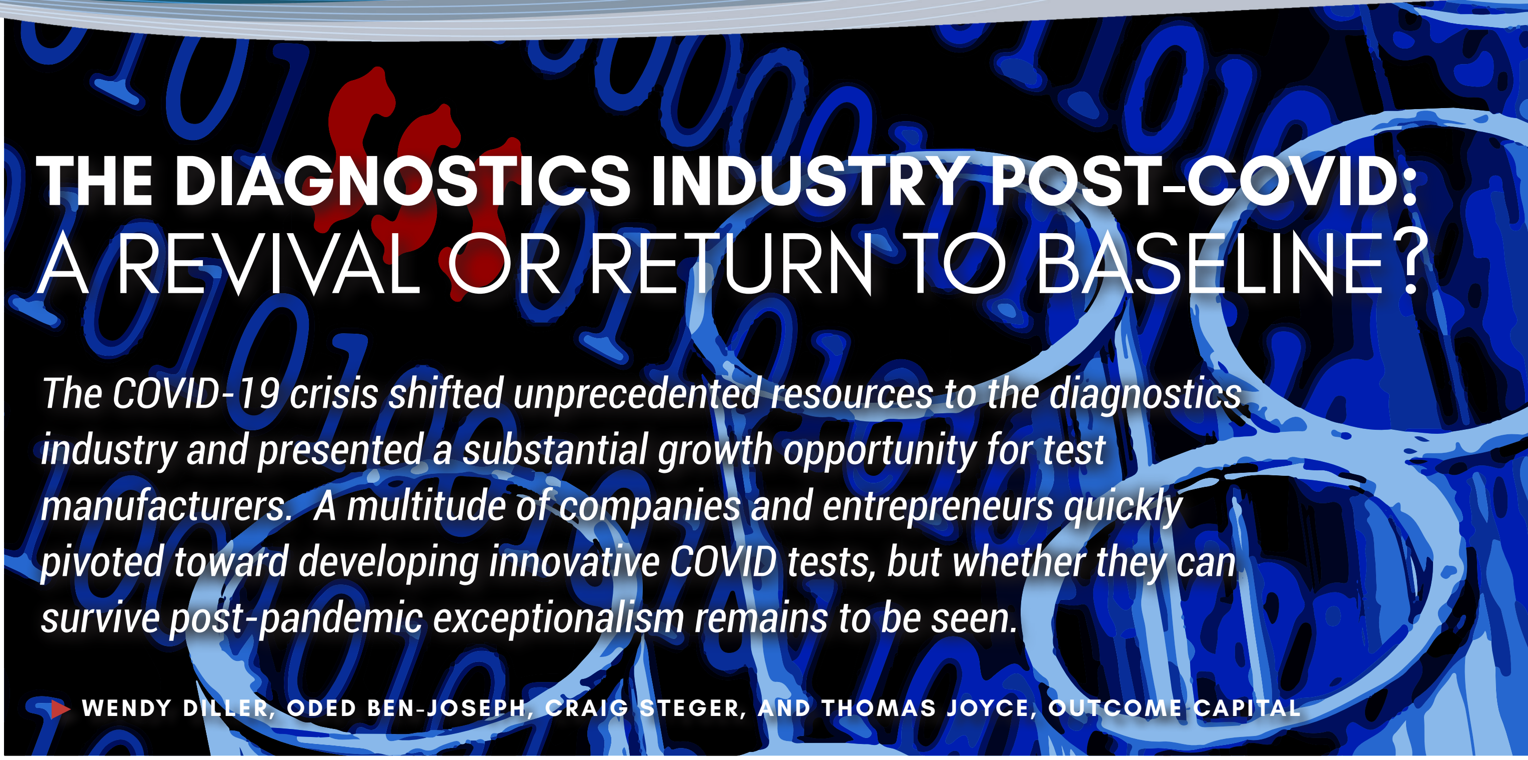

THE DIAGNOSTICS INDUSTRY POST-COVID: A REVIVAL OR RETURN TO BASELINE?

The COVID-19 crisis shifted unprecedented resources to the diagnostics industry and presented a substantial growth opportunity for test manufacturers. A multitude of companies and entrepreneurs quickly pivoted toward developing innovative COVID tests, but whether they can survive post-pandemic exceptionalism remains to be seen.

WENDY DILLER, ODED BEN-JOSEPH, CRAIG STEGER, AND THOMAS JOYCE, OUTCOME CAPITAL

The urgent need for COVID testing, coupled with excitement about technological innovation, resulted in an unprecedented capital flow into diagnostics companies in 2020; $5.3 billion compared with $2.3 billion in 2019, with about 30% of investments related, in some way, to COVID-19. The influx of non-traditional investors into the segment further buoyed diagnostics financings. Nevertheless, diagnostics as an investment proposition remains problematic for all but a mature tier of companies with close ties to leading academic researchers. A low perceived return on investment, continued downward pricing pressure, and long time to exit (up to 20 years) are challenges that few start-ups can overcome.

With an end to the pandemic conceivable, some are hoping that the additional resources and newfound public acknowledgement of the industry's relevance to clinical care will encourage a revised value proposition, but that is not certain. While it is too early to assess their fate precisely, many of the companies which sprung up to solve the COVID-19 crisis, often funded by government investments, will likely not survive on their own. Even though they have effective technologies and are supported by six-months post Emergency Use Authorization expiration to obtain FDA clearance, many may become acquisition candidates or may run the risk of folding.

Outcome Capital, a specialized life sciences advisory and investment banking firm, has tracked the diagnostics industry and its troubled attempts at optimizing value creation for a decade. As the US exited an exhausting year of worry, pain, and resilience, two of the firm's senior executives, Oded Ben-Joseph, PhD, a managing director, and Craig Steger, SVP life sciences and diagnostics practice lead, assessed how diagnostics fared in 2020 relative to its past track record as well as to biopharma's record-breaking capital inflow, and offered a roadmap of predictions for what lies ahead. (*See video "How COVID-19 is Changing the Diagnostics Industry,"* MedTech Strategist, *February 23, 2021.*)

Among the salient takeaways: Diagnostics company financings in 2020 reflected the uniqueness of the moment, more than doubling in 2020 from 2019 in terms of dollars raised to, as noted, $5.3 billion from $2.3 billion, although the number of transactions—85—remained flat year on year. In contrast, M&A value declined from 2019, but 2019 numbers were skewed by **Exact Sciences Corp.**'s acquisition of Genomic Health for $2.8 billion. Although IPO volume more than doubled in 2020 from 2019, this remains a very limited opportunity, as evidenced by the decline by nearly half of the total value of public capital raised (see *Figure 1*). These results may reflect the regulatory and reimbursement hurdles involved in bringing new technologies to market. Despite the flurry of attention around diagnostic innovation in the COVID-19 era, IPOs remain largely inaccessible to young diagnostic companies, and in general, the sector's financial support continues to trail biopharma by far.

The financing deal flow volume, interestingly, was spread almost evenly across Series A, B, and C-stage investments. The average Series A deal size was $11.7 million, $60.1 million for Series B, and $117.3 million for companies undergoing Series C investments. While those numbers are an improvement over years past, they significantly trail the attraction of biopharma companies, which saw nearly 200 Series A deals raise a total of $4.9 billion last year (*see Figure 2*).

Outcome Capital classifies the *in vitro* diagnostics (IVD) sector into four sub-segments, based on strategy and commercial models: Laboratory services, which are CLIA-certified laboratories often providing proprietary testing; Platform, companies offering both instrument and a menu of tests; Reagents companies; and Instrumentation companies. These sub-segments exhibit significantly different market dynamics with varied interest to investors and acquirers.

Curiously, while the number of platform financings declined from 2019 to 2020, investors poured more capital into the sub-segment with an approximately 65% increase to $ 2.1 billion. We observed a trend for more immunoassay, point-of-care, and at-home testing platforms. The laboratory services sub-segment remains dominant in the IVD market. While fewer transactions occurred compared with platform companies, lab services saw more and larger deals with a three-fold increase in capital flow in 2020 (see *Figure 3*). The average deal size for these two categories roughly doubled from 2019 to 2020, from $20.8 million to $42.6 million for platform companies and $47.4 million to $90.7 million for laboratory services. As seen in previous years (Outcome Capital Market Insight 2019), the reagents and instrumentation sub-segments continue to trail laboratory services and platform companies indicating limited investor appetite as a result of unfavorable return-on-capital.

An uptick in the entry of non-traditional investors into the sector was another notable trend in 2020. Funds such as GV and T. Rowe Price participated in select deals, mostly supporting later-stage mezzanine financings (see *Figure 4*). Despite the chaos of the pandemic, however, these investors spent little of their capital on COVID-19-related projects and tended to focus on analytics companies, such as **Tempus** and **Adaptive Biosciences**. These Big Data precision medicine companies have entered strategic partnerships providing value to large IVD and pharmaceutical companies along with influencing patient treatments and outcomes, potentially bringing a different set of potential acquirers to the IVD segment, such as healthcare providers.

Exit opportunities also appear to favor laboratory services companies, which dominated the sector's M&A transactions in 2020. COVID-19 did not impact the appetite for M&A, with a similar number of transactions and total deal values in 2020 and 2019 (see *Figure 5*). Notably, 2019 transaction values are skewed by the Exact Sciences-Genomic Health transaction and the 2020 figures exclude two large deals that were announced but had not yet closed by year end and will certainly shape the sector for years to come: **Illumina Inc.**'s $8 billion acquisition of Grail and Exact Sciences' $2.2 billion acquisition of Thrive Earlier Detection. With the addition of Genomic Health and Thrive, Exact Sciences seems to be focused on a horizontal integration, relentlessly pursuing new cancer tests to add to its commercial portfolio.

In 2020, the largest acquisition was **Invitae Corp**'s purchase of Archer Diagnostics for $1.4 billion, reflecting the former's journey in aggregating cancer genomics testing, including risk profiling, therapy selection, and cancer recurrence monitoring, and supporting its interest in a vertical integration strategy. Archer Diagnostics' investors had to wait only eight years (industry average >14 years) from the company's start to its sale. Invitae was the most active acquirer, having also purchased Diploid, a provider of genomic interpretation products, and Singular Bio, which has a single molecule detection system, earlier in 2020 for $82.3 million and $57.3 million, respectively.

In contrast to biopharma, the window for IPO exits remains quite narrow and unfavorable, especially for younger companies that have limited commercial activity (see *Figure 6*). Across sub-sectors, lab services companies fared best on the public markets, raising $141.8 million in 2020 versus $63.6 million in 2019, as companies such as **Biodesix**, **Castle Biosciences Inc.**, **Exagen Inc.** and **Progenity Inc.** debuted. At the same time, many of the large, publicly-traded IVD players were rewarded by activity around COVID-19 testing, significantly outperforming the Dow and other stock market indices during the year (see *Figure 7)*. Diversified strategic IVD players such as **ThermoFisher Inc.** and **Danaher Corp.** also saw their stocks rise on average more than 40% over the course of 2020, in part because they quickly pivoted and were able to leverage their technological expertise, manufacturing and sales channels to rapidly respond as the scope of the pandemic became clear, whereas **Labcorp** and **Quest Diagnostics** did not achieve those levels likely due to a decrease in routine testing services in 2020.

The COVID-19 capital flow into the sector to some extent distorted results. Early-stage companies, like **CUE Health** have been able to raise an astonishing amount of capital to focus on a new paradigm of at-home testing. While, historically, young diagnostic companies had trouble raising venture money until they had commercial products generating revenues, COVID and government (>$5 billion BARDA granted in 2020) financing has enabled a host of new players to flourish. Focusing on point-of-care testing for COVID through breakthrough technologies in personalized medicine and Big Data analytics have all been key drivers (see *Figure 8*). Whether they will outlast the pandemic or become acquisition targets remains to be seen. The recent acquisition of GenMark by **Roche** was partially attributed to the uptick in revenues seen from COVID testing in 2020 but we will have to see how the market rewards these emerging companies over time. MTS

Oded Ben-Joseph, PhD, is Managing Director, Craig Steger is SVP Life Science and diagnostics practice lead, and Thomas Joyce is an Associate at Outcome Capital.

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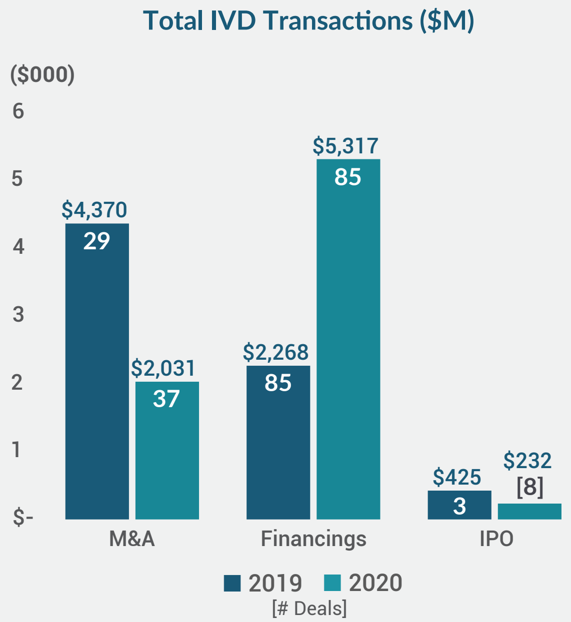
Figure 1

IVD Transactions

OVERALL TRANSACTION ACTIVITY



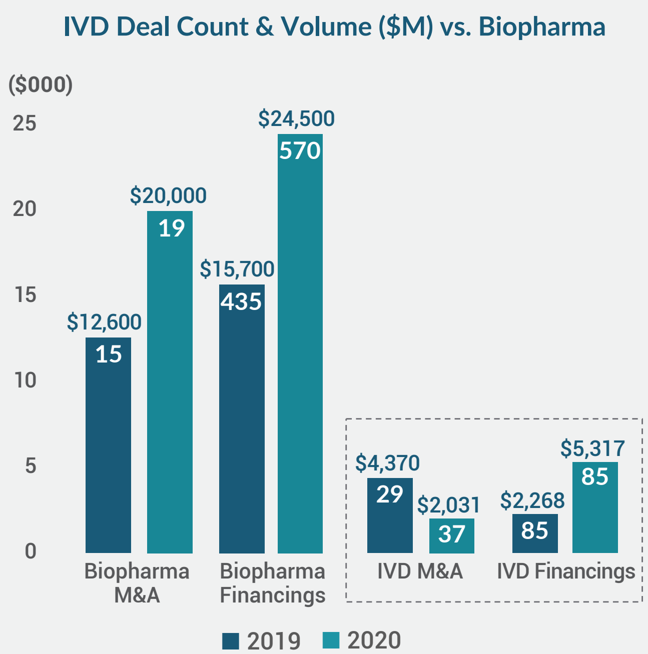
Source: Outcome Capital

- **Similar numbers of transactions in 2019 vs. 2020, however;**
  - M&A transactions flat year-over-year
    - 2019 data skewed by Exact Sciences acquisition of Genomic Health ($2.8B)
  - Increased investment capital flow into segment
  - IPO market generally unavailable to IVD segment
- **Financings driven by:**
  - COVID
  - Liquid biopsy
  - Omics
- **M&A driven by:**
  - Vertical or horizontal integration
  - Relatively unaffected by COVID

Figure 2

IVD Transactions: 2019 vs. 2020

IVD CONTINUES TO TRAIL BIOTECH/PHARMA FOR FINANCINGS AND M&A



Source: Outcome Capital

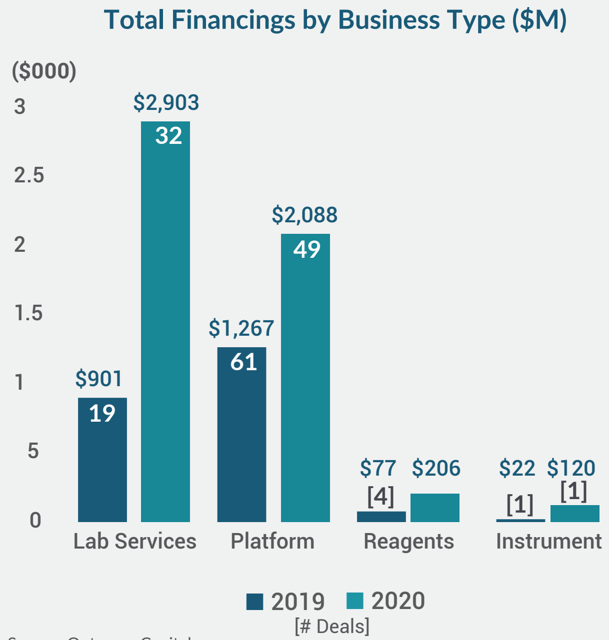
- **Despite COVID-19, IVD financings continue to lag biopharma in both number of deals & total amount invested**
  - Perceived low ROI for IVD companies
    - Barriers-to-entry/competition/crowding
    - Time to exit
    - Clin/reg cost vs. revenue generation
    - Adoption: Downward pricing pressure/ reimbursement
- **Stage of financing 2020 transactions for IVD***
  - Series A
    - 23 deals total $269.7M ($11.7M average)
    - Biopharma: 191 deals total $4.9B ($25.6M average)
  - Series B
    - 20 deals total $1.2B ($60.1M average)
  - Series C & beyond
    - 22 deals total $2.6B ($117.3M average)

* Based on disclosed data

Figure 3

IVD Transactions: 2019 vs. 2020

DIAGNOSTIC FINANCING DATA BY BUSINESS TYPE



Source: Outcome Capital

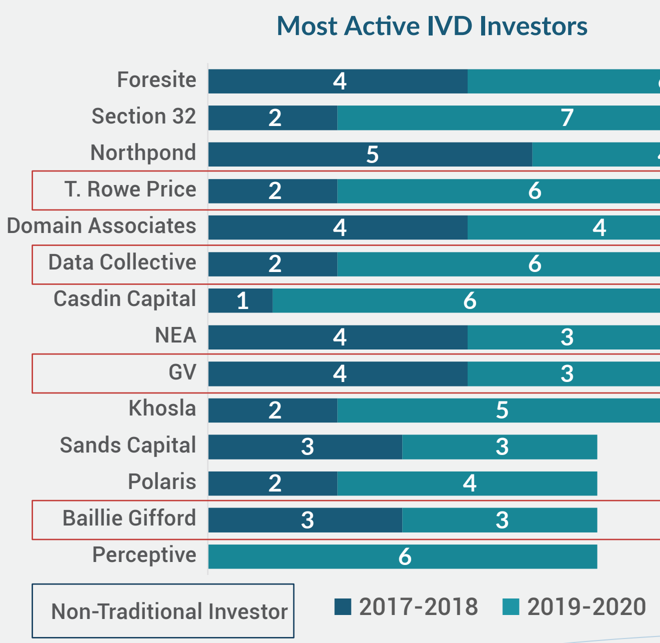
- **Lab Services segment saw more & larger financings deals in 2020**
  - 6 deals >$225M
  - Average: $90.7M vs. $47.1M
  - Median: $20M vs. $15M
- **Fewer platform financings but additional ~$800M in capital put to work in 2019 vs. 2020**
  - Trend for more platforms in immunoassays, POC MDx* & At-Home-Testing COVID-19 related
    - 7 deals >$100M
  - Analytic platforms enhanced area of activity

Lab Services: CLIA/CAP certified labs
Platform: instrument + reagent/kit companies
*POC MDx: point-of-care molecular diagnostics

Figure 4

Figure IVD Transactions: 2019 vs. 2020

NON-TRADITIONAL INVESTORS MIGRATING INTO THE IVD SPACE



Source: Outcome Capital

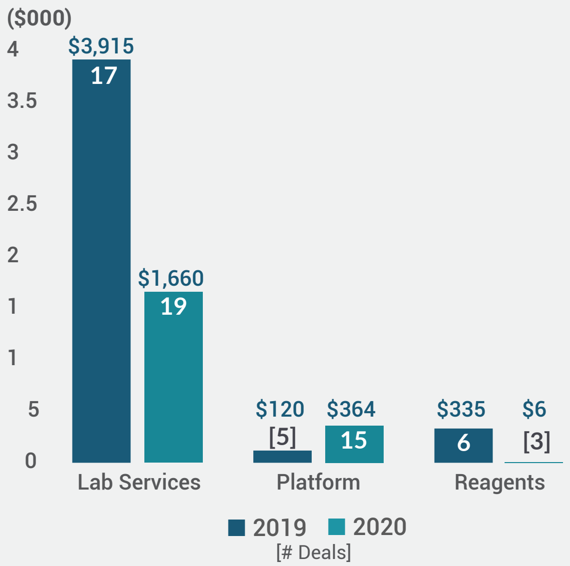
- **Non-traditional investing in much later rounds**
  - Mezzanine-like investments
    - Potential exit via IPO
  - Heavily focused on cancer diagnostic labs
  - Not investing in COVID
- **Traditional investors active at all stages**

Figure 5

IVD Transactions: 2019 vs. 2020

DIAGNOSTIC M&A DATA BY BUSINESS TYPE

Total Deal Size by Business Type ($M)



Source: Outcome Capital

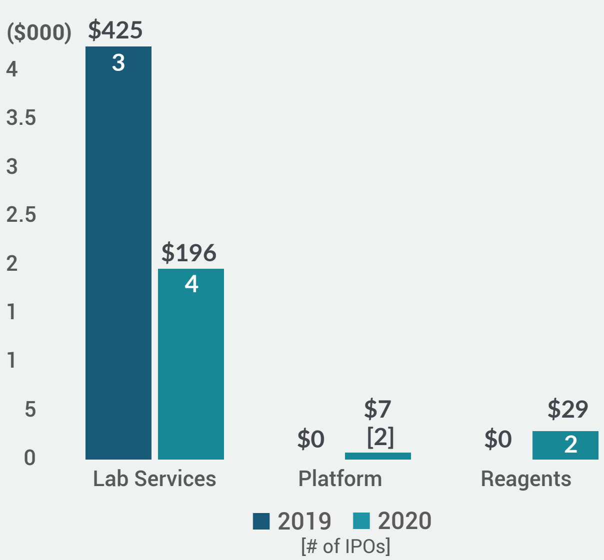
- **Total M&A transaction value impacted by one transaction**
  - Exact Sciences acquires Genomic Health ($2.8B)
  - Otherwise, flat year-over-year
- **Lab Services strong but unlike previous years**
  - Largest deal: $1.4B vs. $2.8B
  - Average: $237M vs. $356M
  - Median: $12M vs. $42M
  - Move towards acquiring analytic platforms in 2020
- **2020 announcements (not closed) excluded:**
  - $8B Grail/Illumina
  - $2.2B Thrive/Exact Sciences

Figure 6

IVD Transactions: 2019 vs. 2020

DIAGNOSTIC IPO DATA BY BUSINESS TYPE

Total IPO Size by Business Type ($M)



Source: Outcome Capital

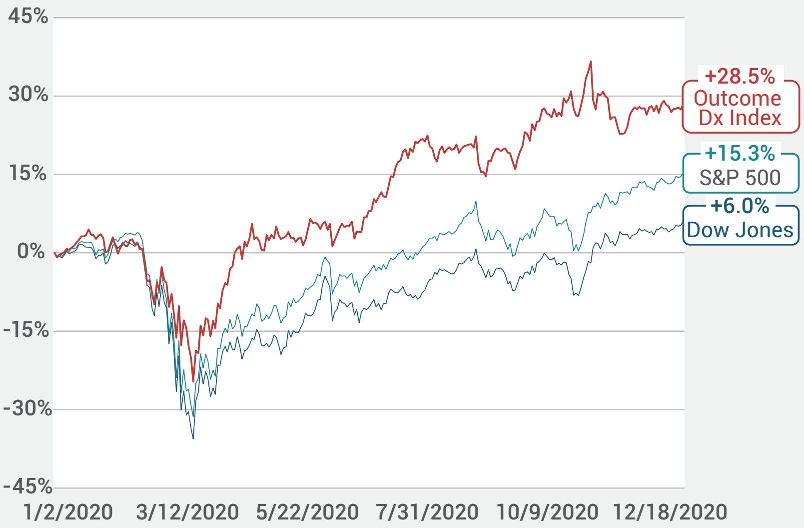
- **Public markets still unavailable for IVD companies**
  - 2019 vs. 2020 Lab Services IPO
    - $141.8M vs. $63.6M (average)
  - 6-month change
    - 10.3% vs. 17.7%
  - Most IPOs on European exchanges are small (<$30M)
    - NASDAQ ($60M - $300M)

Figure 7

IVD Industry In The Time Of COVID-19

LARGE DIAGNOSTICS PLAYERS LEVERAGED TECHNOLOGY GAP, MANUFACTURING, SALES CHANNELS

Market Index Value Comparison 2020



Source: Outcome Capital

Market Insights

- **Dedicated IVD companies , e.g. Quidel (+147) vastly outperformed given core business in POC testing**
- **Diversified businesses unlocked value**
  - Thermo Fisher (+41.5%): IVD development & vaccine distribution/ manufacturing
  - Danaher (+42.3%): participates in every stage of COVID value chain
- **Laboratories LabCorp (+20.3%) & Quest Diagnostics (+11.9%) lagged broader diagnostics index**
  - Possible reason for lag; decrease in routine testing nullified by increase in COVID testing

Figure 8

IVD Industry In The Time Of COVID-19

OBSERVATIONS

- **COVID-19 potentially has shone spotlight on diagnostics for investments**
  - ~30% of 2020 investments had some COVID focus
  - Total capital invested increased ~2.0x from 2019 to 2020
- **Large strategic players capitalized on outsized demand for COVID testing**
  - Small players, typically able to innovate and pivot quickly, succumbed to established sales channels and rapid scale-up capabilities
- **Little effect on M&A activity**
  - Outcome assumes increased investment likely to propel future M&A activity, but too early to determine impact of capital flow into segment
- **Government grants provided for early test development**
  - BARDA ~$5.1B granted in 2020
  - Example of DoD grant: Cue Health received $481M to scale manufacturing
- **Lab services remains dominant in IVD market**
  - Liquid biopsy driving investment activity
    - 6 cancer-driven transactions >$150M
  - Average return on capital >5.0x
- **Non-traditional investors focused on late-stage cancer-focused labs**
  - Potential for future IPO exits

Source: Outcome Capital