

The Diagnostic Laboratory Space: An Ecosystem in Transformation

Executive Summary and Outline

The US diagnostic laboratory industry is experiencing growth and transformation, as independent labs, hospital labs and physician office labs respond to reimbursement pressures as well as direct and indirect consolidation pressures. Herein, we introduce the nuanced interaction of these segments and introduce trends that are shaping the landscape.

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I. Introduction

Marwood estimates the US diagnostic laboratory market at ~\$20B in annual spend, increasing to ~\$23B in 5 years. Over 13B laboratory tests are performed annually in more than ~200,000 CLIA labs (Clinical Laboratory Improvement Amendment certified laboratories). The market is primarily split between hospital labs (~40%), physician office labs (POLs) (~10%) and independent testing labs (~35%) with the balance (~15%) occurring in a variety of other labs (ex., community clinics, nursing homes, public health labs). Marwood routinely conducts analysis on this landscape from a market, healthcare plan as well as regulatory and legislative perspective to identify trends, risks and opportunities in the market. The report herein provides a snapshot of major themes within each of these subsectors.

II. Independent Laboratories

There are ~3,000 independent labs in operation in the United States. However, the top 30 lab companies represent only ~25% of the overall market. LabCorp and Quest Diagnostics are the clear leaders, but together only account for ~14% of the overall market. Other large lab companies including Sonic Healthcare USA (~1%), Exact Sciences (~1%), Myriad Genetics (<1%) and Opko's BioReference Labs (<1%) each represent only a tiny fraction of the full market. Indeed, the majority of independent labs generate less than \$50M of revenue per year.

The independent testing lab market remains highly fragmented despite significant M&A activity. LabCorp and Quest Diagnostics alone have spent in excess of \$20B over the last 20 years in acquisitions. Among LabCorp's largest lab acquisitions have been Genzyme Genetics (\$925M), Dynacare (\$685M) and Dianon (\$600M), allowing the company to grow with a CAGR of ~9%, half of which attributable to acquisitions. Notable Quest Diagnostics acquisitions have included AmeriPath

(\$2B), Smithkline Beecham Clinical Labs (\$1.2B), Unilab (\$1B), LabOne (\$950M) and Athena Diagnostics (\$740M), allowing the company to grow with a CAGR of ~8%, most of which attributable to acquisition.

Despite the strong market position of the largest independent labs, there exists significant whitespace for regional players to serve smaller hospitals/health systems and associated outreach lab functions. Regional diagnostic labs cater to the specialized needs of resource-strapped individual hospitals and small health systems with ancillary services and specialized attention not provided by national providers. Examples include molecular tumor board services, visiting pathologists and even billing support. These additional niche services distinguish the value, and at times justify a higher price point, of regional labs in contracting with hospital and health plan payors against the more transactional and less customized nature of national independent labs. Notably, the latter have been under greater cost pressure by health plan payors over the past several years.

III. Hospital Laboratories

Marwood believes that the push toward efficiency by hospital administrators, is driving not only by consolidation of hospital labs but a search for joint venture opportunities with independent labs. Total lab department costs as a percentage of overall hospital operating expenses is estimated at ~5% over the roughly 6000+ U.S. hospitals. The largest single component of hospital lab department operating costs is the lab employee, a line item recently subject to greater scrutiny as hospitals scramble for a limited pool of talent with expectations of higher salaries in the wake of the COVID-19 pandemic.

Aligned with fixed cost burden, department costs are highest at small independent hospitals that are not part of larger health systems. These hospitals lack the scale necessary to justify high-volume automated instrument systems to offset labor costs. They also lack negotiating leverage with reagent vendors, outside reference labs and other suppliers. These fixed cost considerations are driving smaller hospitals and health systems to consolidate their laboratory operations and/or seek joint ventures with independent labs to take test volume off of their hands or simply manage their operations.

Hospital arrangements with independent labs capitalize on the rate difference in their payor contracts. Hospital-based diagnostics, as a percentage of overall hospital claims, make up a small fraction of payor costs, wherein they become minor points in hospital-payor contracting discussions. As such, the hospital markup on laboratory tests is less scrutinized than other cost centers by payors. Compared to independent labs, and in particular leading independent labs, they are significantly higher. This provides an opportunity for both regional independent labs to partner with smaller hospitals and health systems, preferred for their additional services, as well as larger labs (i.e LabCorp and Quest Diagnostics) preferred among larger health systems for the cost savings generated through their strictly transactional (limited additional services) approach.

In terms of test mix at the average hospital laboratory, inpatient/outpatient testing accounted for ~80% of test volume, with the balance in outreach testing. These outreach operations tend to be rather small and thus ripe for opportunities which may generate efficiencies of scale. Notably, hospital executives view hospital lab services, and in particular those that extend past the hospital itself (i.e., outreach labs) as non-core cost centers and believe commercial labs can provide lower-cost services through various arrangements.

Additionally, commercial health plans have been targeting reductions to hospital laboratory spending through contracting policies and preferred lab networks designed to steer volume to the lowest cost labs. This is pressuring lab testing volumes at hospital outreach labs. Consequently, the last several years has seen several large hospital-owned labs sold to either Quest Diagnostics or LabCorp. Examples include Quest Diagnostics' acquisition of Memorial Hermann Diagnostic Labs in April 2020 and LabCorp's purchase of Pathology Associates Laboratory (PAML) in May 2017.

IV. Physician Office Labs (POLs)

There are over 100,000 POLs and their number is steadily increasing. On average, in-office lab tests represent approximately 1-3% of overall revenue generated at physician practices. The majority of POLs are certified only to perform waived testing or provider-performed microscopy (PPM). These POLs perform only the simplest lab procedures. Specifically, a waived lab can only perform waived tests, which are categorized by CMS as "simple laboratory examinations and procedures that have insignificant risk of an erroneous result." The growth of physician office labs is occurring predominantly in the area of low complexity tests, with high complexity tests more likely to be outsourced than performed in most physician office labs.

Over the last several years, the trend has been for physicians and physician groups to sell their practices or affiliating with a larger entity; thus these labs are being looked at in a broader context (hub and spoke) to increase utilization and test volume in the network at reduced fixed cost. Marwood believes that consolidation among physician office labs as well as joint ventures with independent labs are expected to increase over the next 3-5 years. It is unlikely that this is currently being driven by reimbursement pressure, which has not been as severe as that faced by large independent laboratories, but rather by larger macro trends shaping the industry. Namely, as growing health systems acquire physician practices as part of their geographic footprint, the expectation is that they funnel work back into outreach labs. Marwood routinely examines the impact of this consolidation, including how value-based contracting places physicians in a quandary between supporting the health system's outreach lab and utilizing a third-party independent lab, particularly for complex testing.

V. Future Evolution Of The Lab Testing Market

Consolidation has dominated the landscape over the last several years and contributed to bottom-line growth, even as per-test revenue has declined due to the Protecting Access to Medicare Act of 2014 (PAMA) required significant changes to how Medicare pays for clinical diagnostic laboratory tests under the Clinical Laboratory Fee Schedule (CLFS). PAMA has resulted in an overall 25% reduction in average reimbursement rates which is being phased in between 2018-2022. Marwood routinely provides analysis on this and related federal legislation as well as associated commercial, Medicare advantage and managed Medicaid health plan impacts on the independent laboratory, hospital laboratory and physician office laboratory segments.

Beyond reimbursement, Marwood continues to evaluate the regulatory and strategic impact of automation and artificial intelligence on the industry, particularly in light of the tightening labor market and expanding labor costs. While regulation and enforcement provides a check for the integration of automation, limitations associated with laboratory information systems as well as diagnostic products (sufficiently-validated) for automation present challenges to be overcome. ROI justification for high throughput highly automated workflows create additional considerations, particularly as laboratories

expand test libraries. Closely related, Marwood is investigating supply chain models of delivering service (ex., hub and spoke) as they relate to emerging players, entrenched regional competition and the largest diagnostic labs. As Marwood explores the strategic impact of these developments to the diagnostic laboratory space, we continue to follow federal impacts to the sector, associated healthcare plan payor dynamics and market trends attributable to the COVID-19 pandemic.

About the Author

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