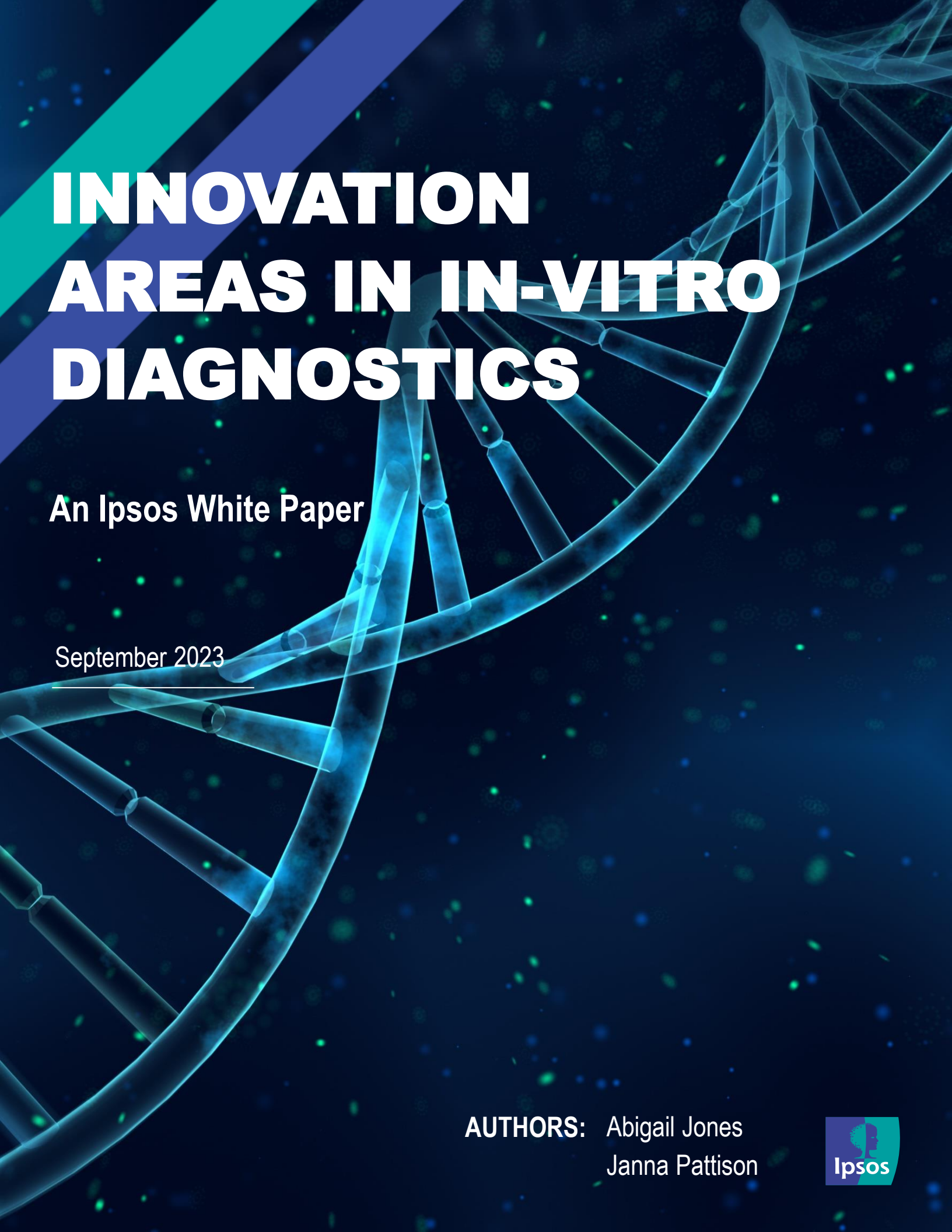

INNOVATION AREAS IN IN-VITRO DIAGNOSTICS

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I. INTRODUCTION

The In-Vitro Diagnostics (IVD) landscape has evolved rapidly in recent years, with next-generation sequencing (NGS), biosensor development, digital health and wearable advancements, and the COVID-19 pandemic being significant catalysts driving increased interest and funding to ultimately revolutionize the market. Today, leaders and pioneers in IVD are partnering with Ipsos to accelerate advancements across several key innovation areas including genomics, point-of-care and at-home testing, advancements in multiplex testing, and the complimentary use of IVD alongside other diagnostic tools like imaging.

This article will investigate IVD innovation areas from a disease state perspective, exploring where white space opportunities exist. By examining established and expanding diagnostic areas, we consider where disease mitigation, invasive testing, accessibility, and time sensitivity present unmet needs that, if addressed, can improve healthcare providers' ability to prevent, detect, and treat old and new diseases alike. We'll take a closer look at the opportunities with established diagnostics categories such as respiratory, sexual health, and hospital-acquired infections, as well as exploring further development and increased application of IVD in areas like oncology, neurology, emergency medicine, infectious disease, and DTC IVD.

II. INNOVATION IN ESTABLISHED DX AREAS

Advancing Respiratory Testing Targets

As the respiratory testing market recovers from the effects of the COVID-19 pandemic and adjusts to a new normal, manufacturers must pivot and reset in a highly fragmented market with provider and patient needs that go well beyond the mainstay testing targets.

The COVID-19 pandemic was a boon for diagnostics manufacturers, providing an influx of cash that funded innovation across their business. With many diagnostics manufacturers playing in both the lab, point-of-care, and direct-to-consumer testing arenas, the rapid decline of overall testing that began in late 2022 has had a marked impact on overall revenue. As this market is unlikely to reach the sales peaks seen during the height of the pandemic, manufacturers need to identify paths to effectively pivot their respiratory portfolios.

Expansion to multiplex Flu A/B, COVID-19, and RSV proved favorable initially; however, the market has become increasingly flooded with “me too” products that test for this respiratory disease combination. Further, laboratories and practices overbought on diagnostic analyzers during the pandemic to account for an unreliable supply chain. As supply chain woes ease, it is reasonable to expect that labs and practices may streamline the number of manufacturers and individual devices maintained in their labs. As these decisions are made, it will be increasingly critical for diagnostics manufacturers to have a strongly differentiated portfolio, including a varied test menu and unique analyzer capabilities, to justify continued placement in any given facility.

With respiratory tests comprising a significant portion of total test volumes at many facilities, expansion of existing test panels to include additional high-impact tests such as lower-respiratory infections, strep throat, or tuberculosis may offer a path to diversification for manufacturers that appeals to both developed and emerging markets. Additionally, expansion of tests to include both viral and bacterial causes provides an opportunity for manufacturers to appeal to antimicrobial stewardship efforts while simultaneously expanding their test menu. Ultimately, it may not be respiratory test availability or performance that justify the presence of a diagnostic analyzer, but rather a diverse test menu that meets the lab or practice’s needs.

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Modernizing Testing Practices in Sexual Health

Test barriers such as invasive and difficult sample collection and a long-standing sole focus on reportable disease testing have resulted in a sexual health diagnostic market that is ripe for innovation.

Sexually transmitted infections are a notable focus of public health due to their universality and ease of spread, the high cost of infection resulting from immediate treatment needs, as well as the risk to patients who go untreated. In fact, recent data finds that nearly 20% of Americans have an STI at any time, and new diagnoses result in $18B in costs each year. While STI screening is recognized as being highly cost-effective, for decades, the vast majority of STI testing volume and development by diagnostics manufacturers has focused largely on those diseases reportable to the CDC. As concern around STI levels rises and the CDC potentially moves to change testing and treatment guidelines, manufacturers should examine their STI portfolios to determine how to address the emerging needs related to STI testing with special attention to patient experience and testing accessibility.

The current diagnosis and treatment process is onerous for patients, relying on invasive and potentially outdated methods and technology. Limited appointment availability increases the difficulty of obtaining treatment, all while patients are dealing with the general sense of embarrassment and stigma that often accompany STI screening. In 2020, COVID-19 lockdowns exacerbated these challenges, resulting in a significant decline in the number of STI screenings performed, which rebounded into a noted increase in diagnoses in late 2020 and 2021. While gonorrhea, and syphilis saw case volumes increase compared to 2019, chlamydia diagnoses were down nearly 10% compared to 2019, likely as a result of decreased testing rather than an actual decrease in new infections. The pandemic lockdowns and subsequent rise in infection rates highlighted the fragility of this public health effort, the importance of easy, effective screening, and, for diagnostics manufacturers, the potential opportunity for introducing new testing methodologies.

In particular, the development and expansion of testing options for alternative site testing (e.g., urgent care clinics, retail clinics, telemedicine, at-home testing, etc.) may help ease both the burden of screening in traditional settings and reduce the stigma of screening, resulting in more people seeking screening and treatment. Further improving the testing process through speed, less invasive sample collection methods, expansion of STI test menus or multiplex testing, etc. offer the potential for an even more dramatic impact on testing and, ultimately, a substantial positive impact on a longstanding public health initiative.

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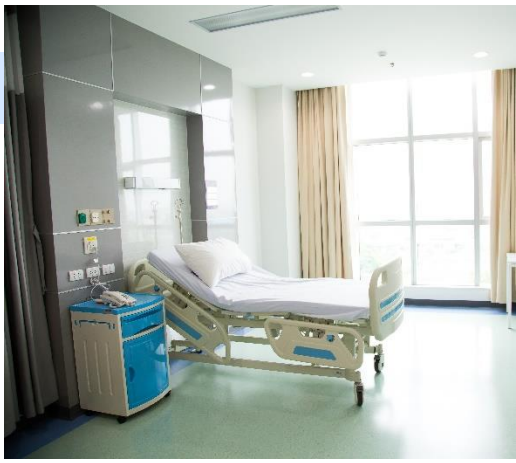
Reducing HAIs With Pre-Emptive Testing



Increased transparency and accountability requirements from the CDC and CMS have further incentivized hospital investment in devices and diagnostics that aim to prevent, diagnose and treat hospital-acquired infections. While early identification is key, hospitals today must make risk assessments based on need, speed and associated expense to patients, payers and health systems.

Hospital-acquired infections are a dreaded diagnosis for patients, physicians, and hospitals alike and, once suspected, a timely and conclusive diagnosis is critical. Conclusive diagnosis is not just imperative for providing care to the patient and reducing the likelihood of spread within a facility, but also for ensuring and preserving the effectiveness of treatment. Following the COVID-19 pandemic, hospitals have seen a substantial increase in levels of antibiotic-resistant infections during hospitalization, with some infections rising by as much as 78% compared to 2019 levels, putting patients at increased risk and setting back antimicrobial stewardship programs. Though the full impact of the COVID-19 pandemic on antibiotic-resistant infection rates is yet to be determined, it is clear that the time for action is now.

While post-infection diagnosis has been the focus of much IVD innovation and development, an opportunity exists to deploy diagnostic testing for infection prevention. This has been a goal of medical device and diagnostics companies for decades, but reluctant physician adoption, the availability of accepted alternatives (e.g., antimicrobial skin cleaners) and lack of cost-effective tests have proven to be significant barriers. The CDC estimates that more than 2.8 million cases of antimicrobial-resistant infections occur in the US each year, with just the top 6 multidrug-resistant pathogens costing more than $4.6 billion annually. The cost of these infections is not felt just in the cost to treat, but also in the reduction of reimbursement from CMS.

To enter this category, diagnostics manufacturers will need to fully understand the healthcare journey from the perspective of both the patient and physician to identify strong initial use cases that encourage uptake. A full understanding of the journey and current challenges with both pre- and post-surgical testing can help manufacturers innovate to meet a need and to solve a problem with the goal of easing current challenges, rather than introducing another step that may further complicate an already complex process. In addition to overall cost, sample collection, contamination avoidance/identification, and workflow integration will likely be key to HAI diagnostic adoption. Ultimately, cost-effective innovations that provide improvements in HAI prevention or increased speed of detection could pay for themselves in saved hospital costs and improved patient outcomes.

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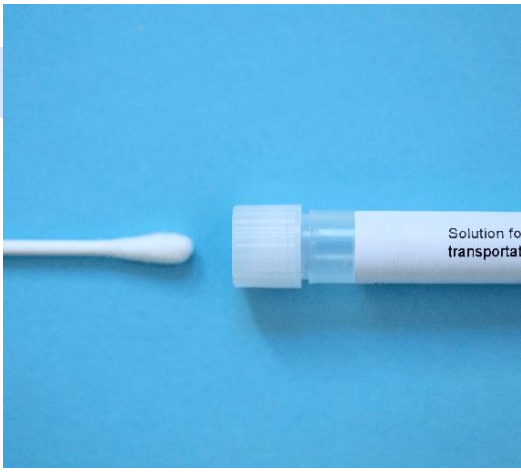
III. EXPANSION AREAS FOR DX INNOVATION

Placing Diagnostic Tools In Consumer Hands

While consumers have had access to diagnostic tests for decades, the market continues to expand as consumers embraced at-home testing for COVID-19 and manufacturers and laboratories rapidly expand their test menus. Introduction of DTC diagnostics in a substantial, meaningful way has the opportunity to revolutionize healthcare for patients and physicians alike.



The last decade has seen marked expansion in the direct-to-consumer testing space, with the market moving beyond the at-home pregnancy, glucose, and drug tests readily available at your local drug store to now include DTC genetic testing, wellness, and expanded infectious disease testing available both over-the-counter and through mail order. The entry of traditional diagnostics manufacturers into the DTC space has been slow (though on-demand testing has already been embraced by major reference labs), but the COVID-19 pandemic and the ready acceptance of at-home testing by consumers and public health authorities alike demonstrated that DTC testing could have a significant role in future healthcare. In all, DTC diagnostics may not be a niche product, but a category of IVD with the potential to provide a serious revenue source for manufacturers that, in turn, drives improvement in healthcare processes, efficiency, and impact for patients and healthcare providers.

Perhaps most obviously, DTC diagnostics that help patients manage or prevent chronic disease offer a significant opportunity for manufacturers. With chronic diseases such as heart disease, cancer, and diabetes making up roughly 41% of total US deaths in 2021, it is no surprise that many are looking for ways to improve and monitor their overall health and wellness. Consumers familiarity and acceptance of products that help them manage their health with the goal of preventing chronic conditions (e.g., blood glucose monitors/CGMs, wearable devices like fitness trackers, etc.) suggest that introduction of diagnostic tests in this wellness category would be a welcome addition.

Looking beyond these “nice to know” situations, it’s also easy to see how at-home diagnostics may be used in conjunction with the traditional healthcare system to enable better health outcomes. Tests for chronic, acute, and/or environmental health conditions or triggers could prompt consumers to seek appropriate care in a timely manner or, conversely, avoid seeking care through traditional channels when follow-up treatment isn’t needed, potentially easing the burden on the healthcare system. While the benefits may seem obvious, garnering acceptance of such tests by the broader healthcare community will require significant investment and understanding on the part of diagnostics manufacturers. Very few DTC diagnostic tests are currently approved by the FDA or CLIA-waived; manufacturers will need to be conscious of accuracy, reliability, consumer comprehension and usability if acceptance by the traditional medical community is desired.

Limiting Widespread Infectious Disease Spread

As the global population grows and density of urban areas intensifies, the world will need to prepare for the spread and emergence of new or different infectious diseases. By anticipating these shifts early through expanded IVD offerings and complementary services, manufacturers can help to ease the burden of emerging infectious diseases across the globe.

A growing urban population globally has generated substantial conversation around the economic and environmental consequences of this migration; however, while equally impactful, public health repercussions are less frequently discussed. As the human population shifts locations, so do the diseases of population and vectors of infectious diseases. With these rapid changes in population distribution, especially notable in emerging markets, governments are likely to be faced with increases in both neglected tropical diseases such as dengue, Guinea worm diseases, river blindness, and others, and re-emerging diseases like malaria, tuberculosis, pertussis, etc., which pose unique challenges to diagnosis, treatment, and outbreak management.

While the circumstances surrounding the emergence of these categories of infectious diseases have different origins and processes for elimination, the underlying concerns and needs of those managing these diseases are likely to be quite similar. Manufacturers stand to gain by developing innovative offerings to meet both existing and future needs. In addition to simply developing individual and multiplex assays necessary to conclusively diagnose disease, manufacturers may need to consider innovations in reagent/sample stability, device durability and transportability, and automated reporting to maximize the applicability of solutions; for emerging markets, additional focus on balancing such feature innovation with cost will be necessary to enable widespread uptake.

Though emerging markets offer the most obvious and immediate area of impact for solutions around emerging infectious diseases, the COVID-19 pandemic and recent outbreaks of mpox and drug-resistant gonorrhea (among others) prove that developed markets are not immune to the challenges of infectious disease. Recent dramatic increase in travel volume (notably to emerging markets where such diseases are more prevalent), climate change, and other societal/environmental factors may all factor into the increasing incidence of emerging disease in developed markets. Developed markets may be better prepared financially to weather the storms brought by such unanticipated disease outbreaks, but still require significant support from diagnostics manufacturers in order to identify and monitor outbreaks. While it is impossible to know conclusive which disease(s) may pose the biggest immediate threat, we can know for certain that global public health authorities will look to diagnostics manufacturers to provide the tools necessary to limit spread. Ultimately, the benefit of manufacturer investment in wider infectious disease capabilities will likely not be limited to emerging markets but may prove critical in preventing widespread disease in developed markets.

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Streamlining Dx and Treatment in Oncology, Neuro, Emergency Medicine and Beyond

Utilization of IVD in conjunction with other diagnostic tools like imaging can help to improve patient outcomes while reducing the amount of non-necessary care (e.g., TBI blood biomarker used to identify concussion in patients may reduce the number of non-necessary CT scans, use of oncology diagnostics to help reduce the amount of chemotherapy/additional treatment)

Though infectious disease has comprised the bulk of much of diagnostic testing to date, recent innovations point toward a future of boundary-breaking in non-communicable diseases where diagnostic tools may increase the speed to diagnosis in time-critical or complex areas that are difficult to diagnose today.

In particular, innovations in blood biomarkers and protein analysis for Alzheimer's, preeclampsia, and concussion diagnosis offer a preview of what's to come. Pairing IVD with traditional methods of diagnosis (e.g., CT scan and patient-reported symptoms, patient history and monitoring, etc.) may prove to be a gamechanger in reducing the amount of non-necessary medical interventions while improving patient outcomes and experience in emergency settings. Ultimately time to result and ease of workflow could be the make-or-break for these types of diagnostic developments, but physicians have demonstrated a willingness to trial or use any helpful tool provided to them.

In oncology, the application of next-generation sequencing (NGS) is facilitating rapid diagnostic and treatment advancements in a number of ways. Firstly, it is enabling patients to receive genetic testing to determine possible risk for hereditary cancers (e.g., germline BRCA gene mutations) and to mitigate their risk of developing cancers in their lifetime. Secondly, through Comprehensive Genomic Profiling (CGP) of the tumor itself, NGS provides oncologists with a simplified, streamlined method to test for a broad range of "actionable" biomarkers. This comprehensive testing afforded by CGP has provided drug manufacturers and physicians the ability to tailor treatments for oncology patients, resulting in more effective treatments, improved patient outcomes and quality of life. Beyond CGP, NGS application for Minimum Residual Disease (MRD) and Multi-Cancer Early Detection (MCED) technologies appear promising for further improving and changing the way cancer is diagnosed, monitored, and treated. There are many start-ups operating in these areas, which may prove to be wise acquisitions for diagnostics manufacturers who are looking to expand their footprint. Furthermore, these technologies, alongside non-genetic biomarkers, offer opportunity for partnership between medical device companies and pharmaceutical manufacturers to develop and provide the companion diagnostics necessary for certain oncology drug usage.

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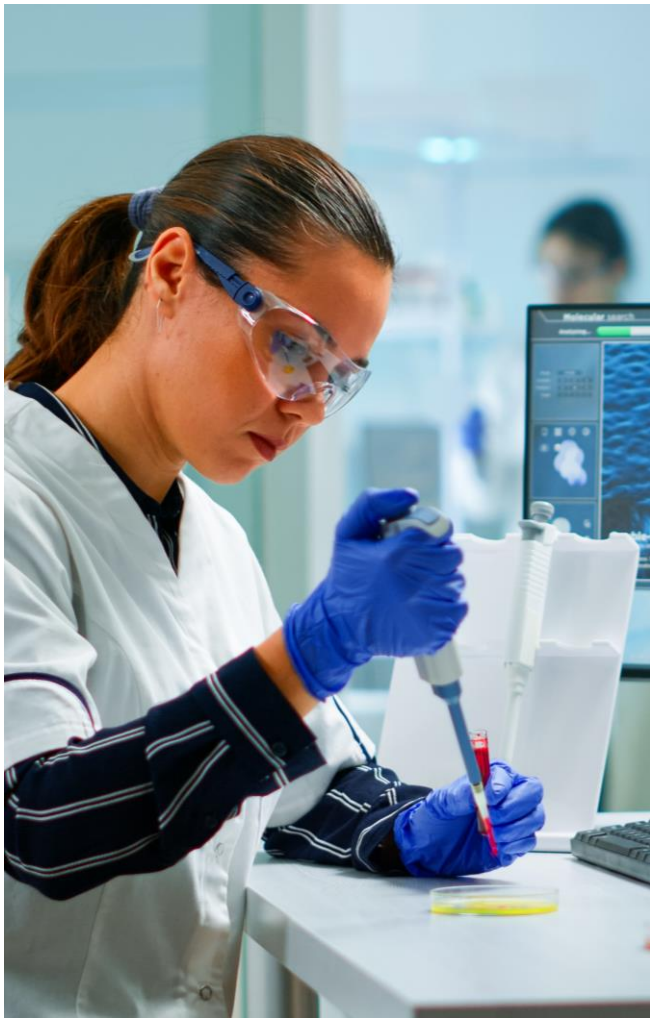
CONCLUSION

Innovation in IVD has evolved rapidly in recent years with no signs of slowing down. Recent developments in point of care, digitalization, and expansion of panel testing/multiplex capabilities provide new avenues for improving early prevention or disease detection. By addressing unmet needs such as accessibility, affordability, accuracy and speed, diagnostics companies can arm consumers, patients, physicians, and health systems with the information they need, ultimately improving health outcomes around the globe.

Clients must take advantage of the knowable market trajectories to identify opportunities and threats and develop strategic options for future portfolios. Ipsos has a global team specialized in medical devices and diagnostics that has a strong history of partnering with clients to uncover trends and develop strategies for meeting the demands of an evolving market. We stand ready to partner with our clients, which include major pillars of the diagnostics as well as new pioneers in the industry, to help identify, optimize, and launch innovative new advancements in diagnostics.



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