FROST & SULLIVAN

GenePOC™

2017 European Molecular Diagnostics for Infectious Disease New Product Innovation Award

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Background and Company Performance

Industry Challenges

Antibiotic Misuse: A Serious Global Threat

Community- and healthcare-acquired infections (HAI) drive increased and sometimes inappropriate use of antibiotics. Consequently, up to 50% of antibiotic use in Europe (EU) is either unnecessary or inappropriate for treatment.[1] As with any drug, antibiotics can have serious side effects, and improper use exposes patients to avoidable risks—such as *Clostridium difficile* (*C. difficile*) infection, a common and potentially life-threatening HAI—without any added clinical benefit. Moreover, antibiotic misuse can lead to antibiotic microbial resistance (AMR), which undermines the ability to treat infections effectively. Drug-resistant bacteria like methicillin-resistant *Staphylococcus aureus* (MRSA) and vancomycin-resistant *Enterococcus* (VRE) pose a severe public threat. In 2016, the United Nations General Assembly in New York designated the fight against AMR a global priority—the fourth time in history that the United Nations has intervened on a health issue.

Comprehensive global and regional initiatives aim to avert the emerging crisis. For instance, antimicrobial stewardship programs across EU promote coordinated efforts on the prudent use of antibiotics for the community and across healthcare settings—such as hospitals, ambulatory care, and long-term care facilities. Frost & Sullivan observes how these action plans seek to optimize clinical outcomes, curtail toxicity and adverse events, hinder the development and spread of antibiotic-resistant strains, and reduce infection-related healthcare costs. With some estimates of 10 million additional deaths and losses of $8 trillion worldwide per year by 2050, Frost & Sullivan agrees that properly guiding proper antibiotic use has never been more urgent, and its success, never more critical.[2]

Molecular Diagnostics: Advancing Clinical Care

Rapid and accurate diagnostics is the cornerstone to effective infectious disease clinical management—timely pathogen detection and identification, proper therapy determination, treatment response monitoring, prognosis assessment, and Integrated Disease Surveillance and Response implementation. Molecular diagnostic (MDx) methods are well-established in clinical practice, offering faster and improved test specificity and sensitivity over the more traditional clinical microbiology approaches like microbial cultures, microscopy, and routine immunoassays. MDx assays employ established molecular biology techniques, such as nucleic acid amplification—deoxyribonucleic acid or ribonucleic acid—to detect infecting pathogens by identifying their unique genetic information.

[1] http://ecdc.europa.eu/en/eaad/antibiotics-get-informed/key-messages/Pages/hospital-prescribers.aspx
[2] https://www.csis.org/analysis/significant-first-step-un-member-states-declare-antimicrobial-resistance-global-priority

To date, polymerase chain reaction (PCR) is the gold standard for molecular tests. Advanced PCR techniques – including real-time PCR (qPCR) - are having a particularly decisive impact on novel diagnostics for infectious diseases, allowing for faster, more accurate, and highly reproducible tests as well as lowering the risk of cross-contamination due to its closed-tube format. Furthermore, qPCR instrumentation facilitates greater multiplexing capabilities—enabling the simultaneous detection of multiple pathogen gene variants for disease screening and diagnosis. Multiplexed qPCR simplifies workflows, increases the information collected per reaction, reduces cost per data point, utilizes minimum sample volumes saving precious clinical specimens, and significantly improves diagnostic speed and confidence compared to single tests. MDx testing is gradually moving away from the single pathogen—or singleplex—approach toward more advanced, multiplex approaches.

Despite its distinct advantages, Frost & Sullivan points out that MDx has limitations, including complex testing and bulky instrumentation that requires time- and labor-intensive sample preparation, highly-trained technicians, and dedicated equipment space. Moreover, the high costs associated with MDx testing are particularly challenging given the immense economic pressures on healthcare systems worldwide. Nonetheless, MDx tests now play a greater role in effective infectious disease clinical management.

Point-of-care Testing: The Rosetta Stone for Antibiotic Use

The need to simplify processes and accelerate molecular testing at lower costs is revolutionizing MDx, spurring innovation in this space. Advanced PCR methods along with emerging disruptive technologies based on microfluidics are driving low-cost, "sample-to-result," miniaturized device development, providing groundbreaking platforms for applications in infectious disease point-of-care testing (POCT). Frost & Sullivan anticipates that point-of-care (POC) infectious disease MDx will redefine clinical management by optimizing strategies for major impact on individual and collective health—achieving better clinical care and health outcomes, while effectively curbing the AMR public health crisis.

According to Frost & Sullivan, the Western European POCT market will reach approximately $3.8 billion by 2020, increasing at a compound annual growth rate (CAGR) of nearly 6% from 2016 to 2020. Infectious disease POCT is surging as one of the most promising segments, with estimates reaching over $950 million at a CAGR of 9% during the same period.[3] Sepsis and urinary tract infections in Germany, Europe's biggest market, and the tuberculosis threat in Spain and Greece, are just a few examples fueling enormous growth in the segment. As the demand for cost-effective infectious disease POC MDx continues to rise, vendors must look ahead and develop affordable, easy-to-use systems with real-time multiplexing and expanded test menu to capture share in this dynamic, high-growth, nascent market. In addition, Frost & Sullivan notes that POC device vendors need to establish the clinical validity—specificity and sensitivity—and utility for broader adoption, considering the often stringent regulatory requirements for decentralized testing.

[3] *Western Europe Point-of-Care Testing (POCT) Market* (Frost & Sullivan, July 2016)

New Product Attributes and Customer Impact

With headquarters in Québec City, Québec, Canada, GenePOC™ develops, manufactures, and commercializes novel, cost-effective, and rapid MDx solutions for infectious disease detection at the POC. The company currently focuses on the HAI, critical infectious diseases, and sexually transmitted infections segments, areas where immediate diagnosis and prompt treatment are of paramount importance given the current environment.

Frost & Sullivan has previously recognized GenePOC for its strategic foresight and entrepreneurship in MDx and now distinguishes the company's disruptive, innovative revogene™ instrument for POC infectious disease MDx. The revogene facilitates affordable, real-time, tailored interventions. By moving diagnosis from the laboratory bench to the patient's bedside, GenePOC effectively bridges the gaps in infectious disease management.

Transformational Leadership

Dr. Michel G. Bergeron spearheaded the first inroads into MDx for infectious disease applications several decades earlier, founding the now world renowned Centre de Recherche en Infectiologie or CRI at the University of Laval in Québec City in 1974 and Infectio-Diagnostic (IDI) Inc. (now BD Diagnostics), in 1995. After successfully incorporating molecular methods to diagnostics, Dr. Bergeron focus switched to the patient's bedside to close infectious disease management gaps even further and, in 2007, created GenePOC™; the culmination of his purposeful path in MDx—saving lives through real-time disease management. The founder's vision of real-time infectious disease detection and treatment became a tangible reality in early January 2017 when GenePOC's flagship product, the revogene, received CE marking. The following month, the company announced the European launch of its first two CE marked in vitro diagnostic (IVD) tests—GenePOC CDiff and GenePOC GBS—conducted on this instrument.

Selected as a *Key Technology to Watch*[4] in 2017 and beyond, the revogene diagnostic instrument enables affordable, simple, fast, and highly accurate microbial testing at the POC. Both pioneering and entrepreneurial, Frost & Sullivan firmly believes that the company will gain an early-mover advantage as a result of providing clinicians with immediate, actionable information to enhance infectious disease clinical management.

Disruptive Innovation through Smart Design

POC technologies currently in the market facilitate a simpler device design with faster, more sensitive, and highly accurate detection systems that support ease-of-use with little hands-on time. Still, most companies struggle to provide cost-effective systems. Most molecular IVD systems currently at the POC allow for either only one, single- or low-plex reaction per instrument or use very complex cartridges. Running one test at a time requires either multiple platforms or additional devices that substantially increase hardware expenses while cartridge complexity often translates into high production costs and, thus, expensive consumables.

[4] *Western European Molecular Diagnostics Market* (Frost & Sullivan, January 2017)

GenePOC's strategic approach to empower simple, straightforward testing combines smart design with centripetal forces and cutting-edge micro technologies to provide a high-quality, user-friendly, and scalable POC MDx solution that is also affordable. The company's proprietary fluorescence-based qPCR platform consists of a fully-automated, portable standalone instrument, the revogene, and single-use microfluidic cartridges, or PIE's.

- revogene — While about the size of a laptop, the instrument holds up to eight PIE's, allowing independent testing of multiple (up to 8) clinical samples and tests per run. This offers a unique flexibility to the user adapting the throughput to his needs. Additionally, the revogene utilizes spinning disc technology, driving the liquid sample flow in the PIE's by rotating, which eliminates the need for valves and multiple piston pumps that increase instrument and cartridge costs.

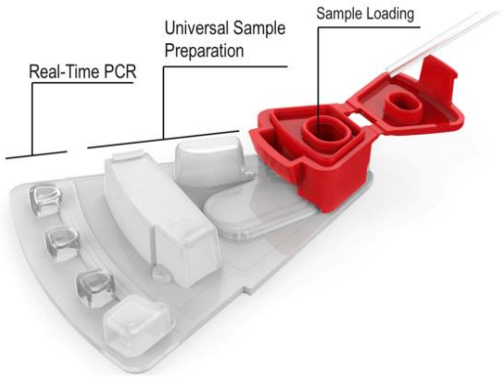
revogene™

Courtesy of GenePOC

http://www.mdpi.com/2072-666X/7/6/94

- PIE — The single-use cartridges are composed of only three pieces of plastic, making it simpler and less expensive to manufacture than competing consumables, which require a minimum of 23 pieces of plastic. Cartridge size is much smaller than any other commercial product currently on the market, resulting in lower handling cost and reducing significantly the waste, both impacting positively the overall operational cost for the end user. The cartridge's unique design incorporates three reaction wells, each a self-contained DNA-based amplification assay able to detect up to four genetic targets. As such, each PIE can detect up to 12 targets per sample, enabling GenePOC to introduce the concept of mini-panels to POC infectious disease MDx.

PIE



http://www.mdpi.com/2072-666X/7/6/94/htm

Cost-efficient, High-value Point-of-care Testing

GenePOC's smart MDx system extends availability and access to proper, personalized, and timely care, effectively bringing rapid, accurate, and cost-saving tools to the patient's bedside to improve clinical outcomes as well as reduce the burdens of public infectious disease.

The revogene's system supports:

- **Affordable, Accessible, Quality Solutions** — Lower manufacturing costs for instrument and consumables allow the company to offer reasonable pricing and unmatched low- to medium-throughput capabilities at the POC, running about 64 samples per working shift in one instrument, allowing its customers to perform assays, both low-plex and multiplex, on-demand and cost-effectively. The company's affordable, infectious disease POC MDx system also taps into a large and underserved customer segment—smaller clinical laboratory hospitals with limited budgets—broadening access to affordable, quality care.

- **Simple, Streamlined Patient-centric Workflows** — From sample collection to assay results, GenePOC's system simplifies workflows and eliminates the need for highly trained personnel, reducing operating costs while providing accurate diagnostics in less than one hour for improved health outcomes.

    - Generic sample processing suitable for a range of biological samples: an easy, three-step—collect, mix with sample buffer, and load—requiring less than one-minute hands-on time.
    - Real-time diagnostics: an integrated, user-friendly touchscreen display along with full automation performs diagnostics, from sample-to-result, within one hour. The user simply loads the collected sample in the PIE, scans the barcode, connects it to the patient ID, closes the instrument, and presses start. The results appear on the touch screen. Ready to deploy connectivity to laboratory information systems and hospital information systems allows for immediate result validation without losing transport time, e.g., from ward to laboratory, which advances real-time clinical decisions at the POC.

- **Reliable and Accurate Results Strengthen Decentralized POC Diagnostics —** The system's clinical validation studies show reliable, consistent, and accurate results across MDx assays. GenePOC's MDx tests perform equally or slightly better than other competing products. Clinical studies for CE-IVD qualification indicated 95% sensitivity and 99% specificity for *C. difficile* detection. The company is also finalizing field evaluations with GenePOC CDiff in France, Netherlands, United Kingdom and Belgium and is starting evaluation studies in Switzerland, Spain, Germany and Italy. GenePOC's cartridge design also drives more specific and sensitive pathogen detection, minimizing false positives and false negatives. GenePOC CDiff clinical studies conducted in six Canadian sites reported a 98% positive predictive value and a 99% negative predictive value. Evaluations for GBS are currently underway in Germany and Qatar.

"GenePOC focuses on bringing the laboratory closer to the patient by developing workable and affordable quality solutions…Since day one, we [GenePOC] tried to bring a smart alternative for MDx to the market, making it as simple as glucose monitoring."

-Herbert Torfs, Vice President of Business Development & Strategy, GenePOC

A Peek into the Future: Opportunities and Plans

GenePOC's multifactorial strategy as it innovates toward global leadership relies on expanding testing menus tailored to specific geographies and well-established distribution networks worldwide.

The company initiated commercial activities for the revogene, and its two CE marked IVD tests in all Western European countries in early February 2017, with plans to expand to Central and Eastern EU shortly after. GenePOC is looking into partnerships in the United States and Canada, as it expects approval by the Food and Drug Administration and Health Canada in the coming months. The company is eyeballing emerging and developing economies for mid- and long-term growth opportunities, evaluating potential distribution partnerships, assessing economic and clinical impacts, and tailoring infectious disease testing according to each region's specific need. Moreover, GenePOC will apply for a Clinical Laboratory Improvement Amendments (CLIA) waiver for its third diagnostic assay and onwards. If approved, the CLIA-waived test will represent a huge competitive advantage and shape the POC infectious disease MDx landscape. Frost & Sullivan believes that GenePOC will further capitalize on the urgency for better infectious disease clinical management, with a promising 2017 and even brighter longer-term roadmap.

Conclusion

With antibiotic misuse posing a serious global threat, proper antibiotic use has never been more urgent, and its success, never more critical.[5] Rapid and accurate molecular diagnostics (MDx) underpins effective infectious disease management. Yet current MDx systems are often complex and expensive, limiting broad adoption. Pioneering and entrepreneurial, GenePOC's groundbreaking infectious disease MDx system, the revogene™, combines a smart design with centripetal forces and cutting-edge micro technologies to provide simple, rapid, accurate, and cost-effective diagnostics at the point-of-care (POC). The company's smart and multipronged approach to product design and commercialization considers the most relevant and growing concerns in today's clinical practice and public health—cost-effective, appropriate, and safe use of antibiotics. Its commitment to advancing molecular diagnostics through technological leadership and patient-centric innovation earns GenePOC the 2017 Frost & Sullivan New Product Innovation Award.

[5] https://www.csis.org/analysis/significant-first-step-un-member-states-declare-antimicrobial-resistance-global-priority

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
Criterion 2: Reliability
Criterion 3: Quality
Criterion 4: Positioning
Criterion 5: Design

Customer Impact

Criterion 1: Price/Performance Value
Criterion 2: Customer Purchase Experience
Criterion 3: Customer Ownership Experience
Criterion 4: Customer Service Experience
Criterion 5: Brand Equity

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

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