The Global Democratization of Point-of-Care & At-Home Diagnostic Testing

OVERVIEW, CURRENT DEMANDS, FUTURE OPPORTUNITY, REGULATORY & DATA PRIVACY CHALLENGES, MARKET ADVANCEMENTS AND TECHNOLOGY ASSESSMENT

MIDI

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MIDI WHITEPAPER

The Overview

The Global Democratization of Point-of-Care & At-Home Diagnostic Testing

One of healthcare's most extensive and rapidly expanding market segments, Point-of-Care (POC) and at-home rapid diagnostic testing, has become an ever-increasing crucial topic in the medical world since COVID-19 was first declared a pandemic. Spurred by sudden dire need and fed by the cooperation of regulatory agencies worldwide, diagnostic technology has advanced in a few short years what may have taken considerably longer otherwise. As a result, innovative new platforms and future applications with the potential to revolutionize healthcare overall have emerged.

Pre-pandemic, rapid diagnostic testing was near the exclusive domain of healthcare professionals, available to those in hospitals, clinical facilities and emergency departments as invaluable tools for real-time data when making critical care decisions. While this left patients, in most cases, without initiative or control over their own care, it was not until COVID-19 that the public at large became aware that better alternative cost-effective diagnostic methods can be made available.

At the height of the pandemic, with worldwide medical systems groaning under the weight of high patient numbers and extreme isolation requirements, researchers and innovators rose to provide rapid testing methods that could be performed by anyone, anywhere—proving to stakeholders across the industry the need and viability of cost-effective rapid testing for use at the Point-of-Care and in patients' homes.

While these testing devices, platforms and methods provided much-needed relief to overburdened healthcare systems worldwide and enabled vastly improved decision-making for providers, they also stoked in patients a new demand for greater access and control within their care that has only grown. Today, innovators are hard at work to meet this demand and improve testing and efficiency for providers while also seizing upon this new demand to produce novel, patient-led methods of diagnosis and delivery.

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Whether administered at home by the patient or at Point-of-Care by a healthcare professional, next-generation rapid diagnostics aims to improve the efficiency and quality of care while making it more accessible and affordable to the patient than ever before.

Most often associated with infectious diseases, the following are common diagnostic therapy segments in the marketplace currently of which require fast, informed decision-making:

Cardiovascular

+ Brain natriuretic peptide (BNP) test (heart failure)
+ PT/INR test (clotting disorder/coagulopathy)
+ Troponin test (heart attack)
+ D-dimer test (clotting disorder/DVT)

STI/OB-GYN

+ HIV
+ Hepatitis B
+ Hepatitis C
+ Pregnancy
+ Streptococcus B

Endocrine applications primarily concerning diabetes

+ Rapid blood glucose test
+ Hemoglobin A1c (HbA1c) test
+ Ketone test

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Gastrointestinal and Colorectal tests

+ Clostridium difficile
+ Fecal occult blood test

General health Applications

+ Blood gas analysis (ABG)
+ Hemoglobin and hematocrit tests
+ Lipid profile
+ Traumatic brain injury (TBI) biomarkers

Infectious disease panels

+ RSV
+ Influenza
+ Streptococcus/Strep throat
+ COVID-19 test
+ C-reactive protein (CRP) test (inflammation/infection)
+ Procalcitonin (PCT) test (sepsis/bacterial infections)

While these rapid tests have been essential tools in managing immediate clinical decisions for some time, there is an emerging new genre of diagnostics that is now expanding to cover many other applications, use cases and end-users that have long been overlooked.

Current Demands & Future Opportunity

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Responding to physicians' demands for enhanced data collection and patients' demands for greater involvement in their healthcare, rapid general wellness panels are increasingly commonplace, testing for vitamin, mineral, and cholesterol levels. In oncology, rapid screenings for cancer biomarkers are in high demand for numerous common cancer types. New rapid tests have emerged checking fecal occult blood (important in detecting colorectal cancers) and HPV status (a risk factor for cervical cancer). Meanwhile, neurological applications have emerged that allow rapid detection of stroke activity and quicker diagnosis of dementia. This is all while existing application areas have and continue to expand steadily; new tests and improved tests have emerged for some STIs and infectious diseases, including meningitis, various strains of flu and COVID-19, gonorrhea and chlamydia.

Even with the rise of at-home diagnostic testing and other personal health solutions, Point-of-Care rapid testing is still a critically important component of the diagnostic market overall, a tool serving distinct, equally important roles to physicians, whether in the clinic or ICU. These tests enable rapid and effective triage in ERs and offices, quickly informing courses of action and treatment by providing real-time information via simple, easy-to-perform tests and often significantly impacting time to diagnosis and appropriate treatment. Meanwhile, their development can be particularly challenging as designers must balance the complexity of collecting samples for accurate results with respecting the existing workflows of healthcare professionals, a critical component for adoption and proper use. Even so, rapid Point-of-Care testing methods are in high demand and projected to become only more relevant over time, particularly as they find more use in oncological applications.

Yet, innovation in Point-of-Care testing has an additional driving force many may need to consider: Artificial Intelligence (AI) advancement. Already viewed as an invaluable tool to physicians worldwide, the algorithmic capabilities offered by machine learning have enabled data collection and analysis on a scale never before seen as possible. AI is currently being leveraged in medical applications, specifically in areas such as medical imaging. AI is currently used to assist in the detection of anomalies in scans often invisible to the human eye. As AI, connected health and rapid diagnostics continue to evolve, there is no doubt their development will be intertwined, with AI bridging the gap between traditional Point-of-Care testing and the newly established data source of at-home diagnostics.

Alongside improved POC testing, rapid at-home diagnostic tests have also seen vast advancement. While these rapid diagnostics relieved some of the burden of testing for healthcare providers, they also imparted several benefits to patients that encouraged a fresh desire for new initiatives and control for their own personal healthcare. Today, patients are more interested than ever in performing their tests, engaging deeply with their treatment plans and building functional working relationships with the physicians entrusted with their care. Since the pandemic's start, the boom in at-home diagnostic testing has widely reflected this desire. While not a replacement for traditional clinical care, at-home rapid tests provide affordable access to critical health services even where facilities are overfilled or cannot be accessed, relieving pressure on understaffed and overworked healthcare teams worldwide.

Meanwhile, at-home diagnostic testing allows for faster, better-informed decisions about isolation measures, diagnoses and treatments, ensuring that patients receive the care best suited to their exact status when treated. While any concerning results must be confirmed with more complex POC testing at a clinic or hospital, at-home screenings remain a significant improvement in both convenience and function. They are set to become a mainstay of an ever-expanding personal diagnostic future medical landscape.

Current Demands & Future Opportunity

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While diagnostics is hardly a new or even young segment of the medical field, it is currently seeing innovation at a pace unlike ever before, with research and technology advancing at breakneck speeds on micro and macro levels as research and development experts seize upon areas of interest previously underserved in the diagnostic marketplace.

At present, there are several primary areas of opportunity and future growth for both at-home and Point-of-Care diagnostics advancement:

1. **Therapy Market Areas:** Useful in far more applications than just viral infection screening, rapid diagnostic tests are now being designed to serve several use cases, from critical life services to general well-being management. Notably, our growing aging population has driven a need for improved diagnostics in dementia and stroke cases and at-home versions of various cardiovascular POC tests.

2. **Ease of Use:** Whether intended for at-home or POC use, one of the most critical aspects of effective rapid diagnostics is proper, seamless integration into the workflow of providers and the lifestyle of patients. Indeed, usage ceremony must evolve into a better and more intuitive workflow with new methods than their predecessors to see widespread adoption. Because of this, much attention is being paid to new and improved sample collection, analysis and interpretation methods, which are critical for the efficacy of test results as well as CLIA waiver status.

3. **Connected Health & AI:** While connected health services have grown, evolved and strengthened alongside at-home testing measures through Apps and Telemedicine, AI is being seen as a key enabler to support physicians in patient data analysis and diagnostic decision-making. As patients continue to seek and gain influence in the

nature and delivery of their healthcare, demanding greater personalization and control, Connected Health & AI will become invaluable solution tools within the diagnostic ecosystem.

4. **Multiplex Testing:** The process of simultaneously detecting or identifying multiple diseases (biomarkers) in a singular POC or at-home diagnostic screening, multiplexing is an important and fast-growing segment of the rapid diagnostic market, further empowering physicians and patients to reap the benefits through optimizing process results- leading to faster decision making.

Click on the MIDI Innovation Vault Podcast microphone link to listen to details on the above topics covered in Episode 1 of The Deep Dive into Global Democratization of Point of Care & At-Home Diagnostic Testing.

Regulatory Challenges

The Global Democratization of Point-of-Care & At-Home Diagnostic Testing

As the diagnostic testing market becomes more decentralized from laboratories to POC clinics and at-home testing applications, there come significant regulatory challenges that are critical for device manufacturers to address. Upon the termination of the FDA's Emergency Use Authorization (EUA) for specific POC and at-home diagnostic devices, the companies behind these devices will not only need to seek traditional 510(k) clearances but also address, where applicable, a combined CLIA waiver status from the FDA.

CLIA, or Clinical Laboratory Improvement Amendments, refer to the federal law establishing quality standards for testing to ensure accuracy, reliability and timeliness of patient results regardless of where the test is performed. Given the already massive and rising number today, the industry stands at the precipice of a bottleneck of current EUA devices that will need to be re-addressed for approval from multiple perspectives, particularly in the case of POC diagnostic systems.

In the case of at-home testing, generally, a test that has been cleared, approved or specifically authorized for at-home use by the FDA will not be regulated under CLIA so long as that test is self-administered in accordance with the FDA authorization and authorized labeling. If the test is either performed by someone other than the individual being tested or the results are interpreted or reported by someone other than the individual, then a CLIA certificate would be required.

Such testing, when performed by an individual, including a parent or guardian, for a child or an adult who is unable to test themselves to the extent authorized in the manufacturer's Instructions for Use (IFU), is considered self-testing for the purposes of CLIA and would not require a CLIA certificate.

Generally, manufacturers include separate IFUs for OTC at-home use and healthcare provider-facilitated testing, the latter of which would generally need to be performed in a facility operating under a CLIA certificate. As such, the appropriate instructions must be followed depending on the setting in which the test is being used.

Data Privacy Challenges

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Although the prospect of revolutionizing and democratizing diagnostics is sure to excite many, few are likely to respond enthusiastically to the idea of widespread data collection and sharing, particularly in the medical field. Yet, data sharing remains critical to ushering in the next generation of diagnostic practices, accelerating scientific discoveries, providing clinical utility, and enabling technological advancements. As such, device companies must commit to instituting ethical data-sharing practices within their business plans.

Throughout development, there are several key components to consider concerning data privacy for Next-Gen diagnostics. These include collecting informed consent, guaranteeing data security, protecting patient anonymity, data usage transparency and properly deploying beta testing for data sharing. As health records contain personal, sensitive information that most prefer to keep private from employers, insurers, friends and even family, their privacy is paramount and even protected by specific federal regulations. Yet, advancements in technology outpace policies and mandated practices, meaning that individuals, companies, stakeholders, and policymakers must all play an active role in ensuring the responsible use of personal data.

Although diagnostic decentralization is undoubtedly a noble goal, ethical challenges should always be balanced equally with technological progress. For example, smartphone applications have become increasingly prevalent as healthcare tools, yet they can easily suffer from insecure data storage and present a significant risk of breaching patient privacy. These risks can complicate informed consent and may come in the form of data leaked through automatic backup systems, accidental sharing to social media or any other insecurities encountered due to connectivity. It is critical that device developers actively address issues such as these during any device and systems development process, initiating ethical discussions with patients, providers and researchers that will shape the integration of molecular diagnostics with electronic medical records.

Market Advancements

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There exists today an ever-growing demand among consumers for at-home test kits to be kept as part of a family's first aid kit to enable faster, more independent medical decision-making without a trip to the doctor. This market movement is called Holistic Health Monitoring. Rapid multiplex testing is meeting this demand— a practice in which multiple biomarkers are detected or identified within a single at-home or POC diagnostic test. For device manufacturers, opportunities abound for at-home diagnostic kits detecting common infectious diseases such as COVID-19, hepatitis, flu and their various respective strains, all within a single multiplexing test. Beyond infectious diseases exists the opportunity in offering wellness monitoring kits allowing patients to record blood sugar, cholesterol, iron and vitamin levels via a single multiplexing test.

A fast-growing segment of the rapid testing market, multiplexing has many benefits, perhaps the most notable of which is its significant impact on medical decision-making. Optimizing process results while allowing for more convenient, comfortable single sample collection. Multiplexing not only identifies disease(s) but also serves as an important process in eliminating potential diseases from a prognosis.

For example, most viral respiratory illnesses are difficult to diagnose based on symptoms alone. Multiplex testing allows physicians to identify underlying infections quickly and accurately, thus making critical decisions towards patient management, e.g., medication or isolation requirements, far more effectively than with standard tests. Meanwhile, they can also identify co-infections that may have worse prognoses and require different treatment techniques than a single pathogen infection might. This is invaluable for informing public health measures, as it allows researchers to more quickly and accurately identify outbreaks to prevent viral spread, particularly in high-risk settings such as hospitals and long-term care facilities.

Market Advancements

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Multiplex testing is especially an indispensable method for high-risk patients such as children, the elderly and the immunocompromised, who are susceptible to co-infection, severe illness and often require specialized treatment.

Beyond respiratory illnesses, demand is rising for molecular diagnostic options for some infectious diseases, including diarrheal diseases, sexually transmitted infections and urinary tract infections. These tests are often faster and more sensitive than standard culture tests.

Click on the MIDI Innovation Vault Podcast microphone link to listen to details on the above topics covered in Episode 2 of The Deep Dive into Global Democratization of Point of Care & At-Home Diagnostic Testing.

Technology Assessment

The Global Democratization of Point-of-Care & At-Home Diagnostic Testing

There exists a variety of Point of Care and at-home diagnostic testing categories and scientific technology applications that are both emerging and available within the market today. Outlined below is a focused overview of various diagnostic applications covering details as related to their science, the value proposition for detection and global health market application.

Antigen Testing

Antigen tests are immunoassays that indicate current infection status by detecting the presence of specific viral antigens. Collected simply with a nasal or throat swab, specimens are placed into the assay's extraction buffer, then exposed to a reagent that reveals proteins identified as part of the target virus. Familiar to most in the form of over-the-counter COVID-19 test kits, antigen tests have accounted for the vast majority of rapid diagnostic tests. Until recently, they have been used most commonly in diagnosing respiratory pathogens such as COVID, influenza and respiratory syncytial virus or RSV. Because of this, they are best suited to identifying individuals at or near peak infection.

Requiring no expensive complex equipment or training to complete, antigen testing is generally faster and less costly than other detection methods, with accessibility that has made it an obvious choice for at-home diagnostics. Yet, the technology contains a large flaw that has its relatively low accuracy compared to other golden standard methods.

Antigen technology testing flaw exists due to a lag time between when an individual gets infected and when the antigens appear and are detectable. If an individual is not near peak infection but is still contagious, the antigen test may result as negative. As such, if a

test is being performed where the patient is at the stage when the virus is still replicating inside the cells, the production and shedding of sufficient protein quantities may not be large enough for detection. In essence, antigen tests performed too far from the peak of infection can return a negative result, even as individuals may be showing symptoms and are actively contagious. Meanwhile, false positives can occur when other viruses are present, improper collection techniques are used, or other bodily substances produced during infection interfere with test results.

Though antigen testing is undoubtedly an invaluable diagnostic tool, there remains the need for methods that allow for earlier and more reliable detection for both POC and at-home diagnostic testing.

Molecular Diagnostics: NAATs

A type of test with varying methods, Nucleic Acid Amplification Tests, or NAATs, are viral diagnostic tests that detect the genetic material of viruses within patient samples by amplifying nucleic acids. More specifically, NAATs replicate viral DNA or RNA sequences that comprise a particular virus's genetic material to a detectable level, making them able to identify even minimal viral loads. With various amplification methods available, NAATs are reliable, highly sensitive diagnostic tests unlikely to return false-negative results.

+ The most common methods of amplification used in NAATs include:
+ Reverse Transcription Polymerase Chain Reaction (RT-PCR)
+ Loop-mediated Isothermal Amplification (LAMP)

- Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR)
- Nicking Endonuclease Amplification Reaction (NEAR)
- Transcription Mediated Amplification (TMA)
- Helicase-Dependent Amplification (HDA)
- Strand Displacement Amplification (SDA)

NAATs can be used in a wide range of settings, such as laboratory facilities by trained personnel, Point of Care settings as well as self-administered at-home test use and other non-healthcare locations. Certain NAATs are considered rapid tests and can return a result within minutes. The level of sensitivity for the detection of genetic material can depend on the method of NAAT application. Sensitivity can vary by NAAT method, but in a general laboratory, based NAATs have higher sensitivity than POC-administered tests.

RT-PCR and LAMP

Each test that allows for the detection of viruses in both symptomatic and asymptomatic patients, PCR and LAMP can utilize nasal swabs much the same as antigen tests.

One of the most widely used methods in molecular biology for over thirty years, PCR testing was the first established method of COVID-19 detection and the standard by which subsequent methods have since been judged. Within this method, RNA from a patient sample (e.g., nasal swab, saliva, blood) is isolated by removing proteins, fats and other molecules before being reverse transcribed to complementary DNA. The complementary DNA is then amplified with enzymes that are activated through thermocycling or repeated alteration between specific temperatures. Fluorescent markers that bind to amplified double-stranded DNA can be measured in real-time through each amplification cycle. The number of amplification cycles needed to surpass a certain threshold of fluorescence indicates the initial amount of RNA found in the sample. In the case of SARS-CoV-2, the initial amount of RNA would correspond to the patient sample's viral load.

A relatively innovative testing method, LAMP is widely considered to be more efficient and cost-effective than PCR testing. While both target the viral RNA of a sample to extract and amplify, LAMP amplification is performed isothermally, at around 60-65°C, rather than necessitating multiple temperature cycles. This eliminates the need for expensive thermal cycling equipment and reduces the time and complexity of the process required to return a result.

Of the two similar but distinct methods, RT-PCR is the gold standard in diagnostic testing.

CRISPR

The modern genome-editing technology at the center of much progress and debate, CRISPR, known in full as Clustered Regularly Interspaced Short Palindromic Repeats, is based upon a process occurring naturally in nature by which bacteria protect themselves from viruses. Within this process, a cutting protein called Cas is guided by an RNA molecule to its matching DNA sequence originating from the invading virus. Once at its target, the Cas protein behaves as molecular scissors which cut the viral DNA, rendering it ineffective and thereby protecting the cell. In 2012, researchers successfully harnessed the CRISPR-Cas9 system for RNA-programmable genome editing, which was then demonstrated in mammalian cells for the first time in 2013. By reprogramming the guide RNA, scientists enabled targeting of any RNA sequence possible, creating, in essence, a tool for editing the genome of any species.

However, CRISPR's application in Molecular Diagnostics has little to do with genome editing; instead, scientists have recently discovered methods of leveraging the technology to perform nucleic acid testing rapidly, accurately and inexpensively with single base-pair specificity– all without the need for complex laboratory equipment.

Diagnostic methods based on CRISPR rely on identifying a particular nucleic acid sequence associated with a pathogen or disease, then cleaving it to produce a readable signal either in the form of a fluorescent reporter or electric signal that occurs upon target binding. Several CRISPR-based diagnostic platforms exist, each utilizing a different Cas protein. These include:

+ Cas9 platforms: Including the FLASH-NGS platform and the CRISPR-CHIP system, these target and cleave DNA via the Cas9 protein.

Molecular Diagnostic Application Focus: RT-PCR, LAMP, & CRISPR

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- FLASH-NGS combines Cas and next-generation sequencing, or NGS, technologies for precise identification of a pathogen, with the Cas9 system cleaving target nucleic acid sequences into fragments for NGS. Applications include identifying antibacterial-resistant strains such as MRSA and VRE.
- The CRISPR-Chip system combines dCas9 with a graphene transistor film to create an electrical signal upon target binding, producing a digital readout within fifteen minutes or less. This platform has been used to detect the deletion of two exons associated with muscular dystrophy.
- Cas12a platforms: Within the DETECTR and AIOD-CRISPR (all-in-one dual) platforms, when Cas12a detects and cleaves the target DNA sequence, it also cleaves ssDNA linked to a molecule producing a fluorescent signal. By implementing a reverse transcription reaction, DETECTR and AIOD-CRISPR can also be applied to detect RNA samples. The DETECTR (DNA Endonuclease Targeted CRISPR Tans Reporter) system has been employed in the detection of human papillomavirus as well as SARS-CoV-2.
- Cas13a: The SHERLOCK system uses Cas13a to detect RNA molecules associated with the target virus. Once bound to the target ssRNA, Cas13a releases a fluorescent signal through collateral cleavage of an ssRNA fluorescent reporter. A newer iteration of the SHERLOCK technology (SHERLOCKv2) utilizes a combination of Cas13, Cas12a, and Csm6 to achieve multiplexed outputs with greater signal intensity, enabling detection of samples with even lower RNA levels. SHERLOCK has been deployed to detect Zika, Dengue, West Nile and yellow fever.

Though each has its competitive strengths and weaknesses, the AIOD-CRISPR and DETECTR methods are generally considered better diagnostic methods than others when comparing the time taken and cost associated with each test and their proficiency in detecting SARS-CoV-2 in clinical samples. As they continue to advance and evolve, these CRISPR-based methods will likely facilitate new Point-of-Care applications in the following generation of novel diagnostics.

CRISPR vs. RT-PCR

Even compared to gold-standard RT-PCR testing, CRISPR-based systems have several significant advantages, including their ability to target the nucleic acid sequences of different pathogens (DNA in the case of Cas9 and Cas12, RNA in the case of Cas13) with single base specificity. This is in contrast to PCR's need for primers, which amplify target sequences but leave potential for off-target effects and non-specific amplification.

Diagnostic applications link target sequence binding with a readout, such as color changes in lateral flow assays or fluorescence. In the latter's case, researchers have leveraged the indiscriminate cleaving properties of Cas12 and Cas13 to produce a fluorescent signal enabling detection. By including nucleic acid reporters that fluoresce when cleaved collaterally upon target binding by the Cas protein, detection methods can directly link cleavage of the target sequences to a fluorescent signal.

Further, CRISPR-based molecular diagnostics are well-suited to POC testing in low-resource settings; unlike PCR methods, they require no complex lab or clinic setup and no thermocycling, instead using only simple reagents.

Molecular Diagnostic Application Focus: RT-PCR, LAMP, & CRISPR

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It is important to note that these detection methods are slightly less sensitive than the more widely used RT-PCR tests. Additionally, most CRISPR-based applications still require a nucleic acid preamplification step to increase the limit of detection. To spur clinical adoption, advancements must be made toward improving test sensitivity and simplifying the workflow involved in these methods. Still, CRISPR-based detection systems have great potential to become the next generation of POC diagnostic testing platforms, marrying the sensitivity and specificity of RT-PCR testing with the ease and convenience of rapid test kits while remaining accessible and cost-effective.

Click on the MIDI Innovation Vault Podcast microphone link to listen to details on the above topics covered in Episode 2 of The Deep Dive into Global Democratization of Point of Care & At-Home Diagnostic Testing.

Summary & Conclusion

The Global Democratization of Point-of-Care & At-Home Diagnostic Testing

Today, the advancement of both at-home and POC diagnostic solutions has allowed for a higher standard of patient care with improved safety and more satisfying outcomes while reducing healthcare spending and easing the burden of resource usage. Patients are now more aware of their power and responsibility in monitoring their own health. They also take a much greater interest in doing so, with consumers now having growing options to track and monitor health status and symptoms.

Diagnostic testing is the first line of defense for prevention, diagnosis, and actionable treatment. Moreover, early detection and diagnosis can lead to better patient outcomes for all types of illnesses and diseases, which can also help drive down costs. Inevitably it will make healthcare more accessible and equitable.

This rapid acceleration and application of Point-of-Care and at-home diagnostic platforms creates the opportunity for a dramatic paradigm shift in the practice of medicine. The wide adoption of these testing platforms, coupled with other advances in care and the participation of companies providing laboratory-like services available directly to the at-home or clinic, represents a significant advance in the delivery of medical care. We are witness to this unique evolving cultural shift and profound opportunity to improve the affordability, accessibility, and effectiveness of medical care for a range of common diseases for all people.

About the Author

Gregory Montalbano is the Co-Founder and COO at MIDI. With over 25 years' experience in medical device innovation and development, Greg's areas of expertise are multidisciplinary ranging from usability research, human factors engineering, industrial design, commercialization and regulatory planning strategy.

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