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The IVD industry is recalibrating as financing availability and valuations revert to pre-pandemic levels, following an unprecedented period of access to capital. Companies are having to do more with less, and the situation could get worse. Diagnostics, however, is too important an industry for investors to ignore, and an investor's goal is spotting the right opportunities for rewards.

CRAIG STEGER, ODED BEN-JOSEPH, PHD, AND CAREY GALLANT, OUTCOME CAPITAL, AND WENDY DILLER

During the COVID-19 pandemic, the US government imposed sweeping pandemic measures on the nation allowing millions of Americans to receive free tests, vaccines, and treatments aimed to prevent spread of a potentially life-threatening, highly contagious disease. These COVID-19 emergency declarations will end on May 11, marking a close to the US response to the global pandemic.

With the end of the pandemic, the *in vitro* diagnostics (IVD) industry is confronting a reckoning—one that was predictable but is still painful. After peaking in 2021, IVD financings, particularly for early-stage companies, are tight, valuations are coming down, and deals, regardless of subspecialty, are smaller in size and volume, according to Outcome Capital's latest survey highlighting trends in the IVD industry from the second half of 2021 through year-end 2022. The downward trends are in line with experiences throughout much of the life sciences industry, but strike particularly hard at the IVD industry, which flourished to a remarkable degree from the enormous influx of funding and demand for COVID testing. Additional funding and resources from the government helped

get start-ups in the field, which otherwise might never have made it off the ground. (*See "Diagnostic Financings Are Robust, Fueled by COVID-19 and Precision Medicine,"* MedTech Strategist, *December 15, 2021*.)

Companies ranging from large multinationals to start-ups benefited from investor appreciation for the value, often overlooked, to the field of medicine. The market's unprecedented appetite for test innovation and regulatory flexibility fueled new highs in 2021, outpacing the S&P by greater than 5%. The IVD industry, including manufacturers and laboratory services, generated an estimated $91 billion in 2022, up from $60.7 billion pre-pandemic (2019). We predict that pace will slow to a sustained overall growth rate in the low single digits through 2030, with an estimated CAGR of 3.3%, reaching $119 billion by 2030 (*see Figure 1*). Growth will be stable in the US and Europe and accelerate in the Asia-Pacific region.

That said, much of that expansion will come from large strategic players, of which the top 10 companies in the industry generate 45% of the global IVD market revenues. The financing environment for start-ups, which generate much of the industry's innovation, is once again precarious, as it has been for decades. Overall, the number of financing transactions peaked in the fourth quarter of 2021 through the second quarter of 2022, but we saw the overall dollars invested dramatically decline during that period. Outcome Capital categorizes 60 IVD financings completed in the second half of 2021, and 66 in the first half of 2022, but the numbers tapered off dramatically in the second half of last year, falling to 51 financings. As a result, small- to mid-sized companies, already at the low end of the life sciences financing food chain, must do even more with fewer dollars and resources. A few pockets of opportunity, (e.g., precision medicine laboratories, AI-assisted diagnostic tools) remain due to large unmet clinical needs and technological advances, but investors, traditionally leery of diagnostics, may not take the bait, reverting to pre-pandemic norms or worse.

The numbers reflect these sobering facts. During the 18-month period Outcome Capital surveyed, it found a total of 240 IVD transactions valued at an aggregate ~$31.4 billion. Investment transactions comprised only 17% of these transactions, totaling ~$5.2 billion invested in the industry. That is only ~5% of the total life sciences investment dollars over the same period, highlighting the dearth of investments made in the IVD industry. Not surprisingly, more than 70% of the invested capital went into later-stage or commercially launched IVD companies, of which the majority were diagnostics laboratories. Venture investment in the IVD industry peaked at ~$1.8 billion in the first quarter of 2022 and declined steadily thereafter, ending at ~$400 million in the fourth quarter, with a dearth of early-stage investment becoming glaring by year-end (*see Figure 2*). More recently, family offices, which might have been a lifeline for some companies, are now ultra-cautious as a result of the recent chaos in the banking sector, led by Silicon Valley Bank's demise. The upshot: money for innovation is drying up, and diagnostics start-ups, always disadvantaged, will struggle to do more, with less.

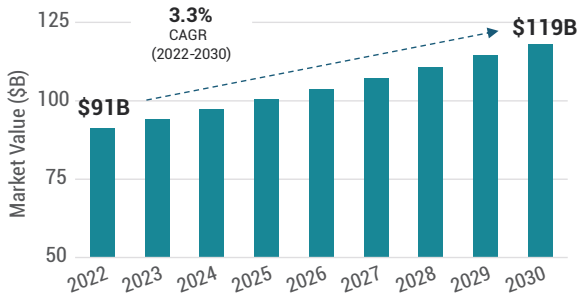
The current market dynamics affected large strategic players, many of which saw double-digit revenue declines in their COVID-19 testing businesses in the past year. These companies, however, have been able to pivot, offsetting those reductions with robust performances elsewhere in their portfolios and, ultimately, growing their top lines in 2022. Many of them—**Thermo Fisher**, **Quidel**, and **Hologic** come to mind—used COVID-19 earnings to undertake transformative M&A and have evolved into very different, yet still healthy, iterations of the entities they were in 2020, when the pandemic first began to grip the world (*see Figure 3*). (*See "The Diagnostics Industry Moves Beyond COVID-19,"* MedTech Strategist, *March 25, 2022*.)

These large strategic players are positioned to drive the industry's long-term outlook, which remains positive, driven by the aging population, growth in chronic and infectious disease incidents, and technological improvements, such as those that enable broader point-of-care, and in many cases at-home, testing. They are likely to continue to place a high value on M&A, but we have seen a change in these transactions as well. During the surveyed period, five major transactions that comprised 85% of the total IVD M&A deal value

Figure 1

IVD Industry Continues to See Sustained Growth Post-COVID

Global In Vitro Diagnostics Market



SELECT KEY PLAYERS

Abbott, BD, Bio-Rad, bioMérieux, Danaher, Exact Sciences, Hologic, labcorp, Qiagen, Quest Diagnostics, QuidelOrtho, Roche, Siemens Healthineers, Sysmex, ThermoFisher Scientific

In Vitro Diagnostics Market Dynamics

Market Segments

- Anatomical Pathology
- Clinical Pathology
- Molecular Pathology
- Point-of-Care
- Diagnostic Laboratories

MARKET DYNAMICS

10 Companies generate more than 45% of the global IVD market revenue

Transaction trends show high value in M&A deals with large, industry altering, acquisitions accounting for a majority of the period's total transaction value

Sustained growth within established (US, EU) markets & significant accelerations within growing (APAC) markets show signs of retracements to 2019 transaction value & volume levels

MARKET DRIVERS

Aging Population: Older populations tend to be at higher risk of age-related diseases that require more frequent testing

Growth in Chronic & Infectious Disease: The increase in chronic & infectious diseases testing is expected to accelerate demand for fast, accurate diagnoses

Technological Advancements: Technology improvements have allowed health care providers to provide in-office or at-home point-of-care (POC) testing

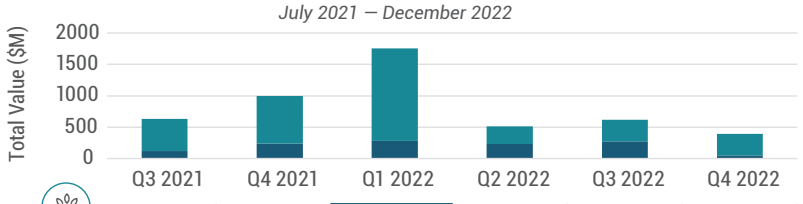
Source: Outcome Capital

Figure 2

Venture Investment Peaked Early in 2022

Total Venture Funding Breakdown: Per Quarter

July 2021 — December 2022



	Q3 2021	Q4 2021	Q1 2022	Q2 2022	Q3 2022	Q4 2022
Late Stage	$511M	$758M	$1,474M	$281M	$342M	$341M
Early Stage	$120M	$239M	$283M	$229M	$274M	$49M

SNAPSHOT

Insight: COVID tailwinds carry lagging investors into Q1 2022

- Total deal value increased by 68% in Q1 2022
- 2.7x increase in later stage average values w/ 8 deals >$100M during 1Q 2022
- Examples: Freenome ($300M) / Billion to One ($125M) / Virtue Diagnostics ($100M)
- Laboratories garnered the majority investor attention
- Significant pull-back in venture appetite for remainder of 2022 as COVID testing decreases

Segment Analysis

July 2021 — December 2022

$5.2B Total Investment

177 Total Transactions

SEGMENT INVESTMENTS*

Molecular Pathology	Diagnostic Laboratories	Point-of-Care	Clinical Pathology	Anatomical Pathology
35%	30%	14%	11%	10%

*Data based on 169 transactions with disclosed deal value.
Source: Outcome Capital

(~$25 billion) occurred. When removed from the analysis, it becomes apparent that deal valuations have also come down across all the IVD segment verticals, with the median acquisition price of $18.8 million. Not surprisingly, diagnostics laboratories, often generating revenue, seem to have the most transactions, potentially showing that most M&A transactions in this industry come after a level of commercial success can be shown.

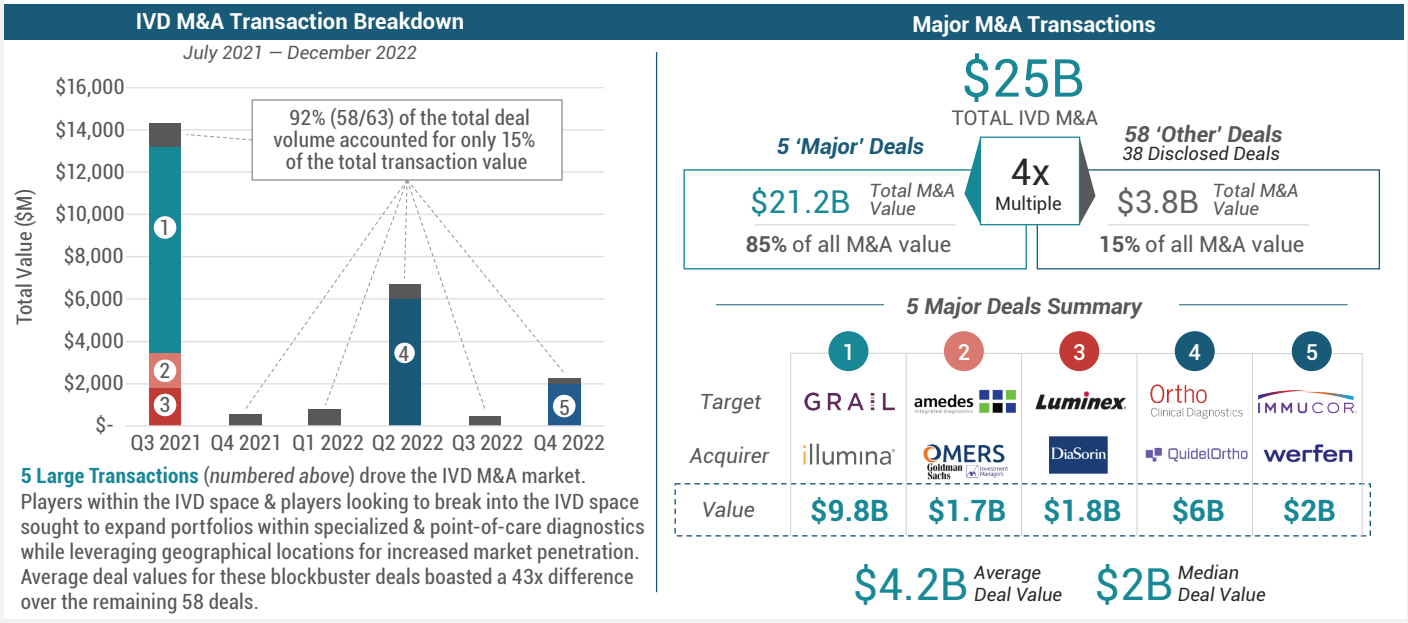
This trend is sobering for mid-sized and smaller companies, whose growth exploded during COVID-19, and which are now up against the brutality of investor sentiment that has turned negative. Just as companies see exit doors narrowing at the same time as COVID-19 revenues decline, investors are pulling back. Both private equity and strategic companies are sitting on cash and poised to step in, but so far, their activities are limited, and they are waiting for valuations to continue to decline as the pandemic recedes. With the initial public offering markets closed, most IVD companies' road to exit is long (~18 years).

The near-term difficulties of smaller companies are highlighted by a few high-profile failures and restructurings, notably **Lucira Health**, which filed for Chapter 11 bankruptcy protection in February 2023, slightly more than two years after receiving the first FDA Emergency Use Authorization (EUA) for a prescription molecular at-home COVID-19 test in November 2020. In February 2023, days after the bankruptcy filing, the FDA granted the company an EUA for the first over-the-counter combination COVID-19 and flu test. Regardless, Lucira, which went public in February 2021, raising $153 million at $17 a share, now has worthless stock; on April 6 **Pfizer** won an auction to buy its assets for an undisclosed price in a transaction that has yet to be approved by the bankruptcy court.

Ellume, the Australian diagnostics company founded at the start of the pandemic, likewise is in the process of being bought by a competitor, **Hough Consolidated**, after its Australian corporate parent filed for voluntary administration in December 2022 (the US subsidiary of the company, which had received roughly $300 million in US government emergency funding during the pandemic, was not part of the Australian filing but is included in the sale). Also in April 2023, **LumiraDx**, a provider of community-oriented point-of-care antigen tests, announced a restructuring and strategic refocusing plan that reduces its workforce by 40% as it concentrates on revenue generation. Other pandemic-era winners such as **Cue Health** are similarly under pressure and in the process of slashing staff and broadening their businesses to include additional categories of tests as well as converting EUAs issued for their COVID tests during the pandemic into full FDA authorizations.

Figure 3

Significant Strategic Transactions Drove Industry Value



Source: Outcome Capital

Diagnostics Is Too Important to Ignore

Amid this market pullback, Outcome Capital emphasizes a number of data-driven takeaways:

- IVD investment sentiment is reverting to pre-pandemic levels. Younger IVD companies in particular must do more with fewer resources.
- The time-to-exit, always a struggle for diagnostics investors, is approximately 18 years. This creates more pressure to progress through to commercial launch of the company.
- Macroeconomics will be a major determining factor for investors and thus for these companies.
- Pockets of opportunity remain bright spots of interest to selective investors (see *Figure 4*). These include:

At-home testing: The FDA is more receptive to at-home, self-collection sampling, and other rapid point-of-care tests now that vendors have proven the use case and value through the pandemic. This market does not seem to support high-cost products, so scaling and manufacturing are important considerations to best manage cost-of-good-sold in this market. (*See "What the NIH RADx Funding Means for Rapid, At-Home Testing Beyond COVID-19,"* Medtech Strategist, *April 14, 2021.*)

Sherlock Biosciences, **Binx Health**, and **LetsGetChecked** are examples of companies that have done deals or financings in this space in the past 18 months and have a reasonable chance of making inroads into what has been a tough, controversial area of diagnostics. Sherlock, itself a start-up, founded in 2019 to bring to market convenient, low-cost CRISPR-based tests, is one of the most active dealmakers. Among other steps, it raised an $80 million Series B in March 2022 and bought consumer-test-oriented Sense Biodection earlier this year for an undisclosed price.

Digital, big data tools, and AI-driven components: The advent of healthtech and healthtech investors means money is going into use of digital tools to enhance traditional diagnostics, particularly for infectious diseases and chronic diseases monitoring. Many of these companies—Delphi Diagnostics and Freenome, for example—have a precision medicine focus. The evolution of computational genomics is also an attractive opportunity, with a subset of companies

Figure 4

M&A Transaction Summary

Transaction Breakdown

COVID has created the at-home market
- POC market will continue to expand to at-home testing market
- New competitive landscape is emerging to capture consumer business

Large transformative transactions
- COVID has provided strategics with strong balance sheets for dealmaking
- Quidel – Ortho Diagnostics has high degree of synergistic overlap making transaction impactful for shareholders

Well managed diagnostic laboratories highly sought
- Both specialty and general diagnostic laboratories are desired
- Businesses have been producing revenue for a sustained time to prove value

Clinical pathology & anatomical pathology segments lag
- General chemistry markets are well established with little growth or innovation
  - Thermo-Fisher acquisition of The Binding Site closed in Jan. 2023 is not included in analysis
- AP segment seeing new AI innovations that may impact future transactions

AVERAGE TIME TO EXIT

18
YEARS

Time from company inception to closing of M&A transaction

AT-HOME TESTING MARKET

>$39B
BY 2030

At-home market expansion (8.7% CAGR)

Source: Outcome Capital

developing supportive software to fuel clinical laboratory applications.

Freenome, a liquid biopsy company, raised $300 million in a Series D in December 2021. The company is in late-stage clinical trials for a blood-based test for early detection of colorectal cancer, developed using multiomics and expertise in molecular biology and advanced computational biology and machine learning. (*See "Diagnostics Outlook 2021: Freenome CEO Gabe Otto on Liquid Biopsies,"* MedTech Strategist, *January 18, 2021.*)

Delphi Diagnostics, founded in 2019, is leveraging machine learning and recent discoveries in the genome-wide fragmentation profiles of cell-free DNA to pioneer a new class of more affordable and highly sensitive liquid biopsy tests. The company, distinguished by the track record of its world-renowned leadership team, raised $225 million in a Series B in July 2022, an exceptional amount given current market conditions.

Delphi is flourishing, even as another young company co-founded by Delphi CEO and co-founder Victor Velculescu, Personal Genome Diagnostics, was bought in 2022 by **LabCorp** for $450 million plus milestones. PGDx makes an advanced platform that enables hospital laboratories to perform a range of liquid biopsy and tissue-based genomic tests rapidly and inexpensively. And while it is not part of the Outcome Capital analysis, **Mercy BioAnalytics**, which is developing extracellular vesicle-based liquid biopsy tests for early detection of cancer, raised a noteworthy $41 million in a Series A in April 2023—a respectable sum that is worth flagging in a tough market.

Specialty diagnostics laboratories: The continued emergence of precision medicine is a particularly bright spot. Continued progress in cancer diagnosis, monitoring, and treatment along with transplant medicine and neurodegenerative diseases diagnosis are areas of growth and innovation that are gaining interest from the investment community.

Given the current environment, diagnostics companies need to plan more carefully and frugally for a future M&A transaction and work to that exit. With the reversion to pre-pandemic venture sentiment for the IVD industry, and the nonexistent IPO market for these companies, at least for the foreseeable future the strategy must be to build toward an eventual acquisition and be realistic about what it can achieve for that exit. Despite the gloomy assessment, the IVD industry is too important, both financially and clinically, to ignore. MTS

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