



2014 European Respiratory Infectious Disease Point-of-Care  
Testing Product Leadership Award



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



50 Years of Growth, Innovation & Leadership

## **Product Leadership Award Respiratory Infectious Disease Point-of-Care Testing Europe, 2014**

### **Frost & Sullivan's Global Research Platform**

Frost & Sullivan is in its 50th year of business with a global research organization of 1,800 analysts and consultants who monitor more than 300 industries and 250,000 companies. The company's research philosophy originates with the CEO's 360-Degree Perspective™, which serves as the foundation of its TEAM Research™ methodology. This unique approach enables us to determine how best-in-class companies worldwide manage growth, innovation and leadership. Based on the findings of this Best Practices research, Frost & Sullivan is proud to present the 2014 European Product Leadership Award in Respiratory Infectious Disease Point-of-Care Testing to ArcDia International Oy Ltd .

### **Significance of the Product Leadership Award**

#### **Key Industry Challenges**

The market is in need of precise and rapid tools for the diagnosis of respiratory infectious diseases. As such, diagnostic companies can penetrate markets with fast and accurate diagnostic platforms that better detect infections. Moreover, the discoveries of new, emerging infections such as severe acute respiratory syndrome (SARS) require diagnostic tools for their identification. Newer respiratory infections are identified every year, creating opportunities for companies to extend their product profiles. Rapid diagnostic kits for use in physicians' laboratories with minimal human intervention are badly needed at the moment.

The primary challenges facing the global respiratory infectious disease Point-of-Care testing market include the integration of point-of-care testing into the existing infrastructure, the cost advantage in central laboratory testing versus near-patient testing, and senior physicians / lab managers preference for conventional testing methods.

#### **Integrating Point-of-Care (POC) Testing into the Existing Infrastructure**

The implementation and management of programs for point-of-care testing (POCT) can be both difficult and expensive because they require input and coordination with many different healthcare professionals.

Additionally, POC testing must compete with already established testing methods and resource availability, as resources are already allocated to labs. In hospitals, the development and use of POC programs requires input from various stakeholders, such as primary caregivers, POC managers, clinical laboratory personnel, and sometimes, hospital administration as well. In addition, hospitals and clinical laboratories hold numerous supplier contracts and have established test protocols that involve the use of expensive and large automated analysers in central labs.

Thus, the appropriate stakeholders need to be convinced of the value of integrating POC testing methods, correct diagnosis to reduce use of antibiotics to absolutely minimum and only used when necessary and for as short period as needed.

### **Cost Advantage in Central Laboratory Testing versus Near-patient Testing**

Centralized laboratory testing, although more laborious, is still widely preferred because of the cost advantages associated with it by virtue of the sheer volume of these tests that are performed at any given time. On the contrary, in POC testing, besides the instrument, there is the additional cost of the disposable kit, which can be expensive and is not always reimbursed by the government. Other factors include the extra costs of out-of-hour service and unnecessary appointments.

Health service providers need to overlook these cost issues by adopting a more holistic approach and identifying the areas of possible savings in the long run. Savings could include reducing the costs associated with unnecessary or inappropriate therapy, sample transport to hospital laboratories, patient transport to the hospital, and unnecessary occupation of a patient bed. Superfluous use of antibiotics causes antimicrobial resistance, while accurate and timely diagnostics remains the main tool in the fight against this emerging global burden.

### **Senior Physicians' Preference for Conventional Testing Methods**

The new generation of primary care providers is employing novel POC diagnostics and has been educated on the advantages of these new technologies. However, senior physicians continue to use traditional methods that they are familiar with. These clinicians are habituated to the old practice of sending out samples to the lab for testing and are difficult to convince regarding POC testing. Research has shown that there is also a prevailing perception among the medical community that POC testing is not as accurate as lab testing. This perception has been found to originate from the fact that doctors and nurses are primarily concerned with patient care and are often not trained in the rigors of quality laboratory testing as experienced laboratory clinicians. Consequently, when entrusted with POC testing devices to base medical decisions upon, they are not confident of the accuracy in the results and are hesitant to perform tests that clinicians would normally perform.

Proper training, education, and post-sales support need to be provided to doctors and senior physicians on POC testing operation and performance to create awareness among them regarding the benefits of POC testing and encourage the wider adoption of this method of patient care.

### Key Benchmarking Criteria for the Product Leadership Award

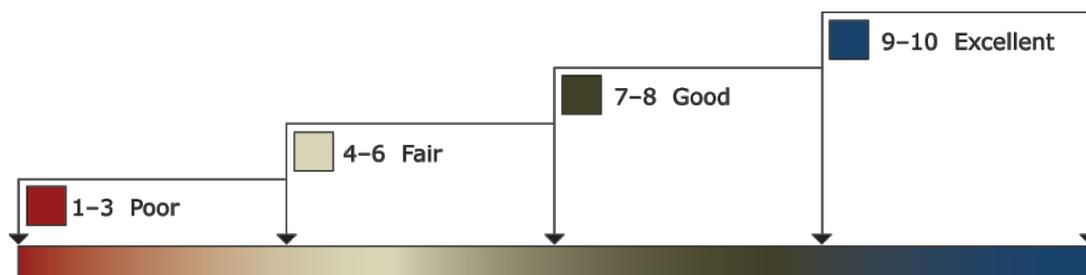
For the Product Leadership Award, the following criteria were used to benchmark ArcDia International Oy Ltd .'s performance against key competitors:

- Product Features/Functionality
- Innovative Element of the Product
- Product Acceptance in the Marketplace
- Provides Customer Value Enhancements
- Product Quality

### Decision Support Matrix and Measurement Criteria

To support its evaluation of best practices across multiple business performance categories, Frost & Sullivan employs a customized Decision Support Matrix (DSM). The DSM is an analytical tool that compares companies' performance relative to each other with an integration of quantitative and qualitative metrics. The DSM features criteria unique to each Award category and ranks importance by assigning weights to each criterion. The relative weighting reflects current market conditions and illustrates the associated importance of each criterion according to Frost & Sullivan. Fundamentally, each DSM is distinct for each market and Award category. The DSM allows our research and consulting teams to objectively analyze each company's performance on each criterion relative to its top competitors and assign performance ratings on that basis. The DSM follows a 10-point scale that allows for nuances in performance evaluation; ratings guidelines are shown in Chart 1.

**Chart 1: Performance-Based Ratings for Decision Support Matrix**



This exercise encompasses all criteria, leading to a weighted average ranking of each company. Researchers can then easily identify the company with the highest ranking. As a final step, the research team confirms the veracity of the model by ensuring 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.

**Chart 2: Frost & Sullivan’s 10-Step Process for Identifying Award Recipients**



**Best Practice Award Analysis for ArcDia International Oy Ltd.**

The Decision Support Matrix, shown in Chart 3, illustrates the relative importance of each criterion for the Product Leadership of the Year Award and the ratings for each company under evaluation. To protect the interests of the award recipient’s competitors, we have chosen to refer to them as Competitor 1 and Competitor 2.

**Chart 3: Decision Support Matrix for Product Leadership Award**

<i>Measurement of 1-10 (1 = lowest; 10 = highest)</i>	<b>Award Criteria</b>					<b>Weighted Rating</b>
	Features/Functionality	Innovative Element of the Product	Product Acceptance in the Marketplace	Provides Customer Value Enhancements	Product Quality	
<b>Relative Weight (%)</b>	<b>20%</b>	<b>20%</b>	<b>20%</b>	<b>20%</b>	<b>20%</b>	<b>100%</b>
ArcDia International Oy Ltd.	9	9	9	9	9	9.0
Competitor 1	8	8	7	8	8	7.8
Competitor 2	7	7	6	6	7	6.6

**Criterion 1: Product Features/Functionality**

ArcDia International Oy Ltd. has developed the innovative mariPOC<sup>®</sup> point-of-care test launched in 2010 with accuracy similar to central laboratory antigen tests. As respiratory infectious diseases can spread faster, the product allows pathogen-specific diagnoses on time. This point-of-care test also allows for the accurate use of virus-specific drugs and antimicrobials. As the results are obtained quickly (within 20 minutes) the point-of-care test enables efficient control of patient flow and efficient in-patient cohorting. Automated read-out results provide high specificity and improved cost-effectiveness. Detection of mariPOC is quantitative, while test results are provided either qualitatively or semi-quantitatively to keep interpretation of results simple.

**Criterion 2: Innovative Element of the Product**

The most innovative element of the mariPOC<sup>®</sup> point-of-care test is the ArcDia<sup>™</sup> TPX technology. This technology is based on two-photon fluorescence excitation and the use of microparticles as solid phase. This technology is one of the most sensitive ones, which facilitate separation-free detection of bioaffinity assays, such as quantitative immunoassays, nucleic acid detection, and enzyme activity assays. As the microspheres are trapped in the later optical forces, microsphere signal (specific signal), and the solution background signal (unbound tracer and matrix) are recorded. This technology allows real-time monitoring and the efficient discrete analysis of matrix effects, thereby eliminating the need for separate calibration of the fluorescence detector. This innovative technology behind mariPOC and the skilled team of employees gives ArcDia International Oy Ltd good possibilities also in the future to launch other new test solutions to support market requirements.

**Criterion 3: Product Acceptance in the Marketplace**

Since the introduction of the mariPOC<sup>®</sup> product in 2010 in Finland, it has been in demand across Europe. The mariPOC<sup>®</sup> based on the immunodiagnostic antigen-antibody reaction performs better in practice as compared to molecular diagnostics, which are prone to compromised specificity and is expensive. The mariPOC<sup>®</sup> has received an excellent response from hospitals among doctors and patients. As a result of the increased demand, since April 2013 ArcDia International Oy Ltd. has been able to expand its sales network significantly to cover 22 countries in Europe as well as the Middle East.

**Criterion 4: Provides Customer Value Enhancements**

mariPOC<sup>®</sup> provides a range of benefits, which can boost customer value in hospitals as well as primary care centers. This product is easy-to-use and it delivers results in 20 minutes, thereby eliminating repeated patient visits. The advantage of this POC test is to reduce manual errors as the diagnostic product is automated. Frost & Sullivan's market analysis suggests that mariPOC<sup>®</sup> has the potential to replace conventional rapid and laboratory antigen tests. This laboratory product can be easily connected to laboratory information

systems making it one of the most compelling offerings on the market today.

### **Criterion 5: Product Quality**

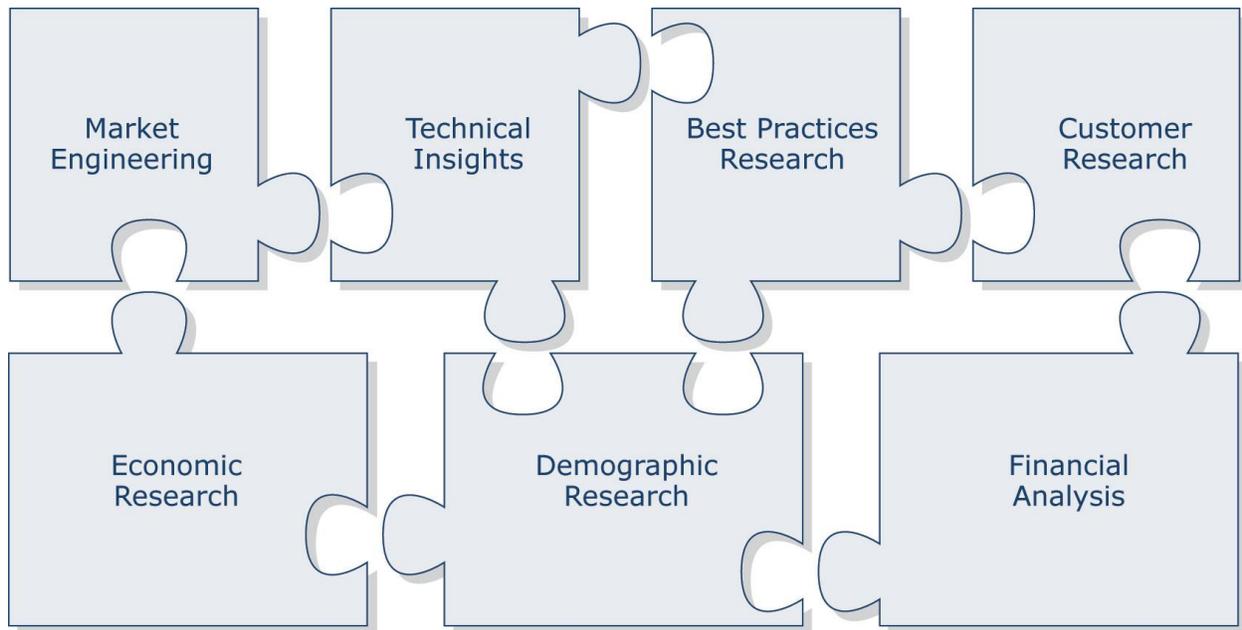
The quality of rapid test results is highly dependent on the quality of sampling, which is an important aspect in the respiratory disease test. The sensitivity and specificity of the mariPOC<sup>®</sup> respiratory tract infection diagnostics is similar to central laboratory tests. The evaluation of the automated multianalyte point-of-care mariPOC<sup>®</sup> test showed 100% specificity for respiratory syncytial virus, influenza A virus, adenovirus, and group A streptococci. 99% specificity was obtained for influenza B virus. In comparison to conventional rapid tests, the results show that mariPOC<sup>®</sup> is much more efficient and accurate.

### **Conclusion**

ArcDia International Oy Ltd. has introduced its innovative mariPOC<sup>®</sup> test for respiratory tract infections. It is the first test system able to provide multianalyte POC testing for more than nine different antigens. mariPOC<sup>®</sup> is a versatile product for hospitals with an automated continuous feed antigen detection test. The test is applicable with nasopharyngeal swab samples and aspirates, as well as for throat swabs. In the course of a year, ArcDia International Oy Ltd. impressively expanded its distribution network, attaining a strong footprint across Europe and the Middle East. In view of the company's vision and growing demand of mariPOC<sup>®</sup> for diagnostics in the battle against unnecessary use of antibiotics, their diagnostic product, and rapid market penetration, ArcDia International Oy Ltd. is recognized with Frost & Sullivan's 2014 Product Leadership Award in the European Respiratory Infectious Disease Point-of-Care Testing market.

### **Critical Importance of TEAM Research**

Frost & Sullivan's TEAM 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 seven of Frost & Sullivan's research methodologies. Our experience has shown over the years that companies too often make important growth decisions based on a narrow understanding of their environment, leading to errors of both omission and commission. Frost & Sullivan contends that successful growth strategies are founded on a thorough understanding of market, technical, economic, financial, customer, best practices, and demographic analyses. In that vein, the letters T, E, A and M reflect our core technical, economic, applied (financial and best practices) and market analyses. The integration of these research disciplines into the TEAM Research methodology provides an evaluation platform for benchmarking industry players and for creating high-potential growth strategies for our clients.

**Chart 4: Benchmarking Performance with TEAM Research**

### 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 50 years of experience in partnering with Global 1000 companies, emerging businesses and the investment community from more than 40 offices on six continents. To join our Growth Partnership, please visit <http://www.frost.com>.