



In Vitro Diagnostic Market Insight: Continued Growth and Consolidation

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Introduction

Driven by a multitude of factors including the ageing population, increasing burden of chronic and infectious diseases, mounting demand for early diagnosis, emergence of personalized medicine and higher demand for testing in the developing world, the global In Vitro Diagnostics (IVD) market is projected to grow at 5.2% CAGR from \$68 billion in 2018 to \$88 billion in 2023¹. We examined recent IVD market dynamics between 2016 and Q3/2019 including financing events, merger and acquisitions (M&As) and initial public offerings (IPOs). We analyzed these dynamics to assess the overall activity of the segment to provide management teams and boards with a market-aligned perspective.

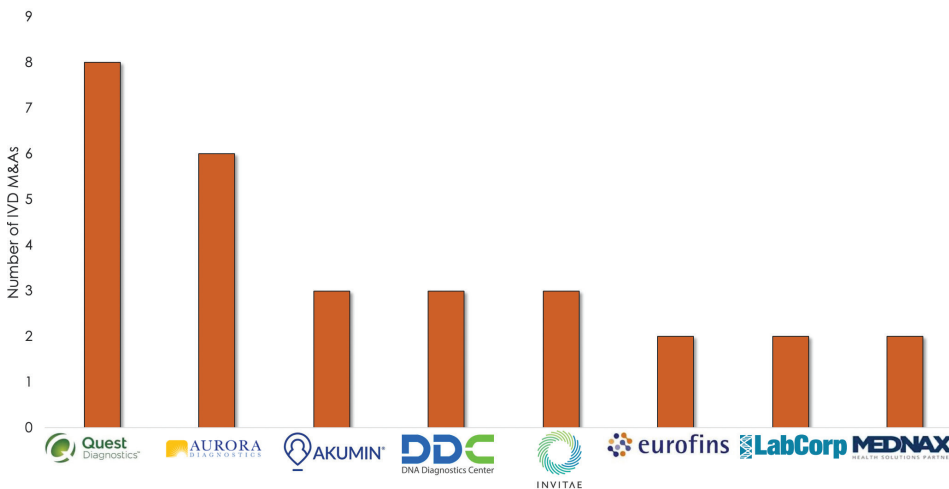
Mature Market Marked by Intense Consolidation

The rapid growth of the IVD market has attracted more than a 100 players², resulting in numerous M&As over the past several years. This has resulted in consolidation as players have made two or more acquisitions over this relatively short time period (Figure 1). Further, we witnessed large transactions, including two venture capital (VC) financing transactions over \$100

million, three private equity (PE) financings over \$200 million, and four acquisitions over \$1 billion (Table 1). With respect to the financing events, both transactions supported growth capital to commercialize and expand product offering and to propel revenue generation, allowing these companies to become large players in the segment. The large M&As afforded acquirers with the opportunity to aggressively expand market share, as demonstrated by

Danaher's acquisition of Cepheid, Abbott's acquisition of Alere, and PerkinElmer's acquisition of Euroimmun. Roche's acquisition of Foundation Medicine is expected to close in late 2019. Roche acquired 56% of Foundation Medicine in 2015 for approximately \$1 billion and has now decided to lock-up that investment by acquiring the remaining Foundation shares for \$2.4 billion. This valuation indicates that Roche was looking at Foundation as a strategic fit for

Figure 1 Most Acquisitive Players in the IVD Market
2016 – Q3/2019, Source: PitchBook and CapIQ.



its pharmaceutical business and their presence in the personalized medicine space, rather than a purely revenue-driven transaction. Foundation was the first Food and Drug Administration (FDA)-approved comprehensive genomic profiling assay and had Centers for Medicare and Medicaid Services (CMS) reimbursement coverage. Given these transactions are

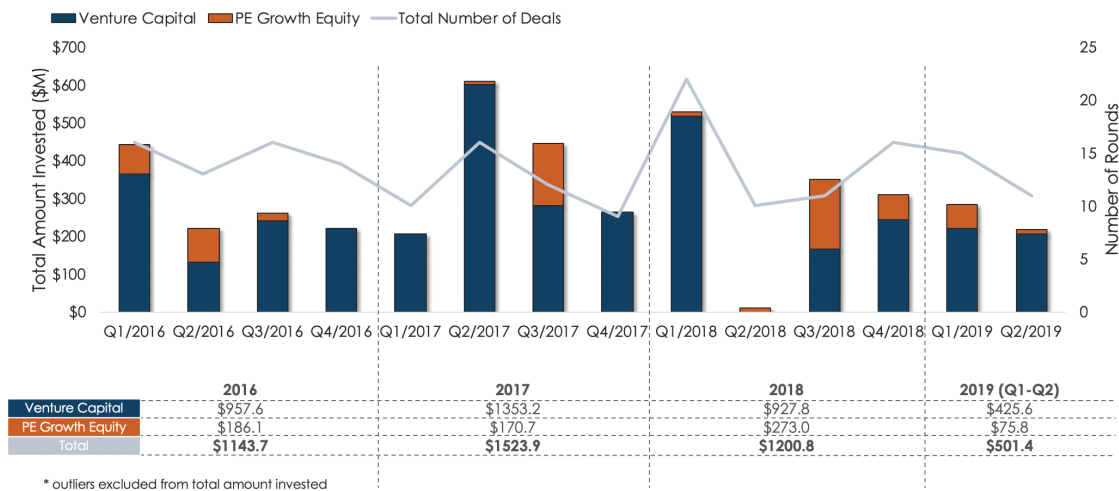
We expect continued consolidation in the next several years as large players will seek to expand platforms, offerings, menus and applications.

Table 1 Large Transactions Expand Market Share
Source: PitchBook, CapIQ, & Press Releases.

Deal Date	Company (Target)	Lead Investor/Acquirer	Deal Value (\$M)	Deal Rationale
Financings				
7-Nov-2017	progenity®	ATHYRIUM	\$125 Series B	1) Accelerate development of its gastrointestinal platform, including precision molecular diagnostics and microbiome analytics 2) Enhance prenatal and broader women's health testing menu and service offerings throughout the U.S.
12-Apr-2017	SYNLAB	NOVO	\$267.8M PE Growth/Expansion	To support proven consolidation strategy
11-May-2017	GUARDANT HEALTH	SoftBank	\$360 Series E	Commercialize liquid biopsy technology and expand their early cancer detection efforts
18-Oct-2017	Ambry Genetics®	INCJ	\$400 PE Growth/Expansion	Joint venture: INCJ contributed \$400 million growth capital while Konica Minolta contributed \$600 million
3-Jan-2018	SomaLogic	iCarbonX	\$200 PE Growth/Expansion	To provide growth capital to their proteomic platform
M&As				
04-Nov-2016	Cepheid.	DANAHER	\$4000	Expand Danaher's diagnostics segment as Cepheid represents the largest global installed base of instruments and test menu available in molecular diagnostics
03-Oct-2017	Alere™	Abbott	\$4606 to shareholders + refinance \$2600 debt	Establishes Abbott as the global leader in point of care testing
19-Dec-2017	EUROIMMUN	PerkinElmer®	\$1300	Expands PerkinElmer's reach into autoimmune and allergy diagnostic markets
19-Jun-2018	FOUNDATION MEDICINE	Roche	\$2400 for remaining 44% not owned by Roche	Supports Roche's personalized healthcare strategy as Foundation offers comprehensive genomic profiling assays to match patients with relevant targeted therapies, immunotherapies and clinical trials

Deal values greater than 4.5x the interquartile range were excluded from average analysis. Source: PitchBook, CapIQ, & Press Releases

Figure 2 IVD Investments
2016 - Q2/2019, Source: PitchBook



outliers, they have been removed from figures assessing total amount invested or average deal size.

A Mere \$5.5 Billion Invested in Private Placements

To assess the likelihood of an early stage IVD company to secure funding, we analyzed VC and PE, financings (Figure 2). VC played a larger role than PE and despite several large transactions, VC firms provided relatively little support for early stage companies in the IVD market. While over \$5.5 billion was invested between 2016 and Q2/2019, this pales in comparison to just the immunology segment investments in the same time (over \$14 billion, Source: GlobalData). Overall, the IVD investments represent less than 3% of total life science venture dollars invested (>\$200 billion invested) during the same period (Source: PitchBook). Figure 2 indicates a flat trend over the past

several quarters of investments made in this space, suggesting that the VC and PE communities do not support earlier stage IVD opportunities and that better return-on-investment multiples are likely to be found elsewhere in the life science sector. Limited venture activity is also demonstrated by a modest 14 Series A financings and 20 follow-on financing (Series B-E) in 2018. Furthermore, average deal values were also modest with an average Series C of only \$17 million and \$20 million in the platform (instrument + associated assays) and instruments only sub-segments, respectively (Figure 3). Average Series C appears to be higher in the lab services segment, indicating that VC investors are more amenable to provide growth capital to services companies that are at- or near-revenues, given the relatively lower regulatory hurdles for these companies to become revenue-generating. Interestingly, for companies developing

an instrument only, or those developing a platform, average deal value does not increase with subsequent series of funding, again, indicating limited appetite for IVD investments. As shown in Figure 4, several firms continue to support IVD companies and are taking multiple shots on goal in the sector. Sands Capital is leading with 8 investments over the studied period. Of note is that the top institutional investor groups consist of traditional venture capital firms, such as Sands Capital and Domain Associates, as well as untraditional investors, such as Keiretsu Forum, an angel investor group, and

Raising private capital in the IVD space represents a challenge compared to other life science segments. Early stage companies should focus on the limited number of VCs active in the segment while seeking early strategic partnerships.

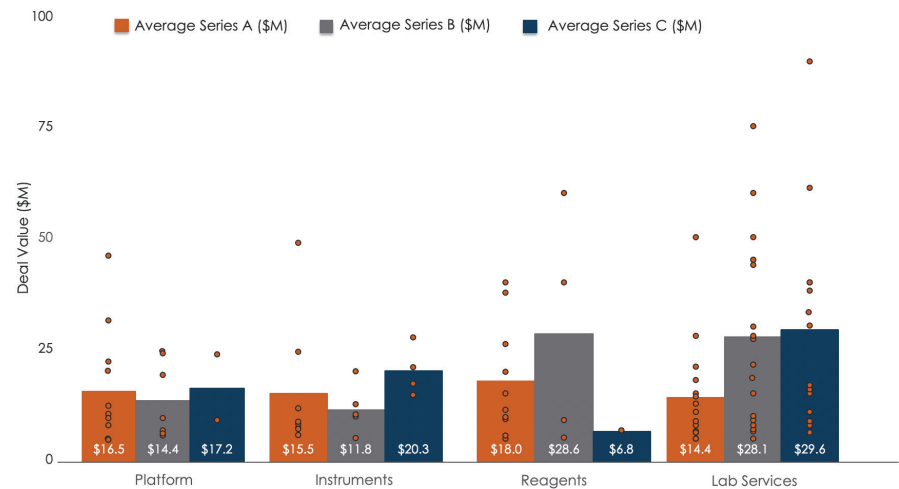
Arboretum Venture, a geography-specific firm.

Healthy IVD M&A Market

The IVD market is marked by intense consolidation with 115 M&As in the studied period. These transactions account for >\$22 billion in total transaction value (Source: Pitchbook) across all sub-sectors. Of these, 66% of acquisition taking place were in the lab services segment (Figure 5A). While we see rapid consolidation in the lab services sector, platform companies and those developing consumable reagents only made up 16.5% and 14.8% of the transactions, respectively. The remaining 3% of IVD transactions were for instrument only companies, demonstrating those are not highly sought-after in this segment. The consolidation of the lab services sub-sector stems from strategics seeking the addition of capabilities (specialty services) or geographic reach. Conversely, platform or instrument-based acquisitions require buyers to strategically align themselves with the target's value proposition.

Interestingly, platform companies command a higher average transaction value of \$175 million, compared to \$67 million for lab services companies (Figure 5B). There were 39 transactions over the period for companies developing reagents, instruments or both, signifying an active space for both labs and IVD products. Of those requiring regulatory approval, companies developing

Figure 3 Flat Investments Across Venture Rounds
2016 - Q2/2019 outliers excluded. Source: PitchBook



either reagents or platforms were more sought after compared to instrument alone.

As shown in Table 2, the average duration to exit of IVD companies exceeds 20 years for most sub-segments, a reality that should be taken into account by management teams of early stage companies. For comparison, the average time to exit in the therapeutic medtech segment is 11.3 ± 6 years (Source: PitchBook). It should be noted that lab services companies show an extremely high variability (average of 21.9 ± 17.9 years) as Clinical Laboratory Improvement Amendments (CLIA) certification requires less capital than FDA approval, allowing these companies to generate revenues quickly. Many of these labs are able to be self-sufficient and grow organically over a prolonged period of time, resulting in an industry that, while consolidating, provides founders with more flexibility with

respect to either growth or exit options.

With respect to company development stage at acquisition, the overwhelming majority of companies were acquired post-product approval by FDA or CE certification (Figure 6A). In addition, only 8% of those companies were acquired at the pre-revenues stage and 56% of companies were generating revenues (Figure 6B). It thus appears that, unlike other life science segments, the IVD segment does not support early exits and, as such, management teams should ensure sufficient capital well

When assessing the path to liquidity, management teams should ensure sufficient capital well beyond regulatory approval at minimum and also anticipate a prolonged time to exit.

Figure 4 Top IVD Investors
2016 - Q2/2019, Source: PitchBook.



beyond regulatory approval (at minimum) and also anticipate a prolonged time to exit.

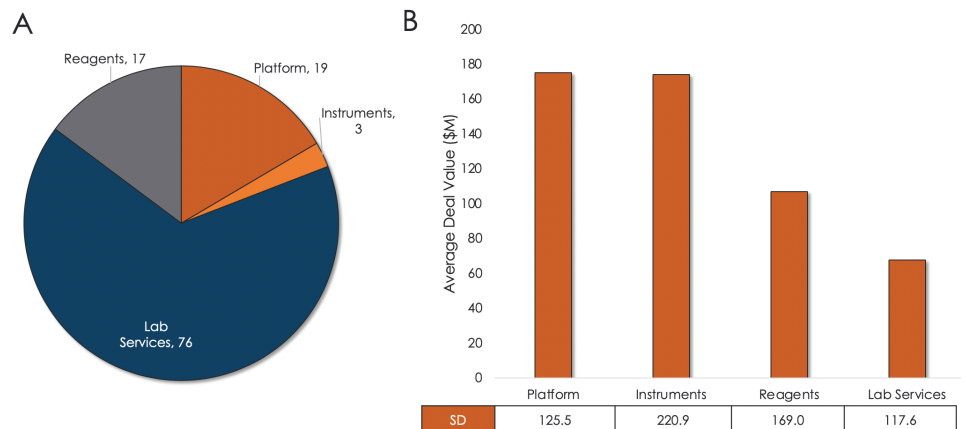
Return on capital multiples for IVD companies (total acquisition price divided by amount of capital raised) is healthy, with an average of 5.1x and range from 0.6 to 8.3x (Table 3). In fact, the majority of exits returned capital to investors, with only one falling below a 1x return. Note that these calculations assume that all milestones were met and that the total deal value was realized. The Bio-Techne’s acquisition of Advanced Cell Diagnostics provided the highest return multiple. Advanced Cell Diagnostics developed an in situ hybridization assay for detection of RNA to monitor single cell gene expression, while retaining tissue morphology. Novel, transformative technologies therefore, expectedly garner higher returns on capital. Structured transactions are

The IVD segment does not support early acquisitions of pre-regulatory approval and pre-revenue companies.

common in the IVD market (Source: Outcome Capital, Capital IQ, and Pitchbook,). An exemplary transaction is the acquisition of GenePOC by Meridian

Biosciences. The GenePOC acquisition total deal value was \$120 million, but the structure of \$50 million up-front payment with various regulatory and sales milestones allowed Meridian to de-risk the investment over time while maintaining a significant upside for GenePOC³. Similarly, a minimal investment in NeuMoDx (\$9.3 million) allowed Qiagen to

Figure 5 Lab Services Dominate M&A
2016 – Q3/2019, Source: PitchBook & CapIQ, outliers removed.



Most IVD M&A transactions are structured, allowing risk mitigation for the buyer and upside participation for the seller.

acquire ~20% of the company with a pre-negotiated milestone-based exit, securing NeuMoDx with capital needed to move forward, but allowing Qiagen to retain the right to back-out of the transaction through 2020 if the undisclosed milestones are not met⁴.

Table 2 IVD Companies Show Lengthy Time to Exit
2016 – Q3/2019, Source: PitchBook, average ± SD.

Segment	Time to Exit (years)
Platform	21.7 ± 17.7
Instruments	35.6 ± 4.0
Reagents	19.9 ± 12.2
Lab Services	21.9 ± 17.9

Figure 6 Strategic Market Seeks Mature Assets
2016 – Q3/2019, Source: PitchBook, Press Releases, GlobalData, Note: Does not include lab services.

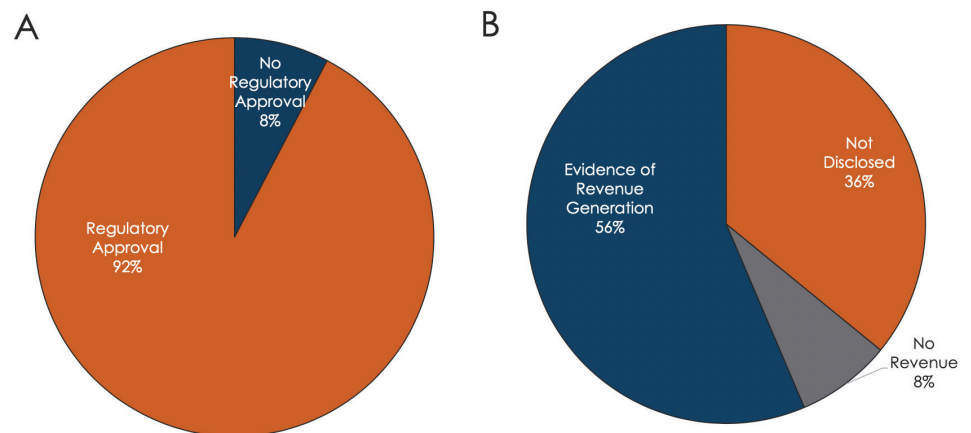


Table 3 Healthy Return Multipliers
2016 – Q3/2019, Source: PitchBook, Note: Does not include lab services.

Target	Buyers	Deal Size (\$USD, M)	Capital Raised (\$USD, M)	Return Multiple
Astute Medical	bioMérieux S.A. (ENXTPA:BIM)	90	160.1	0.6
MolecularMD	ICON Laboratory Services	42.3	15.57	2.7
Immunetics	Oxford Immunotec Global	12	1.8	6.7
Multiplicom	Agilent Technologies	75.93	10.28	7.4
Advanced Cell Diagnostics	Bio-Techne	325	39	8.3

Given the low probability of an IPO, we believe that IVD companies should not focus on the public markets to attract growth capital.

Limited IPOs for IVD Companies

IPOs were relatively limited in the time period examined (Table 4), with only four public offerings for pure play IVD companies in

the studied period. However, while the overall number of IPO was limited, the public markets did support a significant increase in market capitalization at six-month post-IPO (typical insiders' lock-up period). Interestingly, only one IPO, Guardant Health, occurred on a U.S. stock exchange which may provide further insight into what public markets would best support an IPO. Moreover, these IPOs all occurred with mature

and well-established companies, which is a recurring theme for the IVD market as a whole. Note that Siemens Healthineers went public on the Frankfurt stock exchange with a market cap of \$37.8 billion but was excluded as growth was attributed to Siemens' imaging and advanced therapies business and hence not considered a pure play IVD company.

Table 4 IPOs are Limited but Garner Public Market Support
2016 – Q3/2019, Source: PitchBook

Deal Date	Company Name	Amount Raised (\$M)	Market Cap @ IPO (\$M)	Market Cap @ 6-mo post-IPO (\$M)
21-Apr-2017	Tellgen (SHE: 300642)	78.71	453.13	925.22
17-Jul-2017	Getein Biotech (SHG: 603387)	107.90	627.33	1,190.39
04-Oct-2018	Guardant Health (NAS: GH)	237.50	2,690.54	6,024.43
07-Dec-2018	Q-linea (STO: QLINEA)	60.75	174.49	156.79

Conclusions

While IVD represents a well-established market, large transactions continue to occur for mature companies that offer the opportunity to capture market share (Table 1). Venture financing tends to be focused on growth areas with favorable prospects of return. For these reasons, venture financing tends to focus on laboratory services (47% of financing transactions, Figure 3) potentially due to the activity in the M&A market where they can expect a return on their investment (Figure 5). IVD companies require a considerable time to exit (Table 2) and it is imperative that management focuses on achieving regulatory approval and early revenues prior to becoming an acquisition target (Figure 6). However, return multiples demonstrate that investors are likely to get a return on capital if an exit occurs (Table 3). These healthy returns and large transaction values are encouraging some venture firms to take multiple shots on goal (Figure 4). However, IPOs in this segment are limited to mature businesses but those that were able to secure a public funding do garner support with subsequent return on investment (Table 4).

The IVD market will reward technology advancements resulting in novel assays, lower cost of goods and faster turn-around times.

Based on Outcome's presence in the IVD space, we believe that the segment will continue to experience healthy growth over the coming several years. Infectious disease testing will remain a key growth driver as the need for expanded menus continues to press with increasing burden of infectious diseases and antibiotic resistance testing. Advances in molecular "sample-to-answer" testing, coupled with targeted menu expansion, will drive the decentralization from large reference and hospitals labs, through small and medium regional hospitals, to near-patient and point-of-care testing. Outcome maintains that the IVD market will reward early stage companies that are focused on biomarker discovery or on technologies that increase multiplexing and decrease test turn-around-time. However, early stage companies need to focus on managing cost per test and market adoption as these are the two main drivers in the IVD market space.

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About Outcome Capital

Outcome Capital is a specialized life science and technology investment bank with a global reach, providing middle market companies with a value-added approach to mergers and acquisitions, corporate finance and advisory services. The firm uses its proven ‘strategy-led execution’ approach to value enhancement by assisting boards and management teams in navigating both the financial and strategic markets and in implementing the best path for success. Outcome Capital’s strength stems from its unique ability to draw on its wide range of operational, strategic and investment experience, its expertise across the life science value chain, and its broad industry relationships.



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