Provident Perspectives: Investment & Consolidation in the Clinical Diagnostics Industry

The Clinical Diagnostics sector has seen a wave of investment activity as pressures from the COVID-19 pandemic are increasing demand and putting pressure on a highly fragmented market, highlighting the need for consolidation

Provident Healthcare Partners

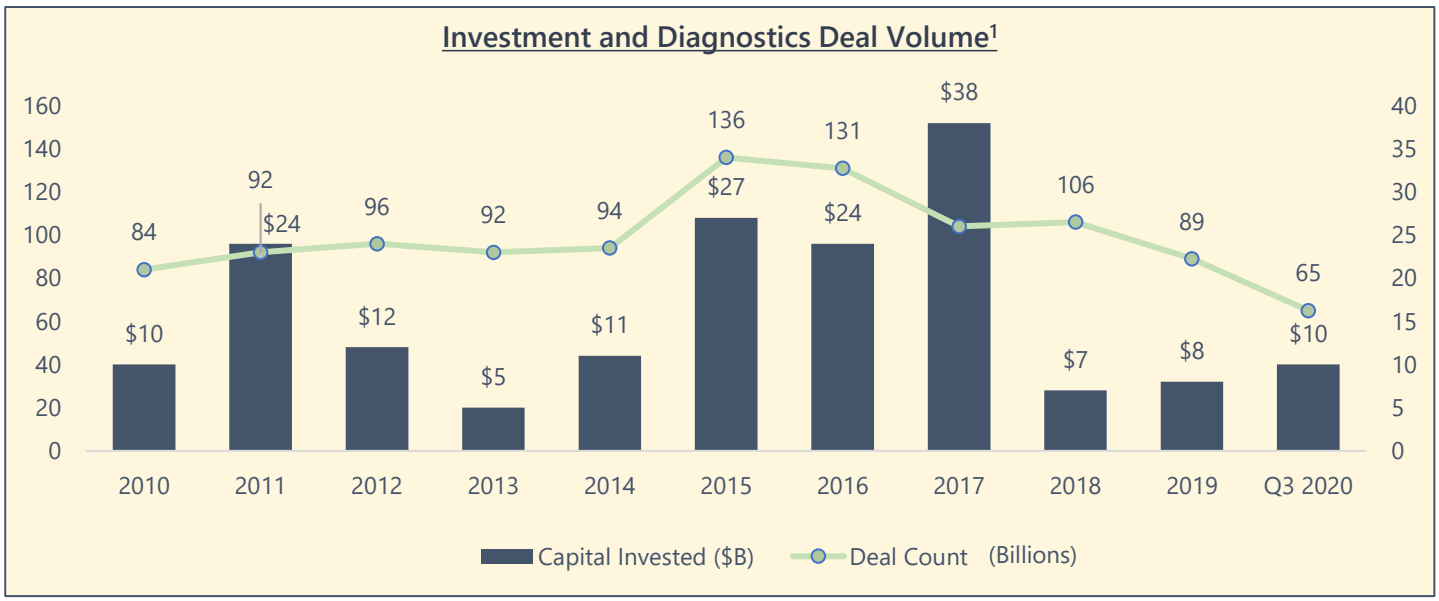
Introduction

Given the strong demand for services and a highly fragmented market, the medical diagnostics (Dx) industry is emerging as an extremely attractive area for outside investment and M&A activity. The demand driven by the COVID-19 pandemic is placing pressure on the industry to increase testing volumes and develop novel testing capabilities. Industry tailwinds such as an aging patient population, increasing private insurance coverage, and technological innovation are also attracting investors towards the space.

In recent years, the diagnostics market has seen an influx of capital as investors flock to the rapidly expanding sector. The diagnostics industry constitutes 2% of all medical spending; however, 70% of all medical decisions are a direct result of diagnostic testing results. As a result of this, diagnostics providers are looking to expand capabilities, which is in turn driving investment. Venture capital, private equity investment, and M&A activity in the space has increased substantially leading to an increase in valuations within the sector. Deal volume has remained strong over the past three years.

Similar to many other industries, the first half of 2020 saw a halt to investment activity due COVID driven uncertainty and difficulties in the debt markets. As an alternative to M&A, companies within medical diagnostics prioritized increasing their own testing volumes to keep up with demand spurred by COVID-19. Despite this, the diagnostics investment deal ecosystem has remained active. The emergence of COVID-19, along with other factors, have brought more investor attention to the diagnostics space:

- ***Consolidation within the diagnostics sector is being driven by increasing external pressures, operational inefficiencies and developing technology***
- ***Innovation within the sector, such as the introduction of integrated technologies, data analytics and machine learning, is driving the value-based care transformation, which has been accelerated due to the deficiencies highlighted by to the epidemic***
- ***The COVID-19 pandemic has ignited demand for development in diagnostic testing, placing pressure on diagnostics providers and exposing areas for growth within the space***



Source: U.S. Department of Health and Human Services, IBISWorld, Pitchbook.com., (1) only includes majority transactions (PE & M&A)

Consolidation Drivers within the Diagnostics Industry

In an effort to more efficiently deliver quality services, diagnostics platforms, like the rest of the healthcare industry, are trying to find ways to augment their ability to create value for the broader healthcare ecosystem at diminished cost. As competition increases in the crowded diagnostics sector, diagnostics platforms are looking to acquire and partner with other providers to gain a competitive advantage. Several macro-level trends are driving this paradigm shift.

Rising External Pressures

External business pressures are one of the strongest forces driving diagnostics consolidation. This is largely a result of declining reimbursement levels and increasing complexity related to private insurance and Medicare. The Protecting Access to Medicare Act (PAMA) continues to put reimbursement pressure on smaller diagnostic providers and hospital outreach labs, making a transaction an attractive option for some groups. To combat this, labs look to widen their testing capability to include more tests, achieving a higher average per-test reimbursement. Another business-centric driver of consolidation is serviceability as a one-stop shop for referring providers seeking an array of testing capabilities. By combining service lines via acquisition, Dx consolidators can also create efficiencies through eliminating back office redundancies and realizing economies of scale in vendor negotiations.

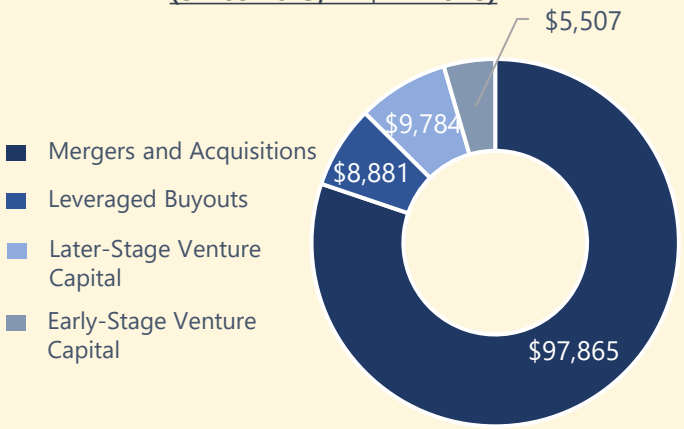
Back-office Centralization

Consolidation generally offers the ability to boost quality and efficiency, while maintaining or decreasing costs. Diagnostics platforms specifically benefit from the ability to improve quality, efficiency, safety, compliance, and data reporting/recording. Increasing reporting requirements as a result of PAMA have made these cost-effective operational changes critical. Given the ever-present competition, this cost saving mechanism represents one of the largest quantifiable benefits of consolidation.

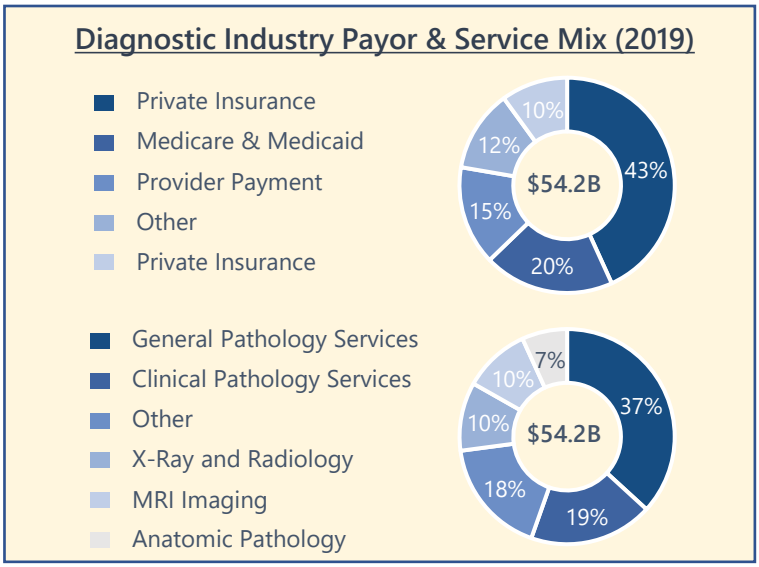
Laboratory Automation

Advancing technologies are helping reduce the cost of laboratory services and increase the quality of test results. Consolidation is aided by the increasing automation and routinization of testing procedures, which allows for more efficient and accurate results. Laboratory automation systems improve sample management and testing turnaround times. These technologies also increase laboratory bench space and decrease the necessity of skilled labor. Groups currently utilizing advanced laboratory automation technology make attractive acquisition targets for Dx platforms.

Capital Deployed by Buyer Type (Since 2015, in $Millions)



Diagnostic Industry Payor & Service Mix (2019)



Source: IBIS World, Agency for Healthcare Research and Quality (AHRQ), The Wall Street Journal, Pitchbook.com

Innovation in Diagnostics is Driving Value Based Care

The value-based care transformation is taking place across the healthcare industry, and diagnostic services is no exception. Responsible for 70% of the healthcare decisions made today, diagnostics play a vital role in the way our healthcare system operates. As healthcare costs continue to rise in the United States, more scrutiny is being placed on the value attributed to these costs. Recent innovations within diagnostics are taking aim at driving the value-based care delivery within the sector.

Integrated Diagnostics Technology

Diagnostic processes are becoming increasingly digital in nature. The reduction in analog processes reduces the likelihood of human error and increases bench space in labs; as a result of this transformation, diagnostic systems are integrating into EHR and EMR platforms. This integration shift significantly reduces the manual entry and faxing of diagnostic results from labs and providers. This process automation reduces costs for providers and third parties such as labs and reduces lead times on delivery of test results for patients. Dx systems that are integrated into a patient's EHR result in a more accurate, complete and timely delivery of test results. Integration allows for schedulers to verify insurance information, eligibility and preauthorization from insurance carriers without any unnecessary paperwork. It also allows for more seamless communication between physicians and Dx providers. The digital footprint as a result of this conversion provides increased data transparency between healthcare providers and payors.

Data Driven Diagnostics

The first step in efficiently allocating resources according to patient outcomes is formulating a data-based approach to decision making. Health systems are leveraging EMR data from their network of patients to analytically predict laboratory pre-test probabilities of testing outcomes. These procedures can be used to identify cases where the value of testing is questionable, and this information can improve clinical decision making. Leveraging diagnostic data is also driving crucial improvements into population health; the ability to aggregate data on a population level is being utilized in the paradigm shift toward evidence-based care. As reimbursement pressure continues to be placed on diagnostics providers, the advantage of data driven care allows for more clarity when negotiating rates with payors.

Source: IBIS World, HHS, Emerj: AI Research and Advisory., *Science Direct*

COVID-19 Highlights Multiple Areas for Growth in the Diagnostics Industry

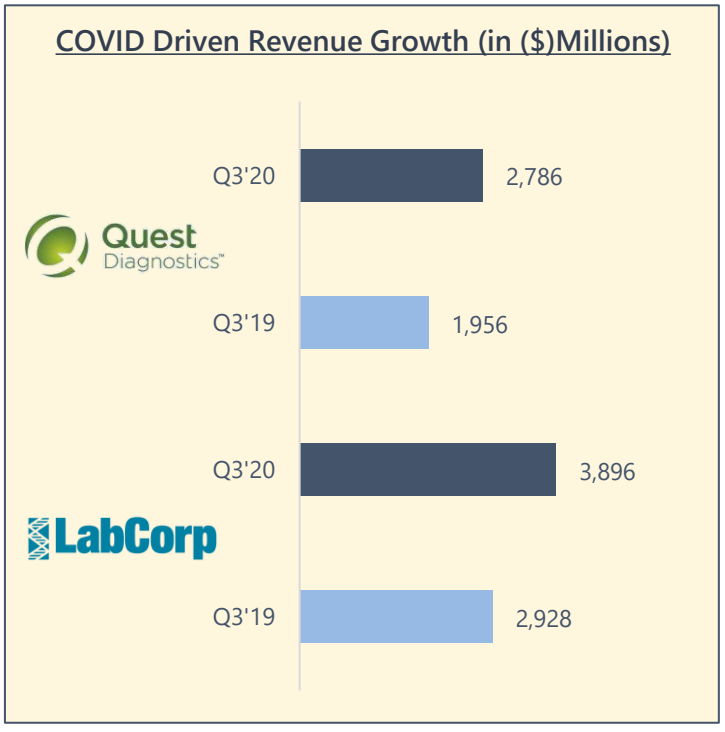
With diagnostics playing a pivotal role in the world's response to the pandemic, the healthcare industry is looking to diagnostics providers for ways to improve testing for the virus. Driven by investors betting on companies involved in the pandemic response, experts estimate that the COVID-19 testing market will reach $44 billion by the end of 2020.

Demand for COVID-19 testing is offsetting losses associated with reduction in referral volume. The second and third quarter of 2020 saw a rebound in revenue generation from the first quarter, as a result of Dx companies involved in COVID test manufacturing and delivery. Abbott Labs, Roche Diagnostics, Hologic, and Danaher, four of the largest providers of COVID-19 tests kits and materials, reported strong earnings. Diagnostic providers saw routine test referrals pick-up as states began to re-open.

State and federal government intervention has taken aim at increasing testing speed and availability. **Smaller regional facilities, however, while not initially equipped for centralized, high throughput testing have seen tremendous growth in late Q2 into Q3 and Q4.**

COVID-19 has sparked interest in new diagnostic strategies, particularly within serology. In an effort to better understand the true number of people that have been infected with the novel coronavirus, researchers are expanding capabilities within serology. Driven in part by the demand related to COVID-19, the serology testing market is on track to reach $4.8 billion by 2025, with a CAGR of ~9% over that time period. Serology tests have also been used to evaluate exposure to diseases such as Hepatitis, Tuberculosis, and HIV, which are all on the rise globally. Serology testing platforms are becoming attractive acquisition targets as large molecular and IVD platforms are looking to diversify their service offering.

As the pandemic continues to restrict the amount of in-person interaction, diagnostic platforms are looking to develop remote testing strategies. The need for rapid turn-around of COVID-19 test results has renewed interest in point-of-care (POC) technologies. Already growing in excess of the industry rate, POC platforms are benefitting from such factors as the mitigation of potential adherence issues, cost reduction and convenience. Additionally, POC platforms provide the ability to respond quickly to emerging outbreaks, with practical use applications in nursing homes and long-term care facilities. POC testing remains one of the fastest growing segments within diagnostics with an estimated CAGR of ~10% between 2019 and 2024. POC testing technologies also increase the ease of integration of test results with a patients' EMR, facilitate faster decision making, and reduce wait times for test results. POC testing also eliminates the need for processing, aliquoting, and transporting the specimen while requiring smaller sample volumes. These uses can reduce patient hospital stay time and remove unnecessary staff, reducing costs.



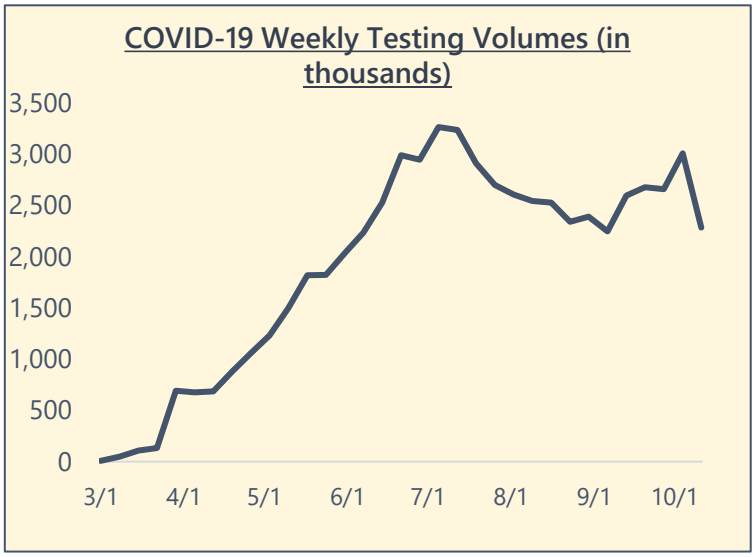
Source: U.S. Census Bureau, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, IBISWorld.

COVID-19 Highlights Multiple Areas for Growth in the Diagnostics Industry - *continued*

COVID-19 testing has been pushing laboratory capacity to the limit as testing volumes skyrocket. As of Q3 2020, over 59 million COVID-19 tests had been performed in the United States, averaging nearly 1 million tests per day. This steep increase in testing demand has put a strain on diagnostics platforms across the country to keep up with the increasing demand. Over the course of the COVID-19 pandemic, commercial labs have effectively tripled their related testing capacity including PCR-based platforms; however, this increase in capacity is not equating to commensurate increases in revenue, as the pandemic is disrupting the demand for non-COVID related tests.

The overwhelming demand is placing added pressure on the diagnostics supply chain which is heavily impacting smaller diagnostics providers. The federal government and in-vitro diagnostics (IVD) providers have been allocating resources to larger labs due to their ability to process higher quantities of tests. Smaller regional facilities are not equipped for centralized, high throughput testing so they are not receiving the same government relief, placing constraints on their supply chain, but many of them have adapted by adding excess capacity quickly.

As a result of these added pressures, larger industry players believe that smaller diagnostic providers are attractive M&A candidates.



Source: U.S. Census Bureau, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, IBISWorld, Pitchbook.com.

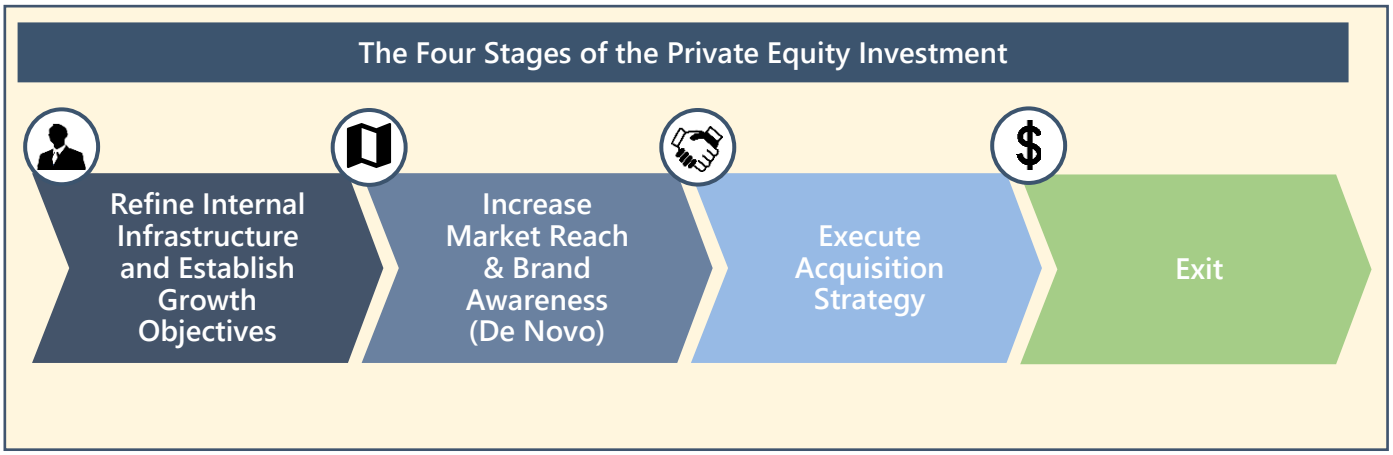
What Is Private Equity?

Although private equity has had a presence in this industry for some time, many operators are still unfamiliar with this form of outside capital and its benefits. Private equity investment refers to investors and funds of capital that seek to make direct equity investments in privately-owned businesses. General Partners (GP) invest the fund's capital in businesses that align with their investment theses, seeking to exit their investments typically within three to seven years for substantial returns. Upon investment, or a recapitalization, a private equity firm will acquire a stake in a private business, providing the shareholders with significant liquidity in the form of cash proceeds as well as retained equity in the newly recapitalized company. Post-transaction, private equity firms provide access to capital and expertise as they seek to improve their investments both financially and operationally by building out the infrastructure to provide a foundation for growth.

The type of growth initiative varies from model to model. In most cases private equity firms will infuse their portfolio companies with capital to execute add-on acquisitions and to enter new segments with the goal of increasing market share.

In past decades, private equity investors sought to acquire businesses entirely, directly accumulating all the profits created by the business. As the market evolved, general partners realized the value in keeping the original business owners involved in the business and have begun to provide more attractive partnership opportunities to owner/operators.

Today, when a diagnostic platform partners with a private equity group, the selling shareholder(s) will have the opportunity, and in some cases be required, to rollover part of their ownership into the new company. This provides individuals with a large up-front payment, taxed at capital gains rates, along with rollover equity investment in the new company, which is on a tax-deferred basis. This investment model allows each operator to share in the profitability of the company as they expand through acquisition and market share increase. After a three to five (and sometimes seven) year holding period, it is anticipated that the business will have grown meaningfully in size, prompting the business owners and private equity group to agree the timing is right to sell the platform to a larger private equity group or strategic buyer. During this second transaction, operators have the ability to cash out entirely (the "second bite of the apple") or reinvest additional equity into the newly formed company.



Concluding Thoughts

Partially driven by the recent pandemic and industry tailwinds, M&A activity within the diagnostics sector has remained active throughout 2020 despite increased uncertainty surrounding the COVID-19 pandemic.

Provident believes there is substantial opportunity to gain market share through financial and strategic partnerships. The primary sources of consolidation will be driven by continued interest from private equity backed platforms and large public and private diagnostic platforms continuing to expand service offerings and buy market position.

The emergence of the COVID-19 pandemic has put a spotlight on the diagnostics industry and exposed many of the inefficiencies as well as highlighted areas for improvement and growth. The increasing testing volumes as a result of COVID-19 has exerted pressure on diagnostics companies, who have responded impressively. Smaller providers who lack the resources necessary to process large testing volumes have been among the standout performers. In recent months, larger diagnostics providers have demonstrated interest in pursuing acquisitions of this size to expand their service offering and testing capacity. As a result, Provident expects the overall clinical diagnostics market to benefit from renewed interest by investors.

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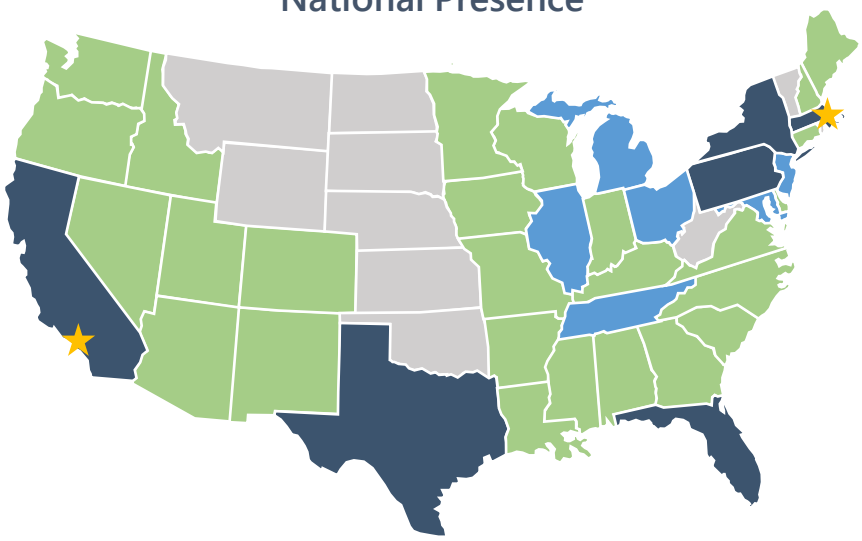
Provident Healthcare Partners

Provident Healthcare Partners' investment banking team works with privately owned healthcare companies to provide advisory services related to mergers and acquisitions. Prior to formal engagement, Provident works with companies to provide the upfront education to shareholders necessary to understand the economics, structure, and motivation of a transaction. Following the education process, if formally engaged, Provident leverages their extensive knowledge of the buyer universe to find the most compatible partner and drive valuations for a company's previously illiquid stock. Driving the entire transaction process, Provident facilitates and assists with deal structuring, negotiations, exit planning/processing, counseling amongst shareholders, and due diligence.

National Presence



1-3 Transactions
4-6 Transactions
7+ Transactions
Provident Office

21+	Years of Healthcare Investment Banking
130+	Healthcare Deals Closed
12-15	Landmark Deals Per Year
25	Banking Professionals

Note: The above map represents states where Provident clients were headquartered. Provident has successfully closed transactions with clients operating in 45 states and Puerto Rico.

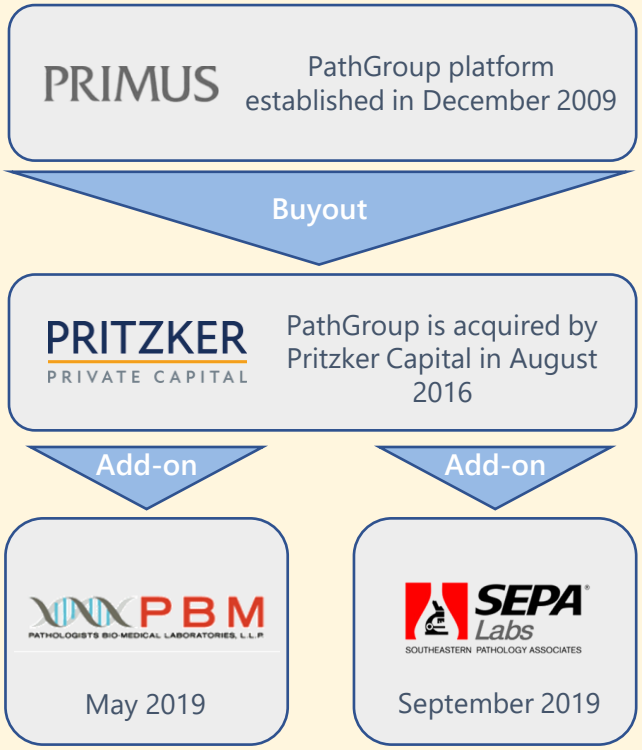
Case Study: PathGroup, Inc.

PathGroup, Inc. demonstrates how private equity partnerships can help a company realize substantial potential over time. PathGroup is a provider of anatomic, clinical, and molecular pathology services.

In 2009, PathGroup received a growth investment from Primus Capital to begin its growth via private equity. With Primus, PathGroup expanded from serving the southeast region to operating nationwide.

In 2016, PathGroup completed a secondary sale with Pritzker Private Capital with a valuation over triple the size from their original sale. With Pritzker, PathGroup began to implement an acquisition strategy. In 2019, PathGroup acquired Pathologists Bio-Medical Laboratories and Southeastern Pathology Associates (SEPA) to expand its services and its client base.

In its fourth year with Pritzker, PathGroup has grown to serve over 95 hospitals, thousands of physician practices and is one of the largest privately-held pathology groups in the country.

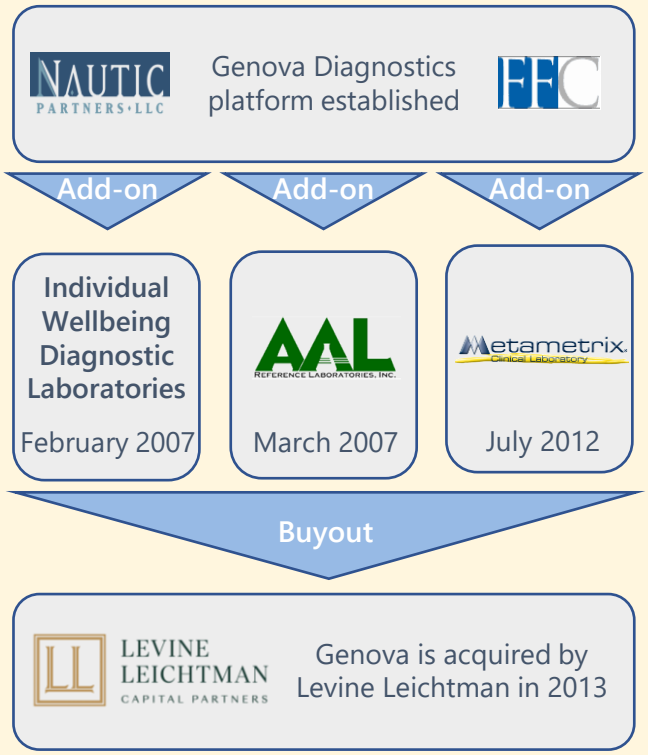


Case Study: Genova Diagnostics

Genova Diagnostics is an example of a successful private equity rollup strategy. Genova Diagnostics is a global clinical laboratory headquartered in Asheville, NC. Nautic Partners and Ferrer Freeman and Company acquired Genova Diagnostics as a platform into the clinical diagnostics market.

In 2007, Genova launched its roll-up strategy with the acquisition of Individual Wellbeing Diagnostics Laboratories. Based in London, this add-on expanded Genova's operations to a global scale. In 2007, the platform acquired AAL Reference Laboratories, and in 2012, it acquired Metametrix, Inc. These acquisitions grew Genova's testing capabilities and market share.

By 2013, the Genova Diagnostics platform served over 10,000 healthcare providers with 125 unique diagnostic tests. Levine Leichtman Capital Partners acquired Genova from Nautic and Ferrer Freeman (Peloton Equity). Levine Leichtman has provided the means to propel Genova's continued development within diagnostics.



Sources: Pitchbook

Provident Spotlight: Halo Diagnostics

Halo Diagnostics is a provider of medical imaging solutions for radiology practices. Halo's medical software is leveraged to better assist radiologists in their discovery of medical advancements. The software utilizes diagnostic imaging data aggregated from each of their operated centers and integrates the data into their proprietary AI technology. The group specializes in diagnosing prostate, breast, and lung cancers. In addition to cancer, Halo also provides coronary angiographies, early dementia and Alzheimer's detection, TBI screening, ultrasound, and virtual colonoscopy.

The company was founded in 2016 in Indian Wells, California. Since then the company has expanded to seven locations; five in southern California, one in Texas and one in Georgia. Through their partnerships with existing radiology groups including Desert Imaging, and ProScan Imaging, Halo has bee able to engage with 65 board certified radiologists with a combined oversight of one million patient encounters per year. Provident, alongside Raptor Group and ProScan Imaging, participated in the Series A financing round. Halo has also secured debt financing from an undisclosed investor that was utilized to fund the company's acquisition of multiple radiology groups.

Provident Direct Investment:

HALO DIAGNOSTICS

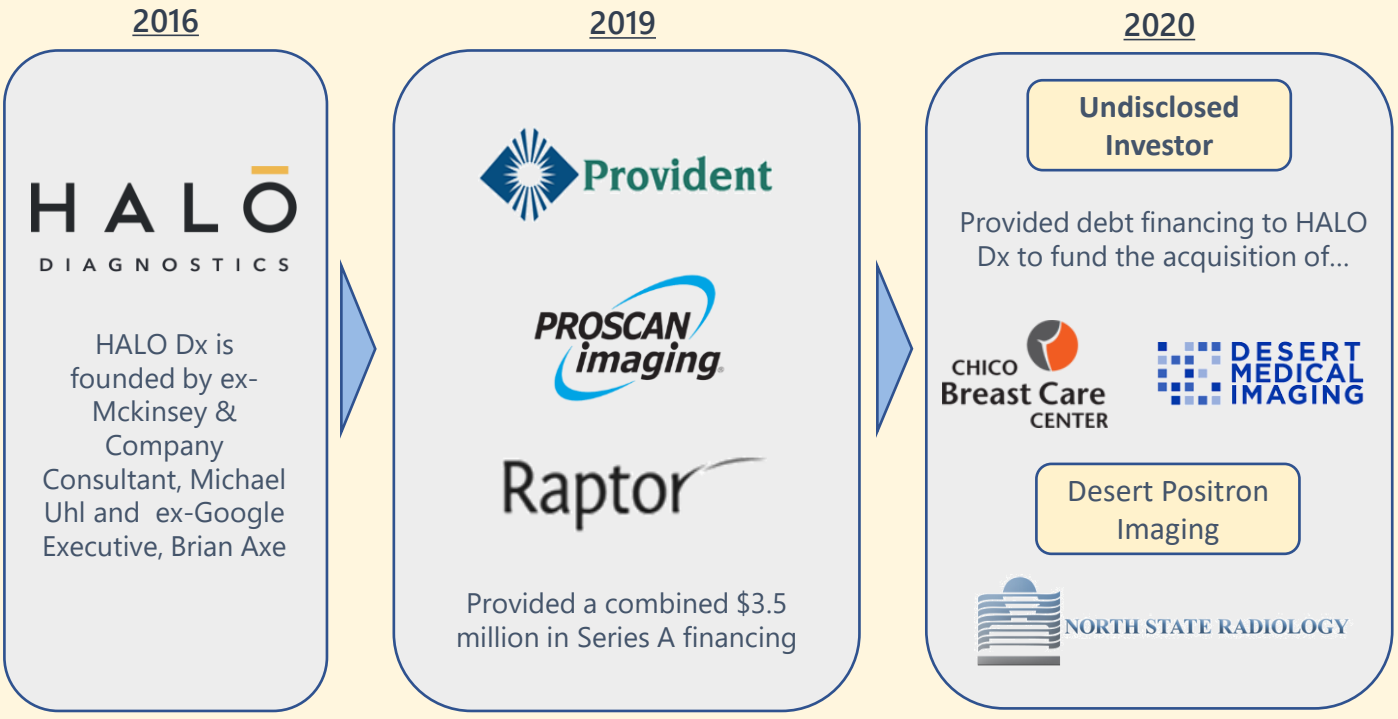
Received $3.5 million in Series A financing from

Provident

PROSCAN imaging

Raptor

Halo Diagnostics Timeline



Source: Pitchbook.

Provident is the leading investment banking firm specializing in merger and acquisition advisory, strategic planning, and capital formation for middle-market and emerging growth healthcare companies.

The firm has a vast network of senior industry relationships, a thorough knowledge of market sectors and specialties, and unsurpassed experience and insight into the investment banking process.

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