flows over an array of probes that test for the targets of interest; for example, Akonni's MDR-TB test includes six tuberculosis (TB) genes and 88 strain-specific mutations. Once the assay is finished, the test is inserted in the TruDx reader, which detects which spots light up, indicating a genetic match. The operational method is easy and takes significantly less computation time in comparison to other diagnostic microarrays. Prior to commercialization, Akonni conducted extensive research and development (R&D) efforts on a variety of assays, including methicillin-resistant staphylococcus aureus (MRSA), multi-drug resistant mycobacterium TB (MDR-TB), an encephalitis panel, a biological warfare detection panel, and influenza subtyping.

To gain end-user trust and excel in proven reliability, Akonni collaborated with researchers from Johns Hopkins University to conduct a study. Under this project, Akonni collected 87 clinical isolates and 246 nasal swab samples from a non-random, high-risk patient population. Of the 87 isolates, the TruDiagnosis platform was able to classify 86, with an accurate identification of 14 mecA dropout specimens that were falsely detected positive in other tests. Akonni also confirmed the reliability of TruDiagnosis by performing similar experiments and studies to maximize the efficiency of its platform.

As compared to competing microarray products, Akonni simplifies workflows with a synergistic combination of conventional target amplification, fragmentation, and labeling processes into a single microfluidic chamber. In addition to simplifying the workflow, the integrated, self-contained design of the microfluidic device alleviates the risk of amplicon

contamination following polymerase chain reaction (PCR) amplification. Pre-clinical studies demonstrate the clinically superior viability of the TruDiagnosis platform in comparison to traditional multiplexed platforms. In cases where a PCR microfluidic device alone is difficult to use, Akonni's system enables detection of both known and unknown isolates.

## Design

At the heart of Akonni's TruDiagnosis solution is the TruArray technology, a patented 3D gel-drop microarray technology for sample screening that instantly indicates the presence of disease markers in real time. The entire system is portable and has been smartly designed for accurate results. The company has built on the licensed platform to improve its product portfolio through extensive R&D efforts; it has 42 issued patents and 69 patents pending, all focused on enhancing the product offerings. In comparison to the design of 2D planar arrays, the TruArray technology is uniquely designed with a drop spacing that promotes higher probe immobilization capacity. This, in turn, enhances the detection sensitivity by up to 100-fold. The company's gel-drop arrays, moreover, offer high manufacturability in comparison to traditional microarrays with easier-to-handle informatics and process-able data.

One of the most significant features of the TruDiagnosis product platform is the one-and-the-same manufacturing capability that can be used to test protein and nucleic acid. Unlike traditional microarray technologies, during manufacture, no highly priced silicon wafers, glass substrates, coatings, or surface requirements are needed. This means that the co-polymerization methodology can be implemented on unmodified plastic substrates. The user-friendly and cost-efficient design approach makes Akonni one of the key participants in the microarrays space.

## Price/Performance Value

The TruDiagnosis platform offers rapid, reliable, multiplexed analysis in a low-cost format. It can easily detect protein, nucleic acid, or metabolite targets and add value to applications such as disease prediction and prevention, early diagnosis, identification of adverse drug reactions or drug resistance, and drug monitoring. Unlike 2D planar arrays, TruDiagnosis provides all of these functionalities at a relatively low cost.

Frost & Sullivan believes that Akonni is properly positioned to serve the precision medicine revolution. Its cost-efficient yet highly accurate formats offer a great mix of multiplexing, flexibility, and robustness. The molecular recognition events at a lower overall cost per array enable high volume multiplexed detection. Currently, Akonni focuses on low-cost and high volume output. The company has modified its TruDiagnosis platform by utilizing a cost-effective polymeric substrate to replace the traditional glass substrate for printing arrays without the need for functionalized coatings as a way to create exceptional design options. Also, Akonni enhanced the manufacturing process for reel-to-reel manufacturing of arrays on film that gives it a competitive edge in terms of cost structure in comparison to competing lateral flow test products.



## Customer Ownership Experience

Akonni has won several commercial projects within the healthcare space, thanks to the TruDiagnosis platform. Some of the leading private as well as government entities in North America and Asia-Pacific have shown interest in the TruDiagnosis platform from which they have developed versatile diagnostic products. For example, scientists from Akonni Biosystems and Novartis Vaccines and Diagnostics have published research demonstrating that Akonni's TruTip sample prep technology is better than established methods at selectively enriching circulating cell-free fetal DNA from maternal DNA in blood samples for subsequent downstream detection and analysis. The TruTip application has the potential to significantly improve non-invasive prenatal testing (NIPT), regardless of the downstream detection method used (i.e. sequencing, arrays, dPCR, qPCR). Additionally, Harvard University and Akonni Biosystems have teamed up to develop and test novel sample preparation and diagnostic methodologies for MDR and extensively-drug-resistant (XDR) tuberculosis. The work is supported by a five-year, \$29 million Centers of Excellence for Translational Research grant awarded by the National Institute of Allergy and Infectious Diseases (NIH, NIAID) to establish a translational research center to develop molecular diagnostic technologies for TB. In addition to discovering new markers for highly drug resistant strains of TB, the collaboration is targeted at optimizing sample preparation and detection in non-sputum samples, particularly cell-free DNA from urine or blood, to improve diagnosis of TB in children who have a very difficult time producing sputum samples for TB testing. Customers and licensees of Akonni's TruDiagnosis platform have successfully completed their projects, which subsequently have created new opportunities in the microarrays landscape, thus minimizing the challenges and limitations that have previously restrained the market.

## Brand Equity

Akonni enjoys a solid market presence due to its customer-friendly approach, strategic execution of business prospects, and cost-efficient pricing strategies. The company has also proven its ability to manage all projects efficiently and has competently expanded its customer base. Customers include hospitals and biotechnology and research facilities across the United States.

In addition, Akonni has developed other products to cater to various industries. These include the TruTip sample prep kits, an automated sample prep instrument for other downstream detection platforms such as NGS, and multiple versions of the TruDiagnosis system for multiplexed diagnostics, the TruDx<sup>®</sup>2000 and TruDx<sup>®</sup>3000 range of products. Essentially, the company is active in maintaining its brand image by delivering effective products that address the various challenges of the MDx industry and by offering customizable solutions to its customers.

TruDiagnosis is an individual patented platform owned by Akonni and is its intellectual property (IP). The strong IP portfolio positions the company to remain open for licensing as a revenue model. Its brand equity is further enhanced through its collaborative efforts

with established entities such as Harvard University, Johns Hopkins University, the University of California San Diego, the New York State Department of Health Wadsworth Center, the National Institute of Health's (NIH) National Institute of Allergy and Infectious Diseases (NIAID), the National Cancer Institute, and the Bill & Melinda Gates Foundation. A number of end users have provided positive feedback of TruDiagnosis, which supplies the company with a highly reputable image.

## *Conclusion*

Akonni Biosystems is a leader in the emerging MDx field and is already regarded by major universities and government agencies for its focus on designing and delivering innovative, market-leading integrated MDx systems. The company's TruDiagnosis platform is a unique, unparalleled platform founded on a comprehensive IP portfolio that enables target detection from a variety of sample types used to construct multiplex assays for applications in pharmacogenomics, chronic human diseases (i.e. cancer and ALS), and infectious diseases, including MDR-TB, extensive drug-resistant tuberculosis (XR-TB), upper respiratory infections, viral encephalitis, and hospital-acquired infections, including MRSA. Akonni has successfully commercialized its wide product platform and obtained upwards of \$50 million plus grants in doing so. Over the next few years, Akonni is likely to continue on its growth trajectory and outperform most of its closest competitors in the MDx space.

Because of its strong overall performance, Akonni Biosystems Inc. is recognized with Frost & Sullivan's 2017 New Product Innovation Award.

## Significance of New Product Innovation

Ultimately, growth in any organization depends upon continually introducing new products to the market and successfully commercializing those products. For these dual goals to occur, a company must be best-in-class in three key areas: understanding demand, nurturing the brand, and differentiating from the competition.



## Understanding New Product Innovation

Innovation is about finding a productive outlet for creativity—for consistently translating ideas into high-quality products that have a profound impact on the customer.



## *Key Benchmarking Criteria*

For the New Product Innovation Award, Frost & Sullivan analysts independently evaluated two key factors—New Product Attributes and Customer Impact—according to the criteria identified below.

### *New Product Attributes*

#### **Criterion 1: Match to Needs**

Requirement: Customer needs directly influence and inspire the product's design and positioning.

#### **Criterion 2: Reliability**

Requirement: The product consistently meets or exceeds customer expectations for consistent performance during its entire life cycle.

#### **Criterion 3: Quality**

Requirement: Product offers best-in-class quality, with a full complement of features and functionalities.

#### **Criterion 4: Positioning**

Requirement: The product serves a unique, unmet need that competitors cannot easily replicate.

#### **Criterion 5: Design**

Requirement: The product features an innovative design, enhancing both visual appeal and ease of use.

### *Customer Impact*

#### **Criterion 1: Price/Performance Value**

Requirement: Products or services offer the best value for the price, compared to similar offerings in the market.

#### **Criterion 2: Customer Purchase Experience**

Requirement: Customers feel they are buying the most optimal solution that addresses both their unique needs and their unique constraints.

#### **Criterion 3: Customer Ownership Experience**

Requirement: Customers are proud to own the company's product or service and have a positive experience throughout the life of the product or service.

#### **Criterion 4: Customer Service Experience**

Requirement: Customer service is accessible, fast, stress-free, and of high quality.

#### **Criterion 5: Brand Equity**

Requirement: Customers have a positive view of the brand and exhibit high brand loyalty.

## 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 practice criteria. The reputation and integrity of the Awards are based on close adherence to this process.

STEP	OBJECTIVE	KEY ACTIVITIES	OUTPUT
1 <b>Monitor, target, and screen</b>	Identify Award recipient candidates from around the globe	Conduct in-depth industry research Identify emerging sectors Scan multiple geographies	Pipeline of candidates who potentially meet all best-practice criteria
2 <b>Perform 360-degree research</b>	Perform comprehensive, 360-degree research on all candidates in the pipeline	Interview thought leaders and industry practitioners Assess candidates' fit with best-practice criteria Rank all candidates	Matrix positioning of all candidates' performance relative to one another
3 <b>Invite thought leadership in best practices</b>	Perform in-depth examination of all candidates	Confirm best-practice criteria Examine eligibility of all candidates Identify any information gaps	Detailed profiles of all ranked candidates
4 <b>Initiate research director review</b>	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-practice positioning paper
5 <b>Assemble panel of industry experts</b>	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 <b>Conduct global industry review</b>	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 <b>Perform quality check</b>	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 <b>Reconnect with panel of industry experts</b>	Finalize the selection of the best-practice Award recipient	Review analysis with panel Build consensus Select recipient	Decision on which company performs best against all best-practice criteria
9 <b>Communicate recognition</b>	Inform Award recipient of Award 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 <b>Take strategic action</b>	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 future 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 our 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, leading to 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, enables clients to 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 practice models to drive the generation, evaluation, and implementation of powerful growth strategies. Frost & Sullivan leverages more than 50 years of experience in partnering with Global 1000 companies, emerging businesses, and the investment community from 45 offices on six continents. To join our Growth Partnership, please visit <http://www.frost.com>.