

US Healthcare Trends Impacting Molecular Diagnostics



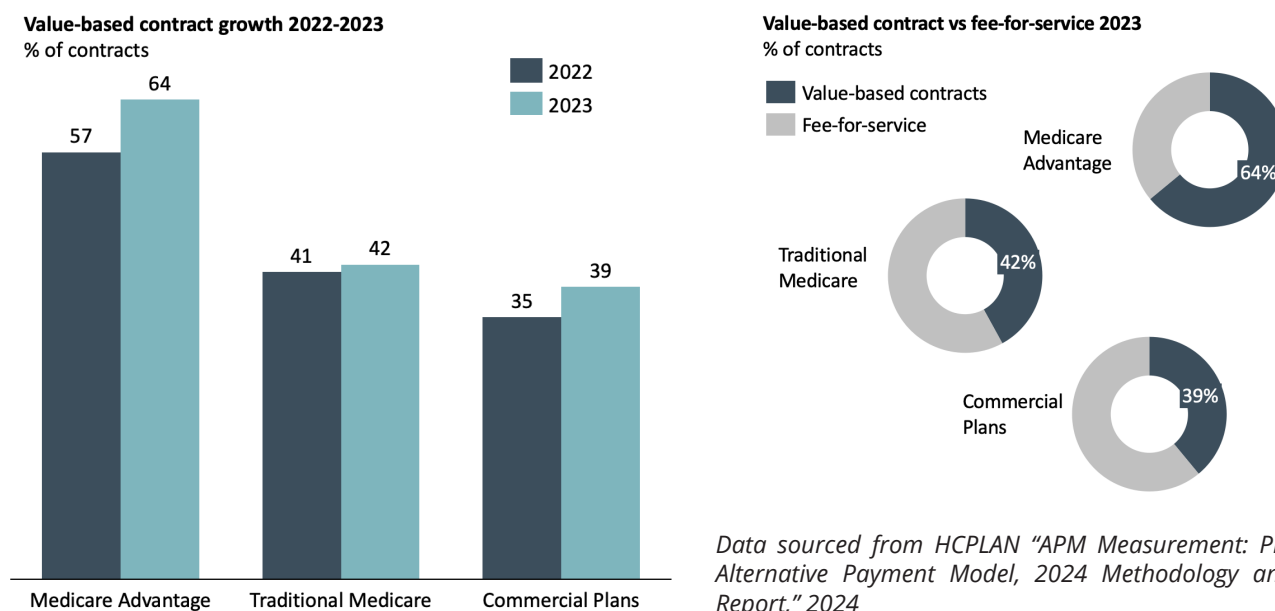
Healthcare Macrotrends

In 2025, the US healthcare market will continue to face challenges around the rising cost of care, with almost half of healthcare executives surveyed by Deloitte citing consumer affordability as a significant trend that will impact their systems 2025 strategy. In addition to cost, other barriers to care, such as proximity to providers and provider shortages can worsen population health outcomes and further strain health systems. To address these issues, health systems are prioritizing preventative medicine, with some moving toward value-based care models that incentivize preventative care or working to bring healthcare closer to the patient. Molecular diagnostics supports both of these trends by facilitating early diagnosis and treatment to prevent future complications and illness progression. As such, these shifts in the healthcare landscape will impact where and how molecular diagnostics are deployed and reshape the go-to-market strategies diagnostics companies should consider.

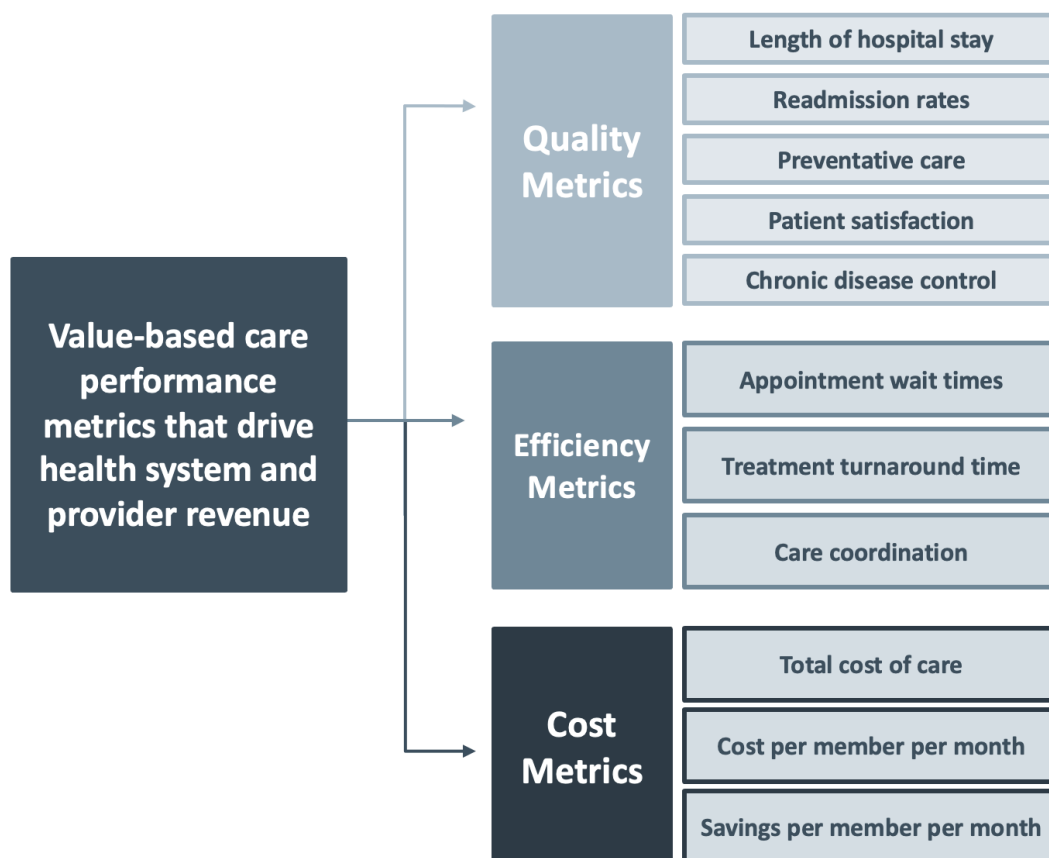
Changes in Healthcare Delivery Models

The growth of value-based care: As healthcare costs rise for consumers, value-based care has emerged as a care delivery model that compensates providers based on patient health outcomes as opposed to fee-for-service, which compensates based on volume of services. Value-based care contracts evaluate success using metrics like patient satisfaction, reduced hospital readmissions, cost efficiency, and preventative care compliance — all of which work to improve health outcomes and, for most health systems, reduce the overall cost of care.

Value-based care has experienced substantial growth under Medicare Advantage's Value-Based Insurance Design Model (VBID), with studies finding that the model lowered hospital readmission and ED admission rates, particularly for chronic disease care. Despite improved clinical outcomes, CMS is discontinuing its VBID model at the end of 2025, as rising drug expenditures driven by expanded access to care and coverage for a growing population with higher rates of chronic conditions have rendered it financially unsustainable. Still, the model consistently demonstrated that linking infectious disease molecular diagnostics testing to specific clinical outcomes generated cost savings for health systems, largely through reduced hospitalization and critical care needs, as well as faster detection that enables timely intervention. Value-based care has proven successful in both lowering costs and improving clinical outcomes for healthcare plans with more balanced demographics and lower rates of chronic disease compared to Medicare Advantage.



Emphasis on testing with clinical value: A key component of the value-based care model is reimbursement that is based on the value of care, meaning all services – including molecular diagnostics – must demonstrate clinical value. An early and accurate diagnosis of infectious diseases can facilitate preventative measures that lower cost of care by reducing the length of hospital stays, rate of readmissions, and mortality. With timely molecular diagnostics results, patients are more likely to receive the correct treatment early on in their infection which helps to improve clinical outcomes, reduce antimicrobial resistance, and decrease the likelihood of contracting healthcare-associated infections due to a prolonged hospital stay. Value-based care contracts include specific target metrics health systems must meet related to quality, efficiency, and cost which determine reimbursement and additional shared savings or bonuses. To effectively sell under this model, molecular diagnostics companies should work with health systems to understand what contract targets the system is working toward and clearly connect diagnostics platforms to improved performance on priority metrics.



Bringing Infectious Disease Testing Closer to the Patient

Growing market for point-of-care testing: Point-of-care testing has grown significantly following the COVID pandemic as health systems prioritize bringing testing closer to the patient in order to increase testing accessibility and alleviate the burden on hospital systems. Outpatient upper respiratory testing has materialized in urgent care and primary care settings as well as at home, which facilitates early diagnosis and treatment, particularly for medications (e.g., Paxlovid, Molnupiravir) that need to be started within a specific time frame for maximum efficacy. While this COVID-induced trend is most pronounced in upper respiratory testing, recent FDA clearances suggest that diagnostics companies are increasingly investing in point-of-care STI panels. Over-the-counter testing kits such as those targeting *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG) infections have the potential to expand customer reach due to existing accessibility challenges and stigma around STIs that lead to low screening rates.

Reimbursement landscape: One challenge that diagnostics companies will need to overcome is unfavorable shifts in the reimbursement landscape, which have impacted the upper respiratory testing space in particular. When the federal public health emergency for COVID ended in May 2023, private healthcare plans were no longer federally mandated to fully reimburse COVID testing. Some payers have also imposed limits on the number of pathogens that are eligible for reimbursement on a multi-plex panel. For example, CMS still covers respiratory panels with 3-5 targets, but does not cover panels with 6-25 targets in outpatient settings. With lower reimbursement rates, providers in the outpatient setting are less likely to perform upper respiratory tests, particularly larger panels.

Positioning in an Evolving Market

Rising costs of care, accessibility challenges, and physician shortages will result in changes to healthcare delivery which is likely to impact the infectious disease molecular diagnostics market. As delivery models move away from traditional fee-for-service, companies that demonstrate the clinical value of their panels and can clearly link that value to reduced cost of care will be advantaged. Given reductions in upper respiratory reimbursement, it will be important for diagnostics companies to offer smaller panels to the outpatient market as well as diversify CLIA-waived panels and at-home testing kits beyond upper respiratory to expand customer reach.

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