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KATLEEN VERLEYSEN,
CEO

**MEDTECH
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**Affordable,
Scalable
and Rapid
Diagnostics**

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MEDTECH STARTUPS

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miDiagnostics

Affordable, Scalable and Rapid Diagnostics

By Alex D'souza

Reverse transcription polymerase chain reaction (RT-PCR) tests and alternative assays are taking centre stage in addressing the widening rift between limited testing availability and unprecedented global demand.

The quest for rapid, reliable and widely accessible molecular diagnosis has stumped many innovators, with the belief that "testing can either be fast or accurate, but never both" is spreading widely in the medtech and diagnostics arenas.

miDiagnostics is on a mission to dispel this belief and bridge the gap between accuracy, convenience and speed in molecular diagnostics through its range of decentralised health screening tools.

"We want to make healthcare accessible and efficient. In pursuit of this, we are developing user-friendly, point-of-care tests that provide clear and reliable results, ensuring speed and simplicity without compromising performance," says Katleen Verleyesen, CEO of miDiagnostics.

The company has forged robust partnerships with industry leaders to bring its technology to life. A strong example of such a partnership is the one with Imec--a silicon-based equipment provider renowned for nanoelectronics R&D--and its pivotal role in developing miDiagnostics products. From a medical perspective, support from Johns Hopkins University is crucial to accelerating the upcoming trials and fortifying the timelines with their extensive knowledge and resources.

Transforming PCR Testing with Innovative Miniaturisation

Laboratory-on-a-chip (LOC) devices shift the paradigm of PCR testing by consolidating key lab functions on a micro-scale chip. They handle small fluid volumes, automating processes through micro-mixers, micro-valves, micro-pumps or micro-separators. The design and development of LOC testers, however, is very challenging due to the sheer number of potential device configurations each based on a specific application. This makes it much harder to anticipate issues.



We understand the intricate process of transforming an idea from a concept to a tangible commercial product. While creating captivating prototypes is important, the real challenge lies in developing an affordable and scalable solution that maintains the desired level of performance

miDiagnostics has developed a proprietary technology for highly accurate results in under 20 minutes. Its core is silicon-based, whereby different chip sample-preparation modules can be coupled with the silicon PCR reaction chamber. Due to the extreme miniaturization and the fact that silicon is very heat conductive, thermal cycling, required for accurate PCR results, leads to 20 to 30 times faster run times compared to the conventional central lab processes. This design allows high-precision and fast test results at a low cost, with minimal fluid volume consumption, enabling lab-quality performance in a decentralized setting.

The disposable test card is inserted into a reader, which conducts ultra-fast thermocycling and optical detection to generate the test results. With faster results, the device is assisting in diverse areas like women's health, sexually transmitted diseases (STDs), viral meningitis and encephalitis, and respiratory infections.

Beyond its exceptional performance across these areas, the miDiagnostics' silicon technology has scalability and affordability that are often lacking in other PCR technologies. In contrast to the conventional limitations in point-of-care settings, the company's technology is a scalable and cost-effective alternative for health screenings.

The societal impact of diseases like STDs and the urgency in determining whether patients are at risk of infecting others is addressed with its decentralised platform and cost-effective tests, precise diagnostics, and super-fast turnaround. Essentially, miDiagnostics plays a pivotal role in enhancing community safety.

Improving Women's Health with Instantaneous Diagnosis and Treatment

Women seeking OB-GYN consultations often experience discomfort related to inflammation (vaginitis), which can be a symptom of a range of indications such as a bacterial or a yeast infection or presence of parasites, which are sexually transmitted. Depending on the reasons for the onset of inflammation, different treatments are needed. The prevalence of these cases has elevated the demand for advanced diagnostic tools that swiftly and accurately identify the underlying causes. Equipped with unparalleled speed, performance and convenience, miDiagnostics' solution is set to change the approach to gynaecological care.

Traditional methods of collecting samples and sending them to central labs tend to delay results. This can hinder caregivers from making informed treatment decisions like choosing the right medications.

miDiagnostics aims to transform this process by offering a rapid testing solution that provides results within the span of a doctor's visit. With this innovative approach, a patient can walk into a clinic and leave with an accurate diagnosis and the appropriate treatment. This aligns with the evolving healthcare space, where individuals seek timely testing without enduring a prolonged wait for results and subsequent treatment.

In the context of vaginitis, numerous women are apprehensive of the existing diagnosis journey and instead choose to self-diagnose or resort to over-the-counter antifungal treatments. This approach does not apply to all types of vaginitis, especially the asymptomatic variant, where patients can go for long periods before realising they have the condition.

miDiagnostics' solution discourages self-care with a comprehensive and swift diagnostic tool that ensures that underlying infections are not ignored. Its proactive approach is vital for young women, as untreated inflammation can lead to complications such as infertility. Above all, the company's contribution to raising awareness of women's health underscores the importance of replacing self-diagnosis risks with accurate diagnoses and appropriate treatments.



Reshaping Cancer Treatment Protocols

As miDiagnostics advances in reshaping diagnostic protocols, the company has entered into a prominent biopharma partnership with Galapagos focused on evaluating its technology for sterility testing and batch release of Chimeric Antigen Receptor T-cell (CAR-T) treatments. Galapagos is a global biotechnology company with operations in Europe and the US dedicated to developing transformational medicines for more years of life and quality of life. The collaboration with Galapagos represents miDiagnostics' entrance into the exciting field of personalized medicines for cancer.

When developing a CAR-T medication, a patient's blood is collected, non-functioning T-cells are isolated and re-engineered to combat cancer, and the resulting sample is reintroduced into the patient. Given the body's immune-compromised state, ensuring the sterility of the re-injected solution is paramount. This necessitates a robust sterility test before releasing the batch for re-injection.

Galapagos aims to make CAR-T therapies more rapid and more accessible to patients worldwide using its innovative decentralized CAR-T manufacturing platform near the point-of-care, as compared to centralized manufacturing of currently available CAR-T therapies.

As part of the collaboration agreement with Galapagos, miDiagnostics will develop a novel closed-flow, ultra-rapid PCR sterility test for CAR-T batch release in a decentralized manufacturing setting, in compliance with regulatory requirements, including those in the U.S., Europe and Japan. This will support fully automated, commercial-scale production of fresh-to-fresh CAR-T therapies at the point-of-care, near the patient.

The sterility testing for CAR-T batch release sets exceptionally high standards for sensitivity and sterility, requiring the detection of pathogens in extremely low copy numbers. Ultra-rapid testing ensures the timely fresh product release to the patients in need.

The collaboration demonstrates the adaptability of miDiagnostics' technology for broader applications.

Catalysing the expansion of applicability, it has the potential to transform patient outcomes and raise miDiagnostics' technological capabilities to new heights.

Blending Convenience and Innovation for Better Care

miDiagnostics has a diverse team with skillsets across engineering, chemistry, clinical, regulatory, manufacturing and supply chain domains and supporting functions like product and project management, quality, IP, IT and finance. The skillset of the combined miDiagnostics team has led to the market introduction of over 130 IVD products worldwide, hence is well armed to take miDiagnostics innovative products to market.

"We understand the intricate process of transforming an idea from a concept to a tangible commercial product. While creating captivating prototypes is important, the real challenge lies in developing an affordable and scalable solution that maintains the desired level of performance," says Verleysen.

In the coming 12 to 18 months, miDiagnostics will focus on conducting trials and submitting regulatory documentation for its core tests. The company is also actively engaged in joint endeavours, aiming to develop next-generation diagnostics that can handle a wide range of applications.

"The core motivation for the team is delivering a meaningful impact by making it more effective and convenient for people to gain a rapid and accurate diagnosis of their health issues," says Verleysen.

Achieving the difficult feat of providing patients with prompt and precise diagnostics, miDiagnostics strives to support them and their families in reliably navigating care journeys without anxiety-inducing delays in test results and treatments. The overarching theme is to establish a diagnostic process that eliminates the need for long waiting times and accelerates care through innovative and affordable screening tools. 