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2025 Data Is In: Diagnostics Is Having a Renaissance

The diagnostic industry, a perpetual valuation laggard to higher-profile subsectors of the life sciences, with a short-lived exception during the height of COVID-19, may finally be having a moment. Reflecting this optimism, industry experts on a recent Arizona State University online seminar highlighted the success of a group of rising young and increasingly profitable tech-enabled diagnostics companies, labeling them the “Terrific 10,” a moniker that references the tech industry’s “Magnificent 7.”

WENDY DILLER

For most of the past 30 years, diagnostics has been the stepchild of the life sciences industry, in terms of investment, reimbursement, and valuation both in clinical care and on Wall Street. In 2021, during the height of COVID-19, capital suddenly flowed into the sector in record amounts, however, and broad public recognition of its importance surged.

But that was short-lived. Then came the withdrawal. The years 2022 through 2024 were, to put it mildly, dark.

What a difference a year makes. At least that was the sentiment from a February 7 “Year in Review” online seminar summarizing the industry as of year-end 2025 and presented by the Biomedical Diagnostics Design program of Arizona State University (ASU). Three speakers from Illumina Ventures and the consulting firm Health Advances (HA) backed their enthusiasm for the future by pointing to leading

companies’ increasing financial health and interest in building new kinds of business models based on emerging technologies and data.

Technological advances, reimbursement, and regulatory wins, notably loosening regulations for laboratory-developed tests (LDTs), and the growing embrace of companion diagnostics (CDx) by the pharmaceutical industry, paved the path for the diagnostics industry’s “landmark year” in 2025, according to the panelists. They called out “The Terrific 10,” a group of companies that they define as a new generation of industry leaders (see *Figure 1*).

These “sequencing-forward” companies are adopters of next-generation sequencing (NGS), advanced multiomic and computational platforms that offer improved performance of existing tests and provide clinicians with previously unavailable information that has the potential to open entirely new doors in medicine.

“2025 was tremendously exciting for the diagnostics industry,” said Mara Aspinall, founder of ASU’s diagnostics program, the only one of its kind in the US, and a partner at Illumina Ventures. Aspinall, who has long experience as a leading executive in the diagnostics industry, and who has been a vocal champion for the sector for decades, started off the program stating, “I’ve been

in this industry a long time, and I've never seen a situation like this, with so many people" on Wall Street enthusiastic about its upside potential.

Mergers and acquisitions deal value set a record in 2025, with mega-deals of greater than \$1 billion totaling \$60.2 billion, almost as large as the value of the combined last decade of deals, according to the year-end review, which used data compiled by TD Cowen. These acquisitions included the purchases of Hologic by Blackstone and TPG, Waters by **BD**, and Exact Sciences by **Abbott**, as well as Nova Biomedical by **Advanced Instruments** (see Figure 2). In comparison, 2021, the year with the second-highest deal value, saw the acquisition of four companies totaling \$17 billion. In 2023 and 2024, zero mega-deals took place in the industry.

2025 also saw a strong, albeit not record-setting, demand for smaller deals valued at less than \$1 billion, with 23 transactions

averaging \$192 million in value. (These figures exclude deals where financial terms were not disclosed.)

While acquirers last year were well-established, mature diagnostics companies and a private equity firm, notably, the rising powerhouses comprising the Terrific 10 also have "firepower," that is, sustained and sufficient resources to pursue their own significant deals, which is essential for industry stability and growth, Aspinall said. (TD Cowen defines firepower as the sum of current cash balance, 20% of current market cap, and incremental debt capacity, assuming a 4 times maximum net debt/EBITDA leverage ratio.)

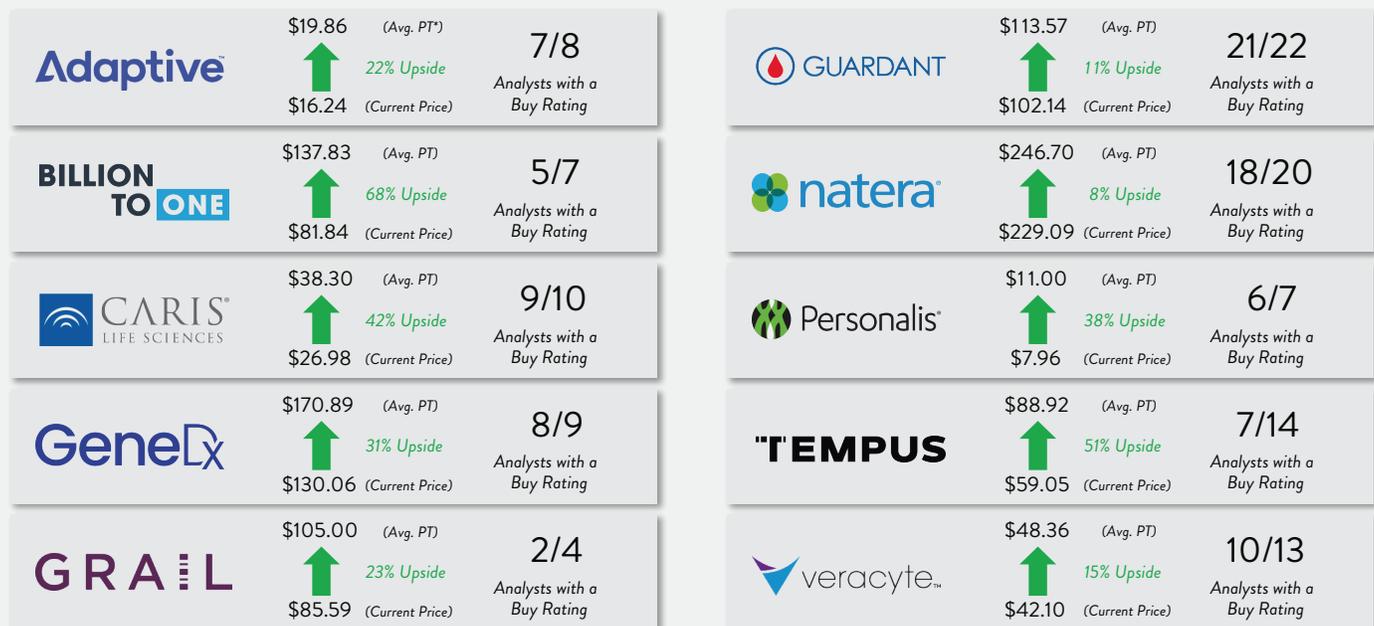
These companies reflect five key characteristics, according to Aspinall: their product portfolios consist primarily of LDTs targeted at high-value opportunities and large indications; their tests aim to have significant clinical impact that changes treatment processes; they do not

rely on traditional laboratory technologies for revenues, but instead offer proprietary, innovative platforms based on NGS and multiomics; they focus on market access very early in test development; and they are incorporating artificial intelligence (AI) deeply into their strategy, for example, creating their own foundation models. "These companies are changing the definition of diagnostics," she continued.

The general diagnostics stock index was up 8% in 2025 from 2024, with large cap companies (market caps >\$1 billion), while the index subset representing small public companies (market caps <\$1 billion), battered particularly hard in recent years, rose 13%.

IPO activity, an indicator of future liquidity options for early-stage investors, also improved in 2024 and 2025, from the dismal performances of the past five years, which saw either zero activity or debuts that subsequently floundered in

Figure 1
The Terrific 10: "Sequencing-Forward" Companies



*PT=Analyst price targets and ratings based on available research.

Sources: Illumina Ventures; Bloomberg; company websites; and Capital IQ as of December 31, 2025

the aftermarkets. There were zero IPOs in 2022 and 2023. The four companies that went public in 2024 and 2025, in contrast, are doing “very, very well,” Aspinall pointed out. The poorest performer, **Caris**, is up 30% over its IPO price, and **Grail**’s stock is up 300%. “The opening of the IPO window is critical going forward,” she added.

The Message Is Success, But Challenges Loom

Despite the rosy picture, the industry still faces challenges. Venture capitalists and early-stage investment continue to lag, with the average amounts of money put into early-stage diagnostics down year-on-year from 2024 to 2025 and flat deal prices, along with a slight decline in volume.

The speakers didn’t dwell on early-stage investors, but notably this assessment is backed by HSBC’s well-respected annual report, released January 8 in advance of the 2026 JP Morgan conference. The

report calculates that early-stage investment in diagnostics (defined as seed or Series A first financings totaling \$2 million or more) struggled for much of 2025, due largely to macro conditions, weak M&A, and a closed IPO market. Activity surged in the fourth quarter, as several recent IPOs performed well in the aftermarket, notably **Billion to One** and **Heartflow**.

Other pressures on the sector include relentless reimbursement limits, particularly for traditional, commodity laboratory testing. Payors are tightening their coverage policies, although LDT and ADLT (advanced diagnostic laboratory tests, which are highly complex and the category for many of the breakthrough technologies driving the industry’s financials) rates remain steady; while biomarker use is rising, the opportunity remains poorly penetrated and clinical knowledge about diagnostics is still subpar, despite technological advances.

In an interview with *MedTech Strategist* following the webinar, Gary Gustavsen,

a partner at HA, head of its precision medicine practice, and one of the three panelists, pointed out that while the new biomarkers are exciting and driving investor interest in the Terrific 10 and other advanced diagnostic testing companies, the clinical utility of many by and large is unproven, even if they have CPT codes.

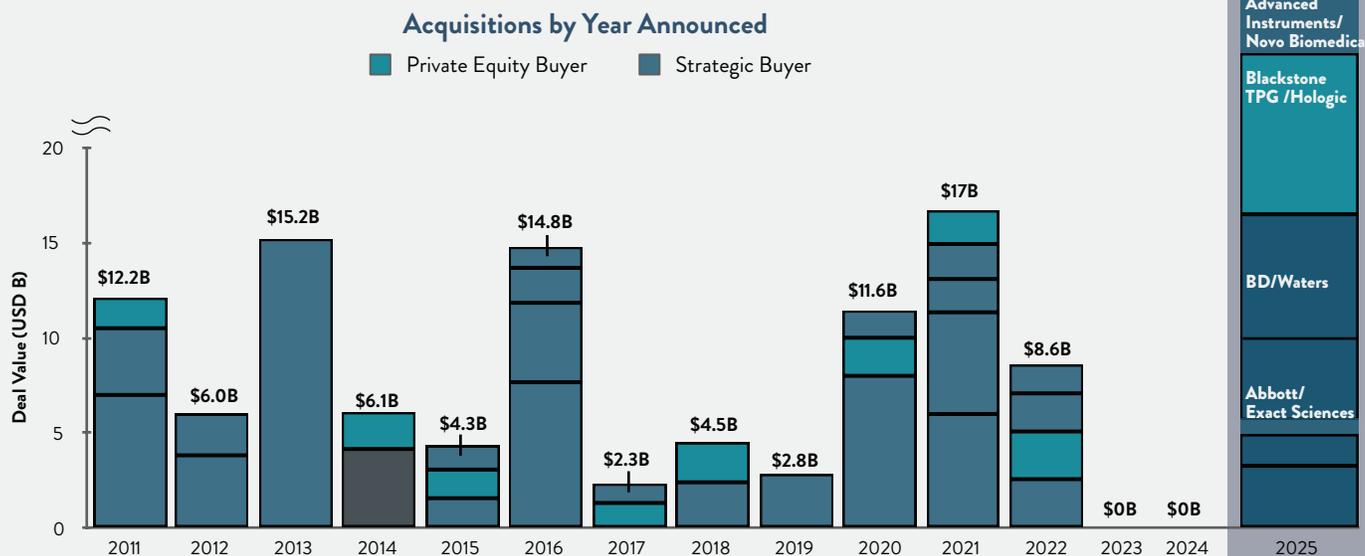
The health of the Terrific 10 and other rising stars in the industry is based more on investor interest and optimism than on sales generated from these tests, pointed out Donna Hochberg, a partner and managing director at HA, who was also on the panel. That said, she noted, “There were a lot of firsts and big activity amongst this cohort.”

Robust Trends, FDA Approvals Behind Diagnostics’ Growth

Trends highlighting 2025 and cited by panelists include:

- Multiomics and genomics combined to make better and

Figure 2
M&A: Industry Transforming Acquisitions (>\$1 Billion)



Source: Illumina Ventures

more effective tests, opening new opportunities for cancer, neurology, and soon, immunology.

- Less invasive techniques, led by liquid biopsies, opened new clinical horizons as new markets and primary care and new industry leaders combined to adroitly apply innovative technologies to address unmet clinical needs.
- US regulatory restraint permitted existing and innovative LDTs to flourish, ending a prolonged period of regulatory uncertainty as a federal district court vacated the FDA's final rule on LDTs and the Trump administration declined to appeal the ruling.
- AI and proprietary clinical data are laying the foundation for

new, high-value tests, enabling the top companies to operate at the intersection of wet and dry laboratories, building proprietary foundation models, and monetizing data through clinical care and drug development partnerships.

- Investor interest in diagnostics is energized, as M&A deal cumulative value reached a record, driven by strategic consolidation.

Among 2025 FDA diagnostic device approval firsts are:

- A blood test for early detection of Alzheimer's disease (**Fujirebio Diagnostics**, Lumipulse G pTau217/β-amyloid 1-42 Plasma Ratio assay for early detection of amyloid plaques associated with Alzheimer's disease

in symptomatic adults 55 and older).

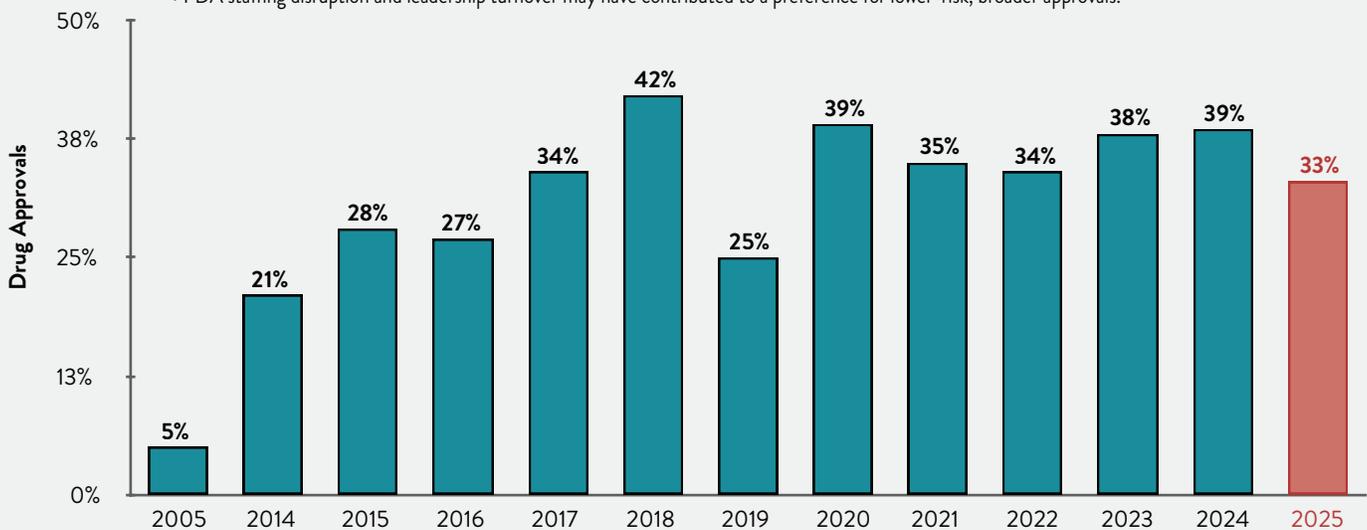
- An entirely at-home, prescription-free test for the most common sexually transmitted diseases (**Visby Medical's** Women's Sexual Health Test).
- The first over-the-counter wearable, cuffless blood pressure monitoring device (Switzerland-based **Aktiia** makes the Hilo Band or GO Blood Pressure Monitoring System).
- The first direct-to-consumer test for risk of celiac disease (**Target Genomics' GlutenID**).
- The first mass spectroscopy test categorized by CLIA as moderately complex (**Roche's** cobas

Figure 3

Biomarker-Dependent New Drug Approvals as % of All Drug Approvals

Why 2025 change:

- Biomarker dependency is heavily driven by oncology volume, and 2025 was not an oncology-heavy year.
- Many 2025 approvals were vaccines, antibiotics, and broad chronic disease treatments that do not require biomarkers.
- Companies appear to be launching with broader initial labels, rather than ultra-narrow biomarker-specific indications unless required.
- FDA staffing disruption and leadership turnover may have contributed to a preference for lower-risk, broader approvals.



Note: When evaluating NMEs (new molecular entities), PMC (Personalized Medicine Coalition) categorizes personalized medicines as those therapeutic products for which the label includes reference to specific biological markers, often identified by diagnostic tools, that help guide decisions and/or procedures for their use in individual patients.

Source: Illumina Ventures

WHAT'S NEW



- Notified Bodies Raise Red Flags
- Optimizing IP Strategy
- Cardiac Ablation in More Places
- Netherlands Spotlight



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lonify 25Hydroxy Vitamin D total assay).

- The first at-home HPV self-collection device (**Teal Health's** Teal Wand), and first multi-modal benchtop point-of-care platform integrating central-laboratory chemistry, immuno-assay, and hematology panels (**TruVian's** TruVeris platform).

Pharma's Fading Reluctance to Embrace CDx

Biopharmaceutical companies' decades-long entrenched resistance to companion diagnostics except in certain oncology indications is declining as it increasingly is willing to invest in biomarker development for broader oncology indications, neurology (CNS), and, at a slower pace, for immunology, as new drugs come online. The full embrace of CDx in oncology is spurring drug developers to hedge more bets in other therapeutic areas, said Gustavsen.

Several factors account for their current interest. The FDA's new, proposed reclassification of companion diagnostics from Class III to Class II devices will make the regulatory path forward easier for these tests. Importantly, as medicine moves from small molecules and traditional monovalent antibodies to more complex, multimodal, advanced treatments, with regulatory approvals faster than expected, the pharmaceutical industry is having a rethink (see Figure 3).

Seven classic biomarkers account for two-thirds of FDA-approved CDx biomarkers for lung and several other cancers, and a majority of these were sponsored by three well-established, large diagnostics companies: Roche Diagnostics, **Dako**, or **Qiagen**, said Hochberg. This scenario presents a future consolidation opportunity for the industry, given pharma's predilection for choosing partners experienced in IVD (*in vitro* diagnostic kit)

regulatory submissions, and the lack of regulatory track records among emerging companies that are responsible for some of the field's most promising, innovative, and complex biomarker modalities. "Getting the best of both worlds might entail larger companies buying smaller diagnostics companies," Hochberg noted.

The groundbreaking 2024 CDx collaboration between **AstraZeneca** (AZ) and Roche Tissue Diagnostics, is an example of the potential of these partnerships. AZ and Roche are co-developing and commercializing a biomarker, TROP2-QCS CDx, using AZ's innovative computational pathology platform to predict patient response to datopotamab deruxtecan for non-small cell lung cancer. The drug, which is co-developed by AZ and **Daichi Sankyo**, is in Phase III clinical trials, with a readout expected later in 2026.

The collaboration is noteworthy because of the complexity of AZ's diagnostic technology, and because until now, standard IHC TROP2 testing has not correlated to patient response to therapy at all, said Gustavsen. Results from an exploratory analysis of the Phase III trial showed TROP2 as measured by AZ's proprietary computational pathology platform, quantitative continuous scoring (QCS), was highly predictive of clinical outcomes in patients with advanced or metastatic NSCLC who received datopotamab deruxtecan. This technology captures information that a pathologist working alone could not, he pointed out.

Despite these successes, it is hard to know if the Terrific 10 or other companies are generating profits from advanced CNS tests, although they are well capitalized due to the sustained commitment of investors who see their potential. "There still is insufficient data on the uptake of these tests. The answer is probably yes, but it is exceedingly early, with the first one just approved," said Hochberg. 