

Life Sciences Practice

Digital diagnostics: A path forward for IVD

In vitro diagnostics players are being tested as their offerings are increasingly commoditized. Digital diagnostics offers a path to growth.

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Growth is slowing in the diagnostics industry as historically unmet demand is being met. This is particularly true in areas such as hematology, clinical chemistry, and immunoassays. Over the past decade, for instance, the price of next-generation sequencing has decreased roughly 100-fold.¹ At the same time, new lower-cost players are entering the market, and the consolidation of health systems and group purchasing organizations is driving down net prices (see sidebar, “Current trends in diagnostics”).² Thus, for in vitro diagnostics (IVD) players, simply having a test is no longer sufficient. It’s incumbent on executives to look for the next area of growth.

A great place to look is digital diagnostics, which combines data and analytics with traditional IVD testing to generate new clinical insights and more-efficient workflows. McKinsey research shows that select digital markets adjacent to diagnostics,

including clinical decision support, remote patient monitoring, and population health management, are projected to outgrow the core diagnostics market over the next several years (Exhibit 1). Of course, this value is not only for IVD players to capture. Other players, such as health tech and data companies, are also eyeing the space. However, as developers of data-generating equipment are already being integrated into key clinical workflows, IVD companies have a right to play and could potentially use their position to become key stakeholders in the healthcare delivery ecosystem.

The question is, where are the best opportunities? And how can IVD players move quickly to capture them? In this article, we discuss these questions and suggest some next steps for IVD manufacturers making the move to digital diagnostics.

¹ “Whole genome sequencing cost 2023,” 3billion, December 29, 2022.

² “In vitro diagnostics market size in 2023: \$130 billion,” Kalorama Information, accessed November 8, 2023; McKinsey analysis.

Current trends in diagnostics

Diagnostics is moving from its traditional back-office, pay-for-service role to a critical stakeholder role within the healthcare delivery ecosystem. Three main shifts occurring today give digital and analytics the chance to play a part in transforming the in vitro diagnostics (IVD) industry:

Improving the diagnostic tests themselves.

Health systems are anticipating two main improvements in diagnostics. The first is providing true measurement metrics for outcome-based healthcare. This means going beyond a simple result (for example, hemoglobin A1c is above the normal range) and tying it to key outcomes (X points of reduction in HbA1c means Y fewer complications for patients). The second is bringing these measurements forward to clinicians as insights rather than just as results, applying local context, trends, and patient-specific data points to help clinicians make more-accurate care decisions.

Transforming care delivery. Diagnostics sits at the center of clinical decision making and therefore is a critical component of enabling care delivery in the future. There are three main elements of future care delivery, the first of which is new care models, such as home and virtual care. As health systems evolve these care models, diagnostics will have to define new workflows and tests that enable remote care without sacrificing quality. The second trend in care delivery is an increased focus on prevention. This necessitates new IVD tests that can help screen patients more accurately and in a cost-effective manner. For example, a molecular colon-cancer screening test powered by algorithms could improve accuracy and enable earlier detection. Finally, personalized medicine (selecting the right treatment based on patient data) will be critical to improving care delivery. Here, IVD players will need to screen new diagnostic panels that will allow physicians

to select the right therapy among increasing options for patients.

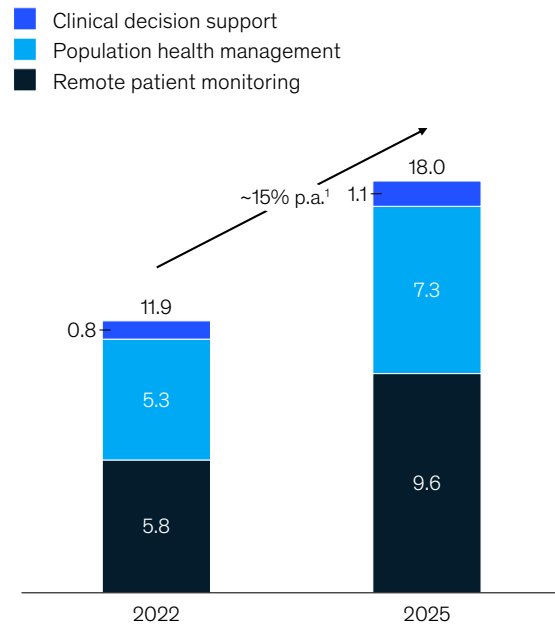
Expanding the remit of diagnostics within healthcare.

Broader applications of diagnostic tests beyond disease identification will generate tremendous impact, both for IVD players and for society. The most vivid example of this is that diagnostics can be used as a primary line of defense for future pandemics and related health emergencies (such as bio threats). Furthermore, diagnostics can increase the efficiency and effectiveness of drug development. This allows for more-targeted medical therapies as well as companion diagnostics to identify patients who are most likely to benefit from a specific treatment or who are at risk of an adverse event due to a therapy, enabling the selection of a more appropriate alternative.

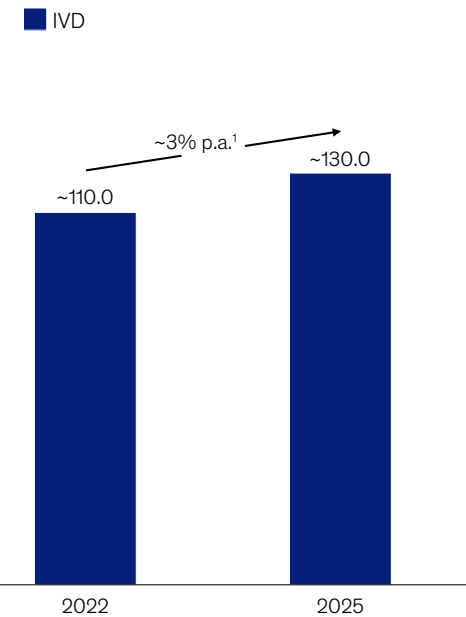
Exhibit 1

Digital markets adjacent to diagnostics are projected to outgrow the core diagnostics market.

Select global digital market sizes, revenues, \$ billion



Global in vitro diagnostics (IVD) market size, revenues, \$ billion



¹Per annum.

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Where to play in digital diagnostics

Any new diagnostic test or solution, digital or not, must meet three criteria to be successful:

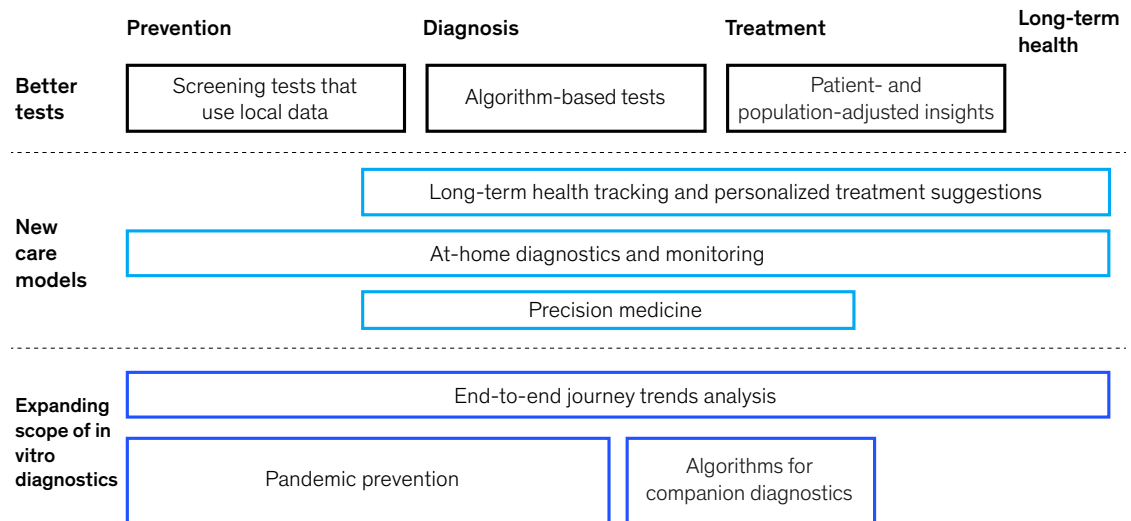
Deliver real, quantifiable clinical value

New digital diagnostics solutions must provide value that health system leaders can easily understand—for example, clearly improving patient outcomes. So while better sensitivities and specificities are great, incremental improvements in these metrics often do not translate into better outcomes because of factors such as inefficiencies within the patient treatment journey and the natural fluctuations of many biomarkers, which limit the diagnostic impact of a test. Instead, ensuring the

appropriate use of a diagnostic test and facilitating its interpretation—and, where necessary, applying patient- and population-specific context—can lead to a greater improvement in outcomes. Therefore, the first step in exploring digital diagnostics is to define where an IVD manufacturer can provide differentiated clinical value. Potential ways to do this exist across the patient journey, including developing screening tests that use local data, providing long-term health tracking and personalized treatment suggestions, and developing algorithms for companion diagnostics (Exhibit 2).

Exhibit 2

IVD manufacturers can provide differentiated clinical value across the patient journey.



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While stand-alone use cases may be sufficient, multiple use cases across the patient journey often need to come together to deliver value. Consider cholesterol testing, which currently occurs at various points across a patient's health journey. A physician then translates the test results into cardiac risk based on a score (often the Framingham criteria). Digital diagnostics can use that risk to assess overall health across the longer term, tracking not just cholesterol but also other blood tests and results. Based on that profile, digital tools can provide tailored recommendations for patients and track those outcomes, resulting in better care. Delivering this end-to-end value requires multiple use cases—patient- and population-adjusted insights, long-term health tracking and personalized treatment suggestions, and at-home diagnostics and monitoring. Diagnostic players, therefore, have to think differently about how to piece together the right use cases and participate more broadly in the health journey, whether organically or through partnerships and M&A.

Integrate effortlessly into clinical workflows

New tests and solutions would benefit from either being integrated seamlessly into existing workflows or through introducing simpler, more efficient workflows. With today's healthcare environment facing worker shortages and burnout, health systems will not be interested in adopting new diagnostics systems that create more work for the organization.

Imagine a new solution for prevention: an at-home test that screens for various common pathologies such as the flu, COVID-19, and strep. All the workflows would need to be in place for this system to be adopted. Data would need to be connected to electronic medical records, appropriate telehealth connections (synchronous or asynchronous) would need to be made, and insights or reports that physicians could easily digest would need to be generated. IVD players may not be able to own all the workflow components (such as telehealth), and they will need to carefully assess where and how to participate to ensure smooth workflows and maximum adoption.

Be cost-effective for health systems

Cost should be a top priority, especially in the near term given inflationary pressures on health systems. IVD players need to be able to communicate hard cost-effectiveness metrics—such as costs of materials and required personnel—to healthcare practitioners (HCPs), laboratories, and other customers.

How to play within digital health ecosystems

IVD players can choose not only where in the patient journey to add value but also how best to deliver digital diagnostics in these areas. These players are well positioned to lead across each type of delivery, but the value of digital varies depending on the type of IVD data generated and the type of offering that an IVD player provides. Certain types of offerings have more value for certain types of data (Exhibit 3).

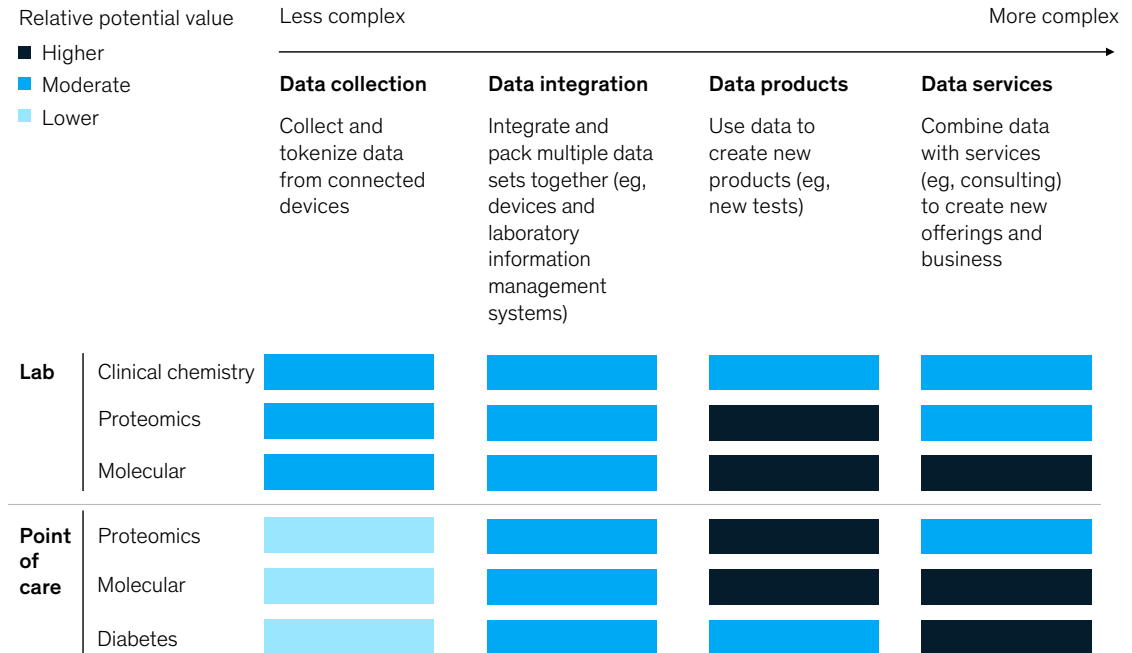
Data collection. Many IVD players are already collecting data. How can they best leverage it? Broadening connectivity across IVD devices to enable centralized, standardized data collection could provide more-powerful data sets to run analytics, understand trends, and manage populations holistically across sites of care. This is particularly valuable for lab players that can generate massive amounts of data across the population.

Data integration. IVD players may not have all the data required to pursue a key use case, so they may need to look at options for combining data sources—either through acquiring data or by acting as middleware (for example, connecting software). Acting as an integrator can then unlock new use cases, whether directly for IVD manufacturers (see the following section on data products) or for customers (for example, payers and health systems) that are eager to acquire larger, more-complete,

IVD players can choose not only where in the patient journey to add value but also how best to deliver digital diagnostics in these areas.

Exhibit 3

In vitro diagnostics players can monetize data through a variety of offerings.



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and more-comprehensive health data sets. The value of data integration increases as more of the patient journey is connected, with diagnostic data being among the most critical components.

Data products. Data-dependent products may be where diagnostics players have the most experience, such as next-generation sequencing, companion diagnostics, and liquid biopsies. However, data products can be more than just algorithms powering a diagnostic test result. IVD players could potentially create customer-facing products that improve clinical decision making, provide a better user experience for clinicians, and streamline operations for IVD customers across sites of care. Data products have been successfully employed for molecular diagnostics (for example, Cologuard from Exact Sciences)³ but could be equally valuable for proteomics—especially multiplexed or ultrasensitive proteomics.

Data services. Moving beyond products to provide services may seem daunting, but IVD players may be very well positioned among medical technology players to achieve this. Pairing appropriate services with real-time data from devices could provide significant value, such as by providing real-time guidance for clinical management, testing cost management, or predicting repairs.

How to get started on digital diagnostics

Digital diagnostics can be challenging because it requires IVD players to build new capabilities (such as connectivity and data analytics), navigate a complex data regulatory environment, and clearly articulate a value proposition that resonates with customers, who are often skeptical. With that in mind, five moves underpin a successful strategy for pursuing digital diagnostics:

³ "Cologuard," Exact Sciences, accessed November 8, 2023.

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Define a clear digital strategy linked to clinical care.

The strategy should explicitly link digital solutions to meaningful improvements in clinical care from the perspective of both outcomes and cost. Too often, organizations focus on how to “monetize” digital and data, prioritizing what customers will pay for in the near term. The reality is that customers (including labs and hospital systems), end users (such as clinicians), and, increasingly, patients themselves aren’t interested in digital for digital’s sake, but they will pay for better outcomes and cost savings.

Be customer-centric, and engage customers in the right way.

IVD players should let their customers guide them based on their needs, which can range across applications (for example, cardiac risk), capabilities (data analytics), and infrastructure (connectivity and the cloud). By working closely with customers to iterate, IVD players can tailor products and ensure uptake early on.

Don’t do it all yourself. Find the right set of partners early and invest at scale. Many data-enabled businesses fail to scale, often because the IVD player has no natural ownership of certain aspects of the solution, such as cloud hosting and cybersecurity. The right partners can bridge those gaps and accelerate a scale-up while allowing the IVD player to focus on the value driven by the diagnostic data.

Begin moving your organization’s operating model to a digital one.

Early in the process, move toward a product operating model that links product development, software development, and customer-centric iterations.⁴ Ensure clear product ownership with multidisciplinary pods to create end-to-end solutions.

Develop and refine a regulatory strategy.

Regulatory requirements for the use of digital in diagnostics are evolving. It’s essential to have a clear plan that outlines factors such as what components of the ecosystem are or are not software as a medical device and what features have a clear regulatory approval path. This plan should be aligned with the latest guidance from regulatory bodies, especially for any data models that will need to be updated or modified based on regional or country-level data regulations.

Many IVD players are likely worried about growth and interested in making use of the vast data sets they have access to. By determining where and how to play in digital diagnostics and approaching strategy in the right way, they can put these natural resources to use and get on the path to growth.

⁴ “For more on product operating models, see Ross Frazier, Naufal Khan, Gautam Lunawat, and Amit Rahul, “Products and platforms: Is your technology operating model ready?,” McKinsey, February 28, 2020.

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