# Lab Services Market Remains Ripe For Private Equity

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Law360, New York (May 4, 2017, 12:24 PM EDT) -- In 2016 alone, the total U.S. clinical and diagnostic laboratory market generated approximately $80 billion in revenue, according to industry U.S. Securities and Exchange Commission filings. Just six years earlier in 2010, that market generated $55 billion in revenues. In light of the progressively aging population, as well as the ever-increasing influence of lab testing on clinical decision-making, there is no reason why the present growth in the market for laboratory services should plateau in the near future, and the laboratory market remains ripe for opportunity.

The two largest, publicly traded lab companies, Laboratory Corporation of America Holdings (LabCorp) and Quest Diagnostics, consistently look for opportunities to expand their holdings. And, private equity investors have also been active in the market, with a number of successful investments occurring in the past few years. A few examples are as follows:

***1. PathGroup:*** In August 2016, PathGroup announced a recapitalization in partnership with Pritzker Group Private Capital and Vesey Street Capital Partners. Founded by pathologists in 1965, PathGroup was providing anatomic pathology and clinical laboratory services to more than 70 hospitals and thousands of group practices throughout the U.S. as of the closing. Primus Capital led a previous growth investment for PathGroup back in 2009.

***2. Quanterix:*** In March 2016, Arch Overage Fund, Cormorant Asset Management and Trinitas Capital announced their investment in Quanterix, a diagnostic company based in Lexington, Massachusetts. Through the investment, Quanterix was able to develop more than 60 new assays and to launch desktop instrument offerings. Quanterix’s existing investors also include Arch Venture Partners and Bain Capital.

***3. Magellan Diagnostics:*** In March 2016, Meridian Bioscience announced the completion of its acquisition of Magellan Biosciences and its subsidiary, Magellan Diagnostics (collectively, “Magellan”). Based in Billerica, Massachusetts, Magellan is a leading provider of blood-based, point-of-care lead testing for adults and children, with a particularly strong position in pediatric offices. Meridian acquired Meridian from an investor group comprised primarily of private equity investors, including Ampersand Capital Partners, Tekla Capital Management, Abingworth and Boston Community Venture Fund.

***4. Bako:*** In January 2016, Consonance Capital Partners, a health care-focused private equity fund, announced the completion of a recapitalization of BPA Holding Corp. d/b/a Bako Integrated Physician Solutions. Bako is a national provider of specialty laboratory testing services, with a particular focus on providing comprehensive pathology solutions for podiatric physicians. Through the recapitalization, Bako received additional capital to further support the development of its national reach and the expansion its testing offerings.

***5. Renaissance RX:*** In November 2014, TPG Growth, the middle-market and growth equity platform of TPG, completed its investment in Renaissance RX. Based in New Orleans, Renaissance RX specializes in pharmacogenetics testing, which assesses how a patient will respond to specific types of medication based upon the patient's unique genetic makeup. At the time of closing, Renaissance Rx was providing thousands of tests daily in 43 of the 50 states.

***6. Precision Toxicology:*** In May 2014, BelHealth Investment Partners announced its acquisition of Precision Toxicology. Precision is a clinical laboratory that specializes in drug testing, particularly for the purpose of assisting physicians in monitoring patients undergoing treatment for substance abuse or pain. At the time of closing, Precision had ongoing relationships with nearly 5,000 physicians that regularly prescribed pain medication.

***7. SynapDx:*** In July 2013, SynapDx raised $15.4 million in equity financing from a number of private equity investors, including Google Ventures, Foundation Medical Partners, North Bridge Venture Partners and General Catalyst Partners. SynapDx continues to develop proprietary blood-based testing to detect certain biomarkers in young children that researchers believe present a high risk for autism, and used the investment capital to fund a 660-patient, 20-site study of that testing. Other recent investors in SynapDx include Kraft Group and LabCorp.

***8. Genova Diagnostics:*** In May 2013, Levine Leichtman Capital Partners, announced the acquisition of Genova Diagnostics in partnership with Genova's management. Founded in 1986, Genova is a global specialty clinical lab focusing on testing related to the personalized diagnosis, treatment and prevention of chronic diseases. Genova offered more than 125 specialized diagnostic assessments at the time of the closing, including testing in the digestive, metabolic, immunology and endocrinology areas.

Despite the significant activity of private equity investors in the laboratory subsector, the acquisition market remains dominated by large institutional providers like LabCorp and Quest. However, the laboratory industry should continue to present attractive opportunities for private equity investment for a number of reasons, including the following:

1. Lab testing represents a relatively small amount of actual health care expenditures, but has a significantly disproportional influence on clinical decision-making. As the emphasis on early detection, preventive screenings and targeted population health continues to grow, the importance and volume of effective lab testing will likely continue to grow. Furthermore, the focus on reducing health care costs and the significant reduction to downstream costs resulting from early detection create attractive opportunities for laboratory growth.

2. Favorable demographics, such as the significant decrease in the uninsured patient population as a result of the Affordable Care Act and the growing aging population, present significant opportunities for potential increases in the volume of laboratory services being performed. In particular, the aging population is an important driver for the laboratory industry, as Centers for Disease Control and Prevention surveys suggest that persons aged 65 and older average 10 to 13 laboratory tests per year, which is five times the volume of testing performed for the under-65 population.

3. The continuing advancement in technology is fueling the rapid development of both new and significantly improved laboratory testing services in most every specialty of medicine. As testing technology and offerings continue to advance, so too will the prevalence of comprehensive laboratory testing as a key component of health care.

4. As personalized medicine, companion diagnostic and direct-to-consumer testing opportunities continue to grow, laboratories will have new avenues in which to provide services. In many instances, these avenues will be better insulated from downward pressure on reimbursement rates that are prevalent in the traditional, government and commercial payor settings.

5. The continued aggressive acquisition strategies of large commercial laboratory providers such as LabCorp and Quest provides a clear exit strategy for private equity investors. There are presently serious ongoing opportunities to make real profits based on prudent investments, particularly in early stage laboratory companies that are developing new and innovative testing

offerings.

6. Compared to other segments of the health care industry, the licensing requirements for laboratories are relatively minimal. While federal law generally requires laboratories to obtain a Clinical Laboratory Improvements (CLIA) certificate in order to perform testing on human specimens, requirements vary greatly based on the complexity of the testing the laboratory performs. Moreover, only 23 states impose licensure or permit requirements on in-state laboratories, and only seven of those 23 states require out-of-state laboratories to be licensed or permitted in order to test specimens collected from in-state patients.

However, private equity investors considering investments in laboratory companies also must understand the significant challenges facing the laboratory industry, which include the following:

1. Both governmental and commercial payors are demonstrating serious concerns about the rapid growth in laboratory services. Accordingly, payors continue to scrutinize laboratory businesses for excessive and unnecessary testing as well as improper financial relationships with referral sources. Due to years of aggressive and sometimes questionable business practices in the laboratory industry, the Office of Inspector General, commercial payors and whistleblowers are constantly finding new grounds for litigation and investigations, and enforcement actions continue to be prevalent and frequent. As the ongoing struggles of Theranos and the stiff settlements agreed to by Health Diagnostic Laboratory and Singulex demonstrate, the failure to implement effective and robust compliance programs can have a disastrous results, especially for laboratory companies that experience rapid growth.

2. The growing need for higher volumes of lab testing continues to put more pressure on both governmental and commercial payors to control costs by reducing reimbursement rates. For example, Medicare payment rates will likely continue to decrease per the congressional mandate for laboratory reimbursement savings of $2 billion between 2017 and 2024. Moreover, there is an ongoing trend of large laboratory companies such as Quest and LabCorp entering into exclusive arrangements with major commercial payors, which decreases the opportunities for smaller labs to provide service and often forces them to accept decreased reimbursement in order to remain competitive. In many markets it is all but impossible for smaller lab companies to contract with payors.

3. The ongoing uncertainty in Washington about whether the ACA will be defunded, repealed or replaced looms large for the laboratory industry. If the uninsured patient population increases as a result of legislative developments, revenues from laboratory services may logically decrease.

4. The increasing costs of developing novel and improved testing offerings may dissuade laboratories from making significant investments if opportunities to receive an adequate return shrink. Commercial laboratory tests (tests performed using commercially manufactured kits and equipment) are regulated as medical devices, and the process of gaining clearance from the U.S. Food and Drug Administration can be lengthy and costly depending on the complexity of the test. Similarly, laboratory-developed tests (tests used solely with a single laboratory that aren’t sold or distributed to other labs or health care facilities) must similarly satisfy rigorous criteria before they can be used commercially, including CLIA efficacy requirements and additional validation standards in certain states, which can likewise be a long and expensive process.

Without a doubt, private equity interest in laboratory business remains strong, and opportunities continue to exist for quality private equity investment despite the financial constrictions and regulatory challenges faced by the laboratory industry. However, as with any health care investment, investors should continue to closely analyze reimbursement pressures for the sector at large and each target’s existing compliance profile and the ability of the target to sustain or amplify performance in a low-regulatory risk fashion.

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