



MEDICAL & DIAGNOSTIC LABORATORIES AN INDUSTRY STUDY

Things you will learn from this whitepaper:

1. How has consolidation affected the industry's landscape?
2. What other industries significantly affect the medical & diagnostic laboratory industry?
3. What are some of the most common issues facing the medical & diagnostic industry?
4. How do current financial regulations affect valuation issues in the medical & diagnostic laboratory industry?

This whitepaper will have special interest to:

1. Attorneys consulting with medical & diagnostic laboratory owners considering mergers or acquisitions.
2. Judges presiding over business disputes & litigation cases.
3. Business mediators & arbitrators.
4. Those concerned with the valuation of medical & diagnostic laboratories.

Notice & Disclaimer

In a forensic accounting setting, the purpose of an industry analysis is to allow a comparison of the subject company to its industry. This comparison is vital to assess the strengths and weaknesses of the subject company, as well as its industry and company specific risks.

The following study contains a brief, selected analysis of the specified industry. It is based upon a review of current economic statistics, articles in the financial press, reviews found in current business periodicals and information posted on numerous internet sites. It does not purport to be all-inclusive or to contain all of the information which a prospective investor or lender may require. Projections and opinions are based upon information provided by third parties. We make no representations or assurances that this information is complete or accurate. Neither Mark S. Gottlieb, CPA, PC nor any of its officers, employees, or representatives make any representation as to the accuracy of completeness of this report or its contents, nor shall any of the foregoing have any liability resulting from the use of the information contained herein or otherwise supplied.

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Industry Overview

The U.S. medical and diagnostic laboratory industry consists partly of 5,000 independent, commercial companies with composite annual revenue of \$20 billion. In addition to these, a large volume of laboratory work is done by labs affiliated with hospitals and clinics, pushing total industry revenue to \$48 billion. Medical labs account for about two-thirds of industry revenue, while imaging centers account for one-third. This report will focus on independent, commercial companies.

Major companies in the industry include Quest Diagnostics and Laboratory Corporation in the medical lab segment, and Alliance Imaging and Radiologix in the imaging segment. These companies provide bacteriological, biological, histological, blood, chemical and pathological analysis; urinalysis; and medical and dental x-rays. Demand for services may originate in the private, public or government sectors; samples come via health service providers (often at the recommendation of individual physicians), or may be done en masse according to pre-established contracts.

Currently, the industry appears poised for moderate growth. The volume of tests is growing, the era of scandals and fines appears to have passed, and pricing has firmed. Managed care, once considered a major threat to industry viability, is having a less severe effect on the sector. New diagnostic technologies are emerging, and have allowed for a sharp growth in “esoteric tests”, which offer a higher degree of specificity in diagnoses.

Competitive Landscape

Medical laboratories benefit greatly from rising national health care expenses. In 2004, health care spending in the U.S. reached \$1.9 trillion, and is expected to top \$4 trillion by 2015. By several measures, health care spending is rising at the fastest rate in U.S. history.

The most expensive component of the health care industry is hospitalization, and it can often be avoided if laboratory tests and x-rays are available to determine whether out-patient care is an option. Therefore, as employers and insurers look to cut costs, laboratory testing becomes more and more attractive. Although there are currently more than 174,000 laboratories operating in the U.S. (including state-run labs), rising health costs should provide ample product for the industry.

Medical labs typically receive samples from a broad geographical base, and there are pronounced economies of scale in the industry. Small labs can compete effectively by providing specialized analyses or services, or by serving geographical regions with few medical facilities. Imaging centers are not affected by economies of scale because they must be stationed within range of patients.

Many laboratories have remained competitive through mergers and acquisitions, and by continually developing faster, cheaper, and less invasive testing procedures. The growth of managed care organizations (MCOs) and hospital groups has encouraged consolidation in the medical laboratory and diagnostic industry. Customers with large memberships often prefer to negotiate contracts with companies that can provide services regionally or even nationally. As a system of health care delivery, MCOs attempt to influence utilization and cost of services, as well as measure performance. As laboratories consolidate, “subscription” rates with clients become increasingly common. With these rates, a client pays one annual fee for all services, rather than paying



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for each test individually. The trend toward managed care has also compelled physicians to order fewer tests in order to cut costs, and to take fewer samples for testing.

Throughout the 1990s, chain laboratories steadily consolidated in an attempt to palliate the effects of MCOs. As in other sectors of the economy, independents felt the squeeze. Though the influence of MCOs seems to have leveled, the trend toward consolidation is expected to continue.

Products, Operations & Technology

Laboratory devices, sometimes extremely large and cumbersome, have begun to shrink in scale. Due to constantly improving manufacturing technology, equipment costs are expected to fall. Some testing devices are already small enough to fit in the hand.

Early-stage testing procedures, which can find disease much sooner than standard tests, have become ensconced in laboratory and diagnostic testing. These procedures are often less invasive and quicker than earlier methods, and have expanded the array of services offered by medical laboratories. One recent example is the AMAS (Anti-Malignin Antibody Screen) test. The AMAS test works by measuring a specific antibody in the blood, and has proven capable of identifying cancer months before conventional medical tests are able.

Throughout the last decade, medical professionals have placed increasing emphasis on prevention as a strategy for dealing with disease. Therefore, demand for early testing has risen. Each year sees a new handful of screen tests. In addition, the successful mapping of the human genome has allowed for a growing suite of genetic tests, expanding the array of products offered by medical laboratory testing centers.

Procedurally, medical and diagnostic laboratories provide analytic or diagnostic services to the medical profession. They may also provide results directly to patients following a physician's referral. Laboratory technicians may take x-rays and computerized tomography scans, analyze blood samples, or perform other clinical tests.

Finance & Regulation

Medical laboratories are regulated by the Clinical Laboratory Improvement Act of 1988. These regulations, implemented in 1992, increased requirements for proficiency testing, thereby raising costs. The cost of proficiency materials tests went up by 67 percent in the first eight months of 1992. While the new regulations increased operating costs for laboratories, they also streamlined administrative costs by unifying separate rules that had been established under previous programs.

In addition to the Clinical Laboratory Improvement Act, state and federal implementation of anti-trust legislation has been a key regulator. Such legislation has been enacted to prevent doctors from referring patients to labs in which the doctors themselves are vested. This has been a victory for independent players in the industry.

Other legal battles have surfaced of late. In 1993, state and federal officials subpoenaed the Medicaid and Medicare records of several of the country's largest medical laboratories in an attempt to



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stop suspected fraud. The results of this highly anticipated legal action were by no means spectacular, though instances of fraud were discovered. The industry has carried on under scrutiny.

With new testing technologies continuously coming into use, regulations governing waste disposal have become a key procedural concern for laboratories, as well. The increasing scope and vigilance of EPA rulings has raised both administrative and base overhead costs. Continuing education with regard to EPA protocol is an important facet of laboratory administration.

Industry Opportunities

Scientific Advances - Rapid advances in understanding human physiology and pathology are creating a need for new kinds of tests and stronger demand for existing tests. Greater understanding of the human gene is expected to expand testing for genetic sequences and the proteins that genes code for; DNA 'chips' can show which genes are active at a particular time, for example. Immunology is another field where a large increase in testing for antibodies is expected. Medical advances also show that specific blood chemicals, such as C-reactive protein, should be measured more frequently. Lab companies are forming stronger links with the biotechnology industry to speed development of new tests.

Non-Medical Testing - Facilitating clinical tests for employers (for drug and alcohol abuse); insurance companies (life insurance policies); police departments (DNA fingerprinting, forensics investigation); and security agencies (identification) are each expected to increase. The possible use of genetic testing by health and life insurance companies is a contentious issue because it could lead to a system where those with a genetic predisposition to a given illness wouldn't be qualified for insurance. Laboratories forge on, however, while legislators address these complex issues.

Clinical Medical Trials - Stricter government requirements for the approval of new drugs and medical devices has led to more use of clinical trials to demonstrate benefits. Many clinical trials involve repeated use of clinical lab tests or imaging. Companies may have long-term contracts with drug companies to provide services for their clinical trials.

Contract Management Services - Because of their acumen in managing for-profit facilities, some companies serve as consultants or contract managers for labs or radiology departments owned by hospitals. This niche is expected to shrink, however, as hospitals continue to outsource diagnostic and laboratory testing to commercial labs.

Private Individual Testing - The greater awareness of health issues by the public has prompted many people to get tests that aren't immediately medically necessary, at their own cost. Up to 10 percent of revenue at Quest in 2002 was due to such testing. Because of the large number of tests they order, bills for such patients average \$120, compared to less than \$30 for typical requisitions.

Population Screening - The low cost and high preventative value of some tests has prompted health officials to recommend that large numbers of people be tested for certain conditions, or that certain tests become routine medical testing for all patients. For example, Centers for Disease Control and Prevention (CDCP) recently recommended that HIV testing be routine for all patients. Mammography and testing for prostate cancer are routine for some segments of the population.



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Screening large populations has been especially useful in preventing the spread of infectious diseases, where carriers may have no symptoms.

Critical Issues

Dependence on Third Parties - The industry has grown rapidly as medical knowledge has expanded, but still depends on payment rates set by third-party payers like Medicare, Medicaid, MCOs, and other health insurers. Legislative reform of such organizations, for better or worse, profoundly impacts medical and diagnostic laboratories.

Cost-Cutting Measures - These changes, largely enacted by MCOs, have presented a particular challenge to the medical laboratories industry. Mergers and acquisitions have been the industry's natural adaptation, and advances in testing procedures have also helped minimize costs. Now that the influence of MCOs has peaked, the industry may have cleared this hurdle.

Lack of Skilled Workers - Professional and related workers, primarily clinical laboratory and radiologic technologists and technicians, make up about 43 percent of all jobs in this industry segment. The remainder is comprised of service workers, including medical assistants, medical equipment preparers, and medical transcriptionists. Health care workers are more likely to remain employed in the same occupation, due, in part, to the high level of education and training required for many health occupations.

As with the health care industry at large, qualified workers are in short supply. Workers in health care tend to be older than workers in other industries, and in the next decade thousands of workers will reach retirement age. This fact, coupled with an aging population's increasing demand of health services, presents one of the industry's most formidable challenges.

Point-of-Care Testing - Because some tests have become simpler to administer, and because emphasis on cutting costs is growing, "point-of-care" testing has increased. With this protocol, tests may be performed in a physician's office (or, in the case of home health care, at home), with testing and diagnosis completed at the place of treatment. By 2001, over half of all simple medical testing was completed in physicians' offices.

Public Health Laboratories - Of the approximately 174,000 laboratories currently operating in the U.S., 2,000 are public health labs. These laboratories play a crucial role in responding to the threat of chemical, biological or radiological terrorist attacks. They also work in disease management and prevention, and food safety. Compared to commercial labs, public health laboratories are understaffed and loosely administered. Many rely heavily upon more profitable commercial labs to supplement their ability to serve communities. Many analysts feel that reform is needed. It is unknown to what degree public laboratory reform will affect commercial labs.

Industry Outlook



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With the increasing demand for screening and tests, and the national budget for health services continuously rising, the medical and diagnostic laboratories industry seems situated for growth. At \$4 billion in annual revenues, esoteric testing is the fastest growing and most promising area of the industry. This new field seems a potentially high revenue generator, as does the U.S. government's increasing emphasis on preventative testing.

As providers continue to consolidate, profit margins should broaden. New technologies promise to diminish costs, while simultaneously offering a growing battery of tests. Legal challenges seem to have ebbed, but regulatory legislation has grown slowly over the past decade, and labs will need to remain compliant while mitigating costs.

Because the industry is so dependent on third-party payers, it is difficult to extrapolate specific growth possibilities. It is almost universally agreed among analysts, however, that the medical and diagnostic laboratories industry today is in as strong a position as it has been for the past thirty years.



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